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Summary of Public Meeting

Use of Quality Assurance Systems in the Fastener Industry

D. E. Edgerly

U.S. DEPARTMENT OF COMMERCE
Technology Administration
National Institute of Standards
and Technology
Gaithersburg, MD 20899-0001

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April 1997

U.S. DEPARTMENT OF COMMERCE
William M. Daley, Secretary

TECHNOLOGY ADMINISTRATION
Mary L. Good, Under Secretary for Technology

NATIONAL INSTITUTE OF STANDARDS
AND TECHNOLOGY
Arati Prabhakar, Director

SUMMARY OF PUBLIC MEETING

USE OF QUALITY ASSURANCE SYSTEMS IN THE FASTENER INDUSTRY

February 4, 1997

TECHNOLOGY SERVICES
NATIONAL INSTITUTE OF STANDARDS
AND TECHNOLOGY
GAITHERSBURG, MD

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I. Abstract

The Fastener Quality Act (FQA) relies on lot control and final inspection of fasteners, and does not recognize the reality of modern mass production using Quality Assurance Systems (QAS). A workshop was organized to explore various methods of complying with the FQA while practicing modern methods of manufacturing. The primary purpose of the workshop was to learn from the industry the role of QAS in the manufacture of fasteners, how the industry is utilizing these modern techniques, and suggested routes for conforming with the FQA when utilizing QAS. Common features in the suggested routes for resolving this issue included the requirement for both buyer and seller of fasteners define the QAS in writing; third party registration and auditing systems or self-certification of the QAS; and NIST recognition of fastener specifications and quality assurance standards of major end users. Overall, several speakers emphasized that NIST should recognize the modern manufacturing techniques by accommodating QAS and quality assurance plans as the required documentation to demonstrate that fasteners conform to the stated standards and specifications. The meeting summary in this report includes the purpose of the meeting, a synopsis of presentations by industry on complying with the FQA while using QAS, and proposed solutions to the problem. Copies of presentations are also attached.

II. Introduction

While the Fastener Quality Act (FQA) has been in the making since the late 80's, the fastener industry has been undergoing major changes in their manufacturing processes. In recent years, automotive industry through their QS 9000 has been the driving force behind the changes in the fastener manufacturing practices. The modern trend in fasteners manufacturing is to produce consistently high quality products through the use of in-process measurements and controls that are approved in advance as part of a Quality Assurance System (QAS). The QAS incorporates defect prevention systems including advanced quality planning, in-process measurements and planning, and final inspection. The traditional manufacturing methods rely on a strict lot control and inspection of samples taken from each lot at the end of the manufacturing process. Conformance to standards and specifications to which the manufacturer claims to have produced the fasteners is obtained by lot testing at the end of the manufacturing process. On the other hand, the modern manufacturing trend is to minimize the final inspection and reach the quality objectives through in-process control and in-process inspection as described in a control plan. Currently, fastener manufacturers utilize manufacturing practices that are within these two extremes.

Sections 5(b)1, 5(c), and 6 of FQA describe the requirement of lot inspection and testing using representative samples to determine whether the lot conforms to the standards and specifications to which the manufacturer represents it has been manufactured. However, the modern manufacturing methods in which the final inspection is largely replaced by QAS are not addressed by FQA. In-process measurements may not always produce test results in the form

required for complying with FQA. As a result, those practicing QAS would have to encounter additional unnecessary expense to produce the required data and certification to comply with FQA. Therefore, there is a need for exploring various methods of complying with FQA while practicing modern methods of manufacturing. The primary purpose of the meeting was to learn from the industry the role of QAS in the manufacture of fasteners, how the industry is utilizing these modern techniques, and suggested routes for conforming with the Fastener Quality Act (FQA) when utilizing QAS.

III. Summary Of Presentations

The meeting summary in the following pages includes the purpose of the meeting, a synopsis of presentations by industry on complying with the Fastener Quality Act (FQA) while using modern Quality Assurance Systems (QAS), and proposed solutions to the problem. In planning this workshop and presentations at the workshop, the phrase Statistical Process Control (SPC) has been used liberally to mean the QAS. Since SPC is only one of the components of QAS, here onwards SPC has been replaced by QAS to accommodate the broad concepts embedded in QS-9000 and similar plans.

David Edgerly, National Institute of Standards and Technology (NIST), opened the meeting with a description of the underlying issue that the FQA relies on lot control and final inspection of fasteners and does not recognize the reality of modern mass production using QAS. Sections 5(b)1, 5(c), and 6 of FQA describe the requirement of lot inspection and testing using representative samples to determine whether the lot conforms to the standards and specifications to which the manufacturer represents it has been manufactured. However, the reality of the modern manufacturing methods is that the final inspection is largely replaced by QAS that are based on defect prevention systems including advanced quality planning, in-process measurements and planning, and final inspection. In-process measurements may not always produce test results in the form required for complying with FQA. As a result, those practicing QAS would have to encounter additional unnecessary expense to produce the required data and certification to comply with FQA. Therefore, there is a need for exploring various methods of complying with FQA while practicing modern methods of manufacturing. The primary purpose of the meeting was to learn from the industry the role of QAS in the manufacture of fasteners, how the industry is utilizing these modern techniques, and suggested routes for conforming with the Fastener Quality Act (FQA) when utilizing QAS.

From the industry side, Dan Reid's (General Motors Corporation) opening talk set the stage by describing the developmental history, goal and components of QS-9000, and benefits of implementation of QS-9000 at Chrysler, Ford, and General Motor Corporations. The QS-9000, in a relatively short period, has been adopted and practiced in more than one thousand corporations in 14 countries. The goal of Chrysler, Ford, and General Motors was to develop quality systems that provide for continuous improvement, emphasizing defect prevention, and reduction of variation and waste in the supply chain. The heart of QS-9000 is a control plan that includes every detail of the special characteristics from prototype production to pre-launch production and the final production processes. These characteristics include specific descriptions of parameters to measure and inspect test methods, sample size, test frequency, and reaction plan. Product identification, traceability, and final inspection and tests are an integral part of the control plan. Process control must be conducted under controlled conditions involving compliance with standards, quality plans, control plans, and monitoring of key process parameters and/or product characteristics. Inspection and testing, using procedures to verify that product requirements are met, are documented in the control plan or in other supporting

documents. In addition, if required by the customer, third party accredited laboratories must be used for testing and inspection.

Chuck Vohsen (McDonnell-Douglas Corporation) briefly stated in his talk that ARD-9000 is based on ISO-9000 with qualifiers added to fit the aerospace industry needs. The Society of Automotive Engineers is responsible for its publication. While the auto industry is fairly ahead in its implementation of the QS 9000, the aerospace industry is in the early stages of ARD-9000 implementation.

The primary focus of Mr. Dorflinger's (Chairman, Industrial Fasteners Institute, IFI; Chairman, Nylok Fastener Corporation) talk was in support of the auto industry's use of QS-9000, and some of the issues faced by the fastener industry in complying with the FQA regulations. He emphasized the need for legislative changes to FQA to accommodate industry's drive to utilize modern manufacturing practices. Otherwise, the industry may suffer under intense foreign competition. The second issue addressed was to assure that no disruption in supply will occur or that present just-in-time delivery practices may continue without interruption. Though it was not the goal of this meeting, Mr. Dorflinger wanted to emphasize several other issues including adequate availability of raw material by the implementation date, importation of subassemblies, and economic impact on raw material manufacturers' due to high cost of laboratory accreditation. Mr. Dorflinger's specific recommendations included revision of regulations to reflect the latest changes in the ASME drafts B18.18.5M, B18.18.6M, and B18.18.7M and an assurance that neither industry technology nor just-in-time delivery is interrupted. Finally, he suggested a delay in implementation to fully incorporate these changes.

Jack McCarthy (Chairman, IFI Division VII, Automotive; President, Kamax-G.B. Dupont L.P.) emphasized that great strides in improved quality, reduced prices, and continuous improvements have caused unparalleled improvements in the industry while delivering parts on just-in-time delivery basis with quality levels unimaginable just 10 years ago. The key for this success has been "aligning with customers and working together to build quality into the products, not inspect defects out. We have achieved the above improvements by process controls including SPC and Total Quality Management (TQM) concepts that deliver quality products on time every time." According to Mr. McCarthy, the problem is that "to conform with FQA, the fastener manufacturers need to conduct significant amounts of final inspection as well as needless duplication in documentation that will represent a significant setback on our journey to excellence." While a complete overhaul of the FQA is not practical, he emphasized modifying the regulations to recognize in process controls as a replacement for final inspection procedures. Further he suggested that the revised regulations reflect current and proposed ASME, SAE, and other quality standard's organizations which emphasize process control as a means to ensure product quality.

Patrick Meade (Chairman, IFI Division VI, Aerospace; President, Hi-Shear Corporation) opened the talk by emphasizing that SPC is not limited to manufacturing only, it is widely used in accounting, engineering, and management. The end users in aerospace industry have

mandated the use of SPC by the fastener suppliers. The fastener manufacturers are required to provide the SPC data in hard copy form on each lot of fasteners produced and shipped to the end user. According to Meade, the ultimate intention of the aerospace vehicle manufacturer is to eliminate final inspection of component manufacturing since it is redundant and costly. The FAA has already approved the use of in-process inspection and elimination of final inspection. The aerospace fastener manufacturers are currently subjected to government audits and certification to military specifications such as MIL-1-45208 and MIL-Q-9858. The quality systems and product performance are audited and qualified by Boeing, General Electric, and Lockheed annually or biannually leading to as many as 50 audits per year. The FQA imposes additional burdens. Meade further stressed the issue of pre-May 27, 1997, produced inventory, raw material's certification, and availability of sufficient number of accredited laboratories may cause disruptions in fasteners delivery to the aircraft production industry. Another subject he mentioned was that fasteners produced overseas and installed overseas in airframe subassemblies are not subject to FQA.

Bill Tudor (General Motors Corporation) presented a brief overview of QS 9000 and a proposal for meeting the FQA requirements. Under QS-9000, the fastener supplier must do the following to assure the part quality:

- establish its qualifications by obtaining a third party registration or by customer approval,
- to maintain that registration, the supplier should undergo periodic inspections,
- provide a satisfactory control plan for specific fasteners and meet other requirements for the Production Part Approval Process (PPAP), and
- supplier's performance should be satisfactory at audits.

Tudor further emphasized that final inspection as required by FQA is redundant and costly. He compared the two approaches-- traditional lot control system and quality assurance plan, using Chart 1 in his presentation. First of all, under the traditional plan operators are instructed on how to do each step; while under the quality assurance plan, a control plan describes each step (equipment, criteria to apply, steps to take to correct non-conformance, and a responsible person for each step). Secondly, quality assurance in the traditional system is based on sampling from each lot to determine if the specified characteristics have been met; whereas, in the quality assurance plan, lot inspection as well as process controls are used that are based on establishing a controllable process that will produce the desired characteristics and validating that the system produces quality products. Error proofing the equipment that can detect and reject non-conforming parts represents the ultimate form of control. Thirdly, in the traditional methods, verification of conformance with the stated standards requires testing and inspection; whereas, in the quality assurance plan a systematic monitoring of the process is the basis. The quality assurance plan produces data that can be recorded, often these data may be as simple as the signature/initials that the required inspection was carried out. In this system, the equipment is calibrated at least once a year using NIST-traceable methods. Also QS-9000 requires that process control charts and records be kept for a period one year.

Tudor's proposal as outlined in Chart 2 of his presentation consists of using statistical process control as part of the manufacturing process, in which the certification of conformance is based on conformance to the control plan shown through the process control sheets and monitoring data. Under this scenario, registration to ISO-9000 or QS-9000 or an equivalent would provide an independent verification.

George Parker (Vice President Engineering Affairs, Association of International Automobile Manufacturers, Inc., AIAM), while focusing on the use of SPC in fastener production, provided an approach for accommodating SPC under FQA. The application of SPC has resulted in higher quality products compared to the end-of-process testing. According to Parker, "SPC is the standard by which most components used in manufacture of motor vehicles are produced." The salient features of Parker's proposed approach are the following:

- Recognition of fastener specifications and quality assurance standards of major end users, and the quality assurance systems (specific control attributes to be monitored, the level of control needed, the system for monitoring the attributes, and other features to ensure that the quality assurance system would result in fasteners meeting the applicable specifications with a high degree of probability) imposed as a result of these standards on the fastener suppliers for major end users.

- Publication by the major end users of these documents as a requirement to form the basis of compliance with the FQA.

- The criteria to be established for acceptance of this plan should be performance based to allow accommodation of advanced quality assurance systems in the future.

- The major end user's quality assurance systems would be based on self-certification and no review by NIST or an independent party would be necessary.

- Under this system the fastener manufacturers operating under an approved quality assurance plan would be required to keep records of control charts and other data records required by the quality assurance system; and these records could be subject to audit by NIST or an independent entity.

- For fasteners manufactured overseas in accordance with the proposed quality control systems, an entry certification would be necessary.

- Since motor vehicle manufacturers conduct defect recalls under the Safety Act, no traceability requirements need be specified for end users that would render obsolete those modifications to existing systems that allow motor vehicle manufacturers to identify components needing recall.

A second recommendation covered by Parker addressed the modification of the FQA Final Rule to recognize that fasteners produced to the requirements of motor vehicles manufacturers should be exempt.

Robert Brunner (General Manager, Shakeproof Automotive Division, ITW Corporation) underscored the role of modern process control and automated inspection methods in achieving improved quality levels and reduced costs. These methods have largely replaced the in-process and end-of-line inspection. However, FQA requires that each lot of covered fasteners be inspected and tested such that associated documentation evidences conformance to the standards to which they are made. This requirement does not recognize modern manufacturing techniques and the time lag involved in standards development and technology development. In practice, technology development precedes standards development. Typically, end-of-line testing and inspection yield defect levels in the thousands and tens of thousands parts-per-million. On the other hand, modern manufacturing techniques involving process control and automated inspection yield defects in the range of a hundred parts per million. On this basis, Brunner proposed the following approach to solve the problem of FQA compliance:

- The QS 9000 is like a standard because it includes a requirement to perform a rigorous process of quality planning for each part prior to its production. This Advanced Quality Planning Process (AQPP) results in a quality "Control Plan," representing the distillation of standards-based requirements, manufacturing workmanship and know-how, past quality history, and available manufacturing and quality control technology-- a concise set of quality control strategies from raw material to a finished product for each part produced. Effectively, the control plan bridges the gap between antiquated standards and modern manufacturing practices resulting in better quality at a lower cost.

Another issue presented by Brunner was an amendment to the regulations that would limit coverage of parts to those designated as "safety critical" by the major end user. A long standing practice of the automotive industry and other major end users has been to designate fasteners used in "safety critical" applications as "safety parts." Examples of this include seat belts and steering column bolts.

Chris Wackrow (Vice President, Quality Assurance and Product Reliability, MNP Corporation) emphasized the role of QS 9000 in improving process reproducibility with a built-in ability to recognize, approve, and incorporate improvements in a controlled fashion. Further, QS 9000 has accountability and provides a means by which the customer and manufacturer work together to accomplish their objective. Therefore, according to Wackrow, it accomplishes the intent of FQA. Then he described the control plan, the process control which incorporates SPC methods, and other improvements such as incorporation of statistical methods to assess errors in measurement processes, and microprocessor technology. Through an example of a control plan, Wackrow illustrated the rigor, completeness, and details of the manufacturing and control processes embedded in the plan.

Tim McGuire's (Director of Product Engineering, Camcar Textron Corporation) presentation outlined yet another approach to accepting the quality systems such as QS 9000 as fulfilment of compliance with the FQA. The specific recommendation included:

- the requirement of both buyer and seller of fasteners to define the quality system in writing, as a required contract prior to undertaking the business,
- the quality system should be approved by a third party, and
- the quality system should incorporate micro-details based on industry's best practices.

Jeff Easter (Director of Technical Services, Elco Textron Corporation) covered several issues including the incorporation of quality systems into the FQA regulations. The current practice of many manufacturers consists of using techniques of Advanced Quality Planning, technical knowledge and past experience to develop a "contract" with the customer in the form of a "control plan." A portion of this control plan identifies the elements included in current documentation systems. Every element of a given standard or specification does not necessarily have documented test results to prove conformance. The documented elements are determined by a combination of a specific customer requirements and the suppliers knowledge of his products and processes. It would be extremely difficult to document every element of a control plan in a test report. Those elements identified in the control plan as documented in a test report are the suppliers commitment to "prove conformance."

Easter further stressed that SPC, among the many elements of an effective quality system, does not guarantee conformance to a standard or specification; however, it is used to insure that a product feature or process characteristics are in control and capable of meeting requirements. Product features are generally identified on drawings or in standards and specifications, while process characteristics such as temperature is not generally defined by standards and specifications, but through the suppliers' knowledge of the process. This makes it difficult to present data to certify that a product is in conformance; however, it can be stated that the process was in control during the manufacture of a given product. Often it is difficult to connect some process characteristics such as temperature to a product feature such as hardness.

Further, Easter pointed out a problem with respect to the fastener industry's ability to effectively comply with FQA regarding salt spray test requirements contained in the majority of finishing standards. The sampling frequency described in the ANSI B18.18.2 Appendix is excessive. The sampling plan should be based on the capability of the process. Since the process standards are generally developed by the processor and/or the chemical supplier, and there may or may not be customer input into the process standard.

Steve Engleman (President, Industrial Products Group, SPS Technologies, Inc.) presented two issues related to the workshop subject. First he reiterated that soon QS 9000 will become the standard of this industry in which development and adoption of AQPP approach and control plan is a must. While QS 9000 requires that inspection and testing conducted per the documented procedures, compliance with FQA requires additional requirements to be satisfied. For example,

customer specifications require proof load, tensile and a hardness test be conducted on six samples per lot which is described in the control plan. However, since the customer print refers to SAE J429, this standard requires testing of eight samples per lot; which is an increase of 33% more samples for testing. This may impact not only cost, but also may affect Just-in-Time delivery supply as well as increased inventory investment. The proposed solutions include change in the regulations requiring fastener manufacturers to follow the major end user's quality program which meets defined minimum requirements. An additional change in the regulations is required in which inspection and testing to demonstrate conformance to specifications is replaced by demonstration of conformance to control plans. These changes to the regulations will still retain lot traceability, head marking, laboratory accreditation, etc. Finally, the regulations need to define how the conformance to control plans would be demonstrated, for example based on an audit and/or certificate with each lot.

Y. Imai (Director, Sannohashi Corporation, speaking on behalf of the Fastener Institute of Japan) covered three topics relevant to the use of SPC in fasteners manufacturing. The Japanese fastener manufacturers use various quality control techniques (to be described by Mr. Fukuda) to meet the respective quality requirements of their automotive customers. These requirements are based on the following objectives:

1. to secure lot traceability;
2. to control changes in manufacturing conditions;
3. to confirm process capabilities of the manufacturing equipment;
4. to produce reliable, high quality products which are continuously improved during the manufacturing process, rather than relying on final inspection.

According to Imai, while the role of SPC is widely recognized, 70-80% of fastener companies in Japan use SPC and most of these supply to automotive applications. He pointed out that conformance with FQA is burdensome with no additional benefits.

In Japan there are approximately 20 in-house testing laboratories for fastener testing and the same number for metal testing. While the fastener industry in Japan is making preparations, it may not be able to meet the May 27, 1997, implementation date.

Imai's proposal to resolve the FQA/SPC issue included the use of quality control during manufacturing process, rather than in final inspections, while meeting the FQA goals by the following systems:

- to enable product traceability,
- to verify that SPC techniques are being correctly applied,
- to verify that technical skills of workers are maintained, and
- which establish methods for verifying material composition and preventing the introduction of nonconforming materials.

Yasukazu Fukuda (Deputy Director, Management Standards Division, Standards Department, Agency of Industrial Science and Technology, MITI) specifically addressed issues related to FQA/SPC by focusing on Japanese Industrial Standards (JIS) and the JIS marking system. The JIS is a voluntary national standards body for industrial and mineral products, and its standards are based on a consensus of producers, consumers and related parties. The JIS has 12 standards for fasteners within the scope of FQA covering materials, class and quality characteristics of fasteners, and mode of JIS marking on products and packages. The JIS Marking System is a recognition that the factory is certified as having the technical capability to produce continuously and stably the product conforming to JIS. This recognition is offered based on factory examination rather than just inspection of the final products. The products within the scope of JIS Marking System are designated by the Minister-in-charge. The factory examination system in JIS Marking System considers a factory as one system as a whole and examines its technical capability to produce continuously and stably products conforming to JIS rather than only checks produced commodities whether or not they conform to JIS as "product inspection system" does. To certify the manufacturing facility's technical capability to produce products conforming to JIS, the JIS Marking System examines the following:

- Arrangement of company standards to ensure conformity to JIS
- Introduction of quality control methods and verification of quality control stability
- Appointment of responsible person for promotion of quality control
- Other requirements for systematic management for securing quality

Though the current JIS Marking System uses government certification based on factory examination, a new system based on private certification bodies is being developed. This system will utilize ISO 9002 (JIS Z 9902) as the requirement for quality control from the viewpoint of these quality systems to ensure production of fasteners with the quality specified in JIS.

In summary, the following are the main points covered by speakers on the subject of the fastener industry's use of QAS and other advanced manufacturing techniques, and the impact on such users of complying with the FQA:

1. Almost all speakers claimed that the FQA imposes undue burden on the industry by requiring that final inspection be carried out on the fasteners to prove conformance to the stated standards and specifications. In addition to the additional cost of complying with the FQA, the industry felt that the FQA does not recognize modern manufacturing techniques that emphasize prevention systems as opposed to detection systems.

2. The fastener industry has made great strides in improved quality, reduced prices, and continuous improvement that have caused unparalleled improvements in the industry while delivering parts on just-in-time delivery basis with quality levels unimaginable just ten years ago. The key for this success according to the speakers has been aligning with customers and working together to build quality into the products, not inspect defects out.

3. Other contributors to these improvements are the implementation of modern manufacturing techniques that are based on Total Quality Management (TQM) concepts and ISO-9001 and 9002 quality systems. The result is a widespread application of QS-9000, which is based on ISO-9001 and ISO-9002, in the automotive sector; and ARD-9000 in the aerospace sector. A majority of fasteners used by automotive, aerospace and heavy machinery and other industries employ these advanced manufacturing techniques, embedded in these umbrella systems are detailed quality assurance plans and quality assurance systems (QAS).

4. The QAS are based on establishing a controllable process that will produce the desired characteristics, often utilizing statistical process control techniques, and validating that the manufacturing system produces quality products consistently. The heart of the QAS is control plans. "The Control plans are unique documents containing complete details of manufacturing systems, and that harmonize the standards to which a part is manufactured with the capabilities and technologies available to the manufacture."

5. The control plans contain such details as special characteristics for prototypes, pre-launch production processes, characteristics to be tested and inspected, test methods, sampling sizes, test frequency, reaction plans, and details of product identification and traceability.

6. QAS, among the many elements of an effective quality system, do not guarantee conformance to a standard or specification; however, it is used to assure that a product feature or process characteristics are in control and capable of meeting requirements. Product features are generally identified on drawings or in standards and specifications, while process characteristics such as temperature are not generally defined by standards and specifications, but through the suppliers' knowledge of the product. This makes it difficult to present data to certify that a product is in conformance; however, it can be stated that the process was in control during the manufacture of a given process. Often it is difficult to connect some process characteristics such as temperature to a product feature such as hardness.

7. Under this system, the fastener manufacturers operating under an approved quality assurance plan would be required to keep records of control charts and other data records required by the QAS.

8. Final testing is one of the integral steps in quality assurance plans, though it is not employed as extensively as in traditional lot inspection-based methods. However, conformance to the control plan is shown through the process control data. Registration to ISO 9000 or QS-9000 or an equivalent would provide an independent verification, much like that supplied by the accredited laboratories.

9. Common features in the suggested routes for resolving this issue included the requirement for both buyer and seller of fasteners define the QAS in writing; third party registration and auditing systems or self-certification of the QAS; and NIST recognition of fastener specifications and quality assurance standards of major end users. Overall, several speakers emphasized that NIST should recognize the modern manufacturing techniques by accommodating QAS and quality assurance plans as the required documentation to demonstrate that fasteners conform to the stated standards and specifications.

10. The criteria used to accommodate QAS within FQA should not restrict the adoption of more advanced quality assurance systems in the future.

IV. Proposed Solution to the SPC Issue

NIST has reviewed the material presented during the February 4th open meeting and written comments submitted subsequent to the meeting. We have also researched the Act and its history and found a basis there for Departmental authority under both Sections 5(b)(2) and 6(a) of the statute to recognize the in-process inspection elements of prevention-based quality assurance systems as meeting the stated purpose of the Act.

Section 5(b)(2) of the Act provides the Secretary the authority to establish sampling procedures when the standards and specifications being used by fastener manufacturers do not provide for such. At present, Section 280.10 of the regulations default to the use of 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, as appropriate. These sampling plans refer to more traditional final inspection and testing of finished fasteners.

The American Society of Mechanical Engineers (ASME) has developed three additional quality assurance standards which incorporate the use of QAS. These standards, which are now under balloting by ASME, include: ASME/ANSI B18.18.5M, Inspection and Quality Assurance Plan Requiring In Process Inspection and Controls; ASME/ANSI B18.18.6M, Quality Assurance Plan for Fasteners Produced in a Third Party Accreditation System; and ASME/ANSI B18.18.7M, Quality Assurance Plan for Fasteners Produced in a Customer Approved Control Plan. ASME/ANSI B18.18.6M is a proposed standard specifically designed to be used under a quality assurance system such as QS9000 that has been certified by a third party process using independent audits under the provisions of a third party accreditation program administered by a consensus standards organization. Accordingly, an amendment to Section 280.10 of the regulations to incorporate the above mentioned standards (once they have been formally adopted by ASME) may allow fastener manufacturers to use them as sampling plans in connection with meeting the inspection and testing requirements of the Act and regulations.

Section 6(a) of the Act provides authority to the Secretary, through the Director of NIST, to issue regulations for the accreditation of fastener testing laboratories. Under this authority, we believe that NIST can accommodate the concept "accreditation" to mean either accreditation of a testing laboratory or of recognizing a fastener manufacturer's quality assurance system. The in-process inspection elements of a fastener manufacturer's quality assurance system might be considered acceptable for purposes of the Act and regulations if it satisfied all of the following conditions:

1. It is based upon a published quality assurance system standard of a consensus standards organization or a major end-user of fasteners that has been recognized by NIST as meeting the definition of "Fastener Quality Assurance System" offered below;
2. The fastener manufacturer has been "registered" as meeting the requirements of such quality assurance system by an independent third party registrar accredited by an entity recognized by the NIST Accreditation Body Evaluation Program (ABEP) using applicable national and international standards; and
3. The quality assurance system provides that tests on any lot of fasteners that are not accomplished during in-process inspection shall be performed by a laboratory listed in the NIST Accredited Laboratory List.

We believe that amendments to the regulations are necessary to accomplish the above. The potential solution presented in this paper is being considered by the Department. In order to continue the dialogue begun at the February 4 meeting, the Department is seeking input on this approach. Should the potential solution prove an acceptable means of recognizing QAS within the existing FQA, a proposed rule to implement the change, along with procedures for applying for NIST recognition of registration accreditation bodies and for recognition of a Fastener Quality Assurance System would be published in the Federal Register for public comment.

Potential Amendments to Recognize QAS

In Section 280.2 Definitions - amend the existing definition of "Accreditation" as follows:

"Accreditation for purposes of the Act and these regulations means accreditation of a testing laboratory or the registration of a fastener manufacturer to the in-process inspection elements of a fastener quality assurance system of a consensus standards organization or of a major end-user by an independent third party registrar."

Add the following new definitions to Section 280.2 Definitions:

"Major end-user means a user of standards and specifications developed by consensus standards organizations and modified to meet specific needs of the user, as stated in available operations and quality manuals, as agreed to and inspected by an accredited registrar. A major end-user purchases fasteners and installs them into a structure or sub-assembly or complete assembly, and may distribute fasteners to authorized dealers for servicing such structures, subassemblies, or assemblies."

"Registration means evaluation and certification of a manufacturing facility employing a fastener quality assurance system as conforming to applicable system standards by a third party registrar accredited by an entity recognized by the NIST Accreditation Body Evaluation Program (ABEP) using applicable national and international standards."

"Fastener Quality Assurance System means a manufacturing system incorporating advanced quality planning, continuous improvement, defect prevention, and in-process inspection embodied in comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems and for which records are kept regarding inspections and testing of fasteners during the manufacturing process. These records are available for inspection at any time."

Add the following new Section 280.104 to Subpart B -- Laboratory Accreditation:

"280.104 <u>Accreditation of In-Process Inspection Activities of Qualifying Manufacturing Facilities Employing Fastener Quality Assurance Systems</u>

(a) Registration of the in-process inspection activities 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 of these regulations. Records documenting the inspection and testing of a lot of fasteners that are performed by a certified in-process inspection facility shall be maintained by the facility in accordance with the requirements of Section 280.7.

(b) Tests on any lot of fasteners that are not accomplished during in-process manufacturing and inspection shall be performed by a laboratory listed in the Accredited Laboratory List."

VIEWGRAPHS AND PRESENTATIONS OF SPEAKERS

Open Meeting
Statistical Process Control (SPC)
in the
Fastener Industry

David E. Edgerly, Deputy Director
Technology Services

February 4, 1997

National Institute of Standards

and Technology (NIST)

General

Federal Register Notice of Meeting issued on January 15, 1997.

Purpose of meeting is to solicit views on use of SPC in fastener industry.

Persons wishing to present oral comments during the meeting had to contact NIST.

17 requests received for 12 available time slots.

NIST selected speakers based on balance of persons/organizations.

Written comments may be submitted until March 6, 1997.

NIST will publish summary of meeting.

Agenda

0900 - 0930	Welcome and Purpose of Meeting
0930 - 1000	QS9000 Overview
1000 - 1030	ARD9000 Overview
1030 - 1100	Break
1100 - 1530	Presentations from Public
	Lunch (1230 - 1330)
	Break (1445 - 1500)
1530 - 1630	General Discussion by All
1630 - 1700	Wrap-Up

Speakers

Dave Edgerly, NIST
Dan Reid, General Motors
Chuck Vohsen, McDonnell Douglas Aircraft
Max Dorflinger, Chairman, IFI
Jack McCarthy, Chairman, IFI Division VII (Automotive)
Pat Meade, Chairman, IFI Division VI (Aerospace)
Jeff Bobeck, AAMA
George Parker, AIAM
Bob Brunner, ITW Shakeproof
Chris Wackrow, MNP
Tim McGuire & Jeff Easter, Textron
Steve Engleman, SPS
Yasukazu Fukuda, MITI
Y. Imai, Sannohashi Corp.

Department of Commerce Panel

Daniel Cohen - Office of the General Counsel
Thomas Barbour - Office of the Chief Counsel for Export Enforcement (BXA)
William Arvin - Office of the Deputy Assistant Secretary for Export Enforcement (BXA)
Mark Bohannon - Chief Counsel, Technology Administration
Michael Rubin - Deputy Chief Counsel, NIST
David Edgerly - Deputy Director, Technology Services
Subhas Malghan - Program Manager, FQA, Technology Services, NIST
David Alderman - NVLAP, Technology Services, NIST
Lynne Hare - Chief, Statistical Engineering Division, ITL, NIST
Ralph Veale - Manufacturing Engineering Laboratory, NIST

At Issue.....

...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.

FQA Requirements

Sect. 5(b)(1) "...manufacturer of a lot of fasteners shall cause to be inspected and tested a representative sample ...to determine whether the lot conforms to the standards and specifications to which the manufacturer represents it has been manufactured. Such inspection and testing shall be performed by a laboratory accredited in accordance with the procedures ...under section 6. The standards and specifications to which the manufacturer represents such lot has manufactured shall be disclosed by the manufacturer to the laboratory at the time the lot is submitted for inspection and testing under this paragraph."

FQA Requirements (cont'd.)

Sect. 5(c) "...a laboratory performing the inspection and testing...shall provide to the manufacturer a written inspection and testing report with respect to such lot. The report...shall-

(1) state the manufacturer's name, part description, lot number, grade identification mark and insignia...

(2) reference the standards and specifications disclosed by the manufacturer...

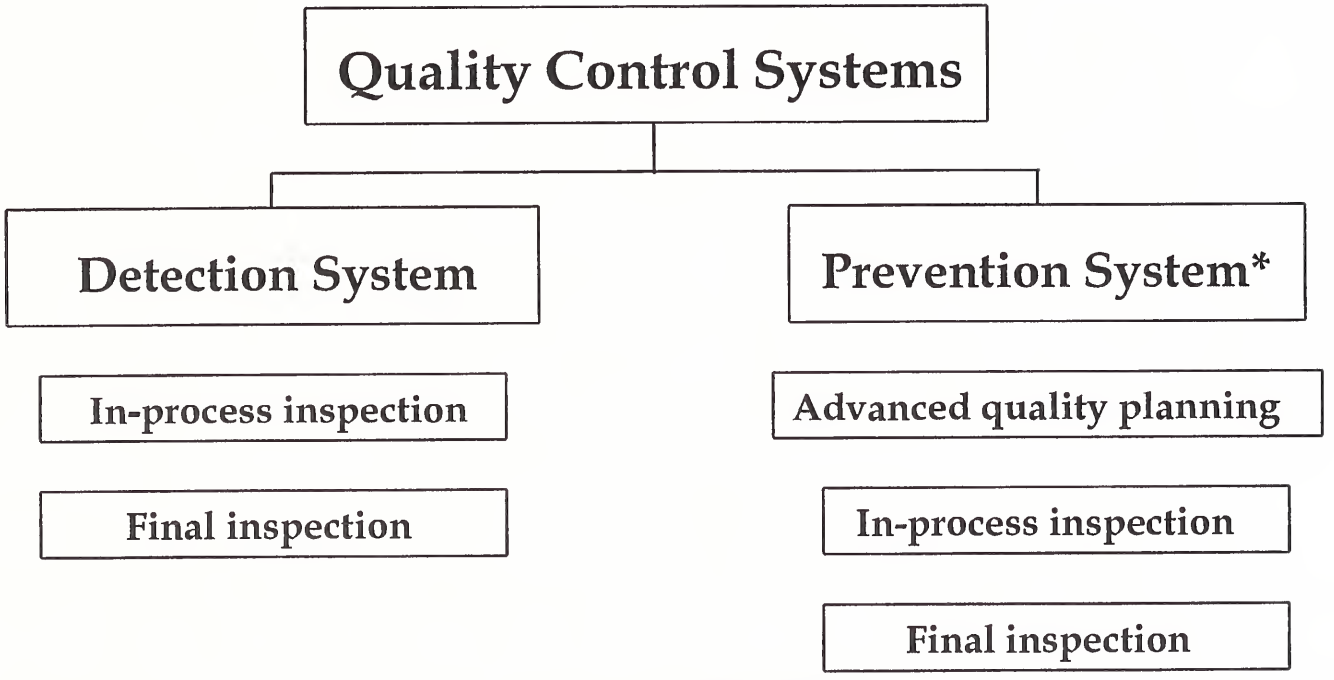
(3) ...specify the results of inspection and testing...

(4) ...state whether such samples...have been found ...to conform to such standards and specifications; and

(5) ...bear the original signature of a laboratory employee..."

Potential Challenges with SPC under the FQA

- **Use of SPC in quality control systems is focused more on "prevention" than "detection" of fastener defects.**



* SPC applied to control system to reduce variability of output.

ASTM F1470-93

Standard Guide for Fastener Sampling for Specified Mechanical Properties and Performance Inspection

Comparison of Detection vs. Prevention Sampling Plans*

Characteristic: Hardness Testing

Sample Size

Lot Size	Detection Process	Prevention Process
10,000 pcs.	→ B - 15 pcs.	→ C - 4 pcs.
	Must be checked at final inspection	In-Process Check

* Information provided by Mike Connelly, Quality Assurance Manager, Casey Products Corp.

Potential Challenges (cont'd)

- **In-process measurements may not produce test results sufficient to satisfy the FQA.**

Examples:

Use of lasers to do dimensional measurements on-line.

Use of "Go"/"No-Go" gauges on-line to reject nonconforming parts.

Monitoring of influence factors to control "hardness" in heat treating of fasteners.

Potential Challenges (cont'd)

- **In-process controls complicate the laboratory accreditation process under the FQA.**

Examples:

Laboratory manager often does not control measurements made outside of the laboratory (e.g., in-process).

In-process measurements of some fastener characteristics (e.g., dimensions, hardness, etc.) may not be covered by established test methods.

Potential Challenges (cont'd)

- **QS9000, ARD9000, ASME FAP1 and similar quality assurance standards are not sufficient as stand alone documents to assure compliance with the FQA.**

U.S. Consensus Standards for Covered Fasteners*

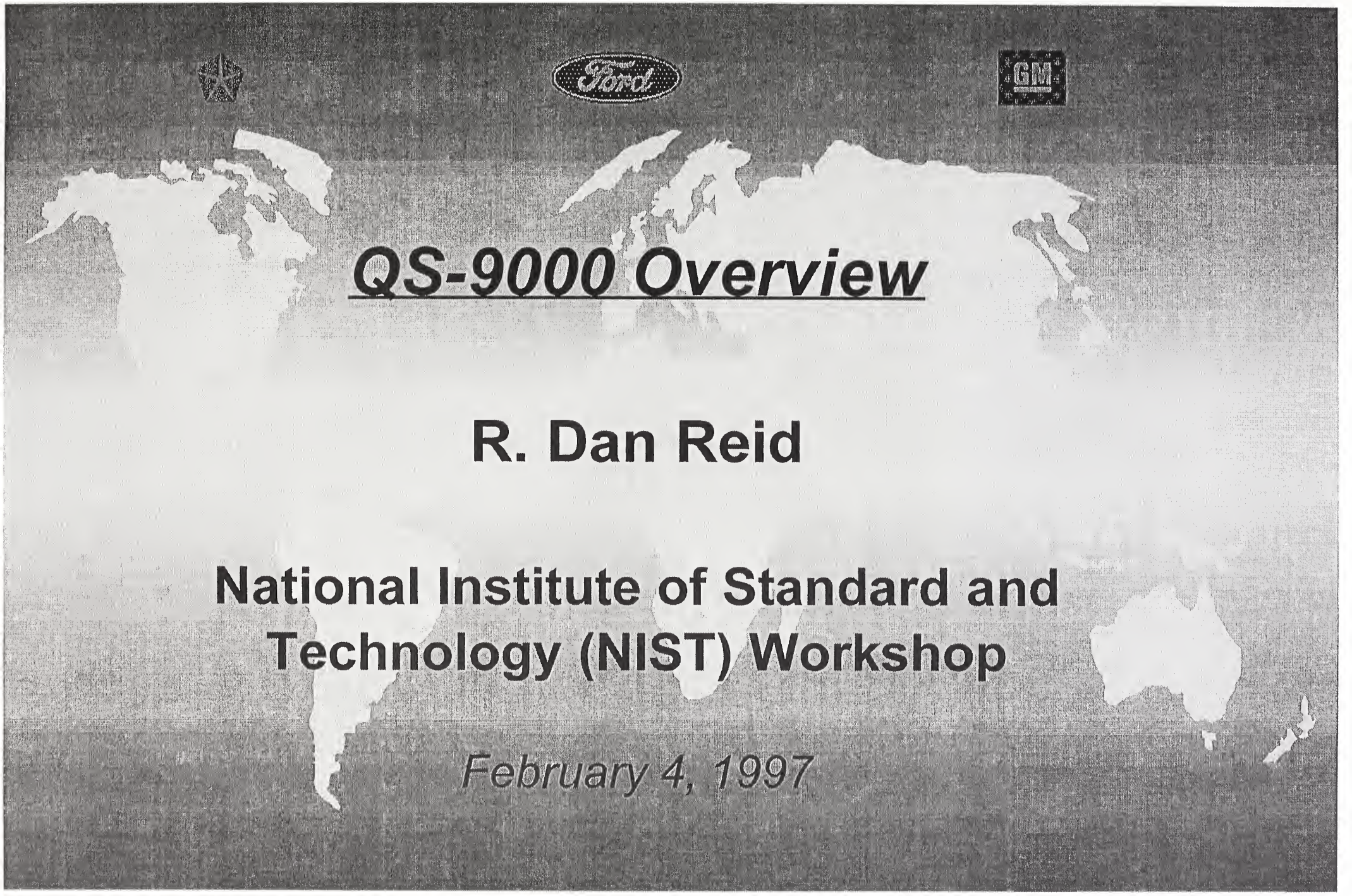
Steel: screws, bolts and studs:
SAE J429, ASTM A193, A325, A490, A574, F879, F912, A449, A354, A394, A687, A325M, A490M, A574M, F879M, F921M, F568

Stainless and non-ferrous screws, bolts and studs:
ASTM A193, F593, F594, F738M, F836M, F837M, F879M

Steel, stainless, and non-ferrous nuts:
SAE J995, ASTM A194, A563, F593, F594, A563M

Washers:
ASTM F436, F436M, F959, F959M

* Joe Greenslade, Article in Jan/Feb issue of American Fastener Journal.



QS-9000 Overview

R. Dan Reid

National Institute of Standard and Technology (NIST) Workshop

February 4, 1997

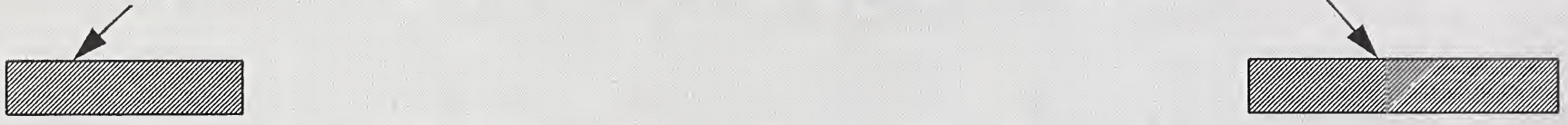
Chrysler, Ford, GM Quality System Requirements
Goal
– is the development of quality systems that provide for continuous improvement, emphasizing defect prevention and the reduction of variation and waste in the supply chain.

Chrysler, Ford, GM Quality System Requirements
Purpose
– defines quality system expectations
– for internal and external suppliers
– of **production materials**; production or service parts; heat treating, painting, plating, or finishing service
– to ensure **customer satisfaction**
– begins with conformance to requirements
– continues with reduction of variation and waste

QS-9000 and ISO 9000

Systems which meet ISO 9001 or 9002

Implementations which work for ISO, but not QS-9000



SYSTEMS WHICH MEET *QS-9000*

All *QS-9000* systems meet ISO 9001/2, but not all ISO 9001/2 systems meet *QS-9000*

QS-9000 Benefits

- Harmonization of requirements
- Early feedback/concerns
  - *complex, lack of qualified auditors, costly*
- Recent supplier feedback:
  - *productivity improvements*
  - *cost savings*
  - *improved business processes*
  - *improved quality*
  - *improved customer satisfaction*

QS-9000 Registration Requirements

- GM suppliers by December 31, 1997
  - communicated to suppliers October 1994
  - suppliers to GM-APO (excluding Australia) by December 31, 1999
- Chrysler suppliers by July 31, 1997
- Ford -- no requirement for registration
  - except in Australia by December 31, 1997
  - Non-Q1 suppliers to Ford-Brazil

Code of Practice

- For Quality Systems Registrars Making Assessments to the *QS-9000*
  - to address variation in registrar practices
    - *cover all quality system elements*
    - *evaluate effectiveness of system elements*
    - *surveillance frequency requirements defined*
    - *supplier report requirements defined*
    - *registrar training requirements defined*
  - supplier to include in contract with registrar
  - accreditation body to control its use by registrars

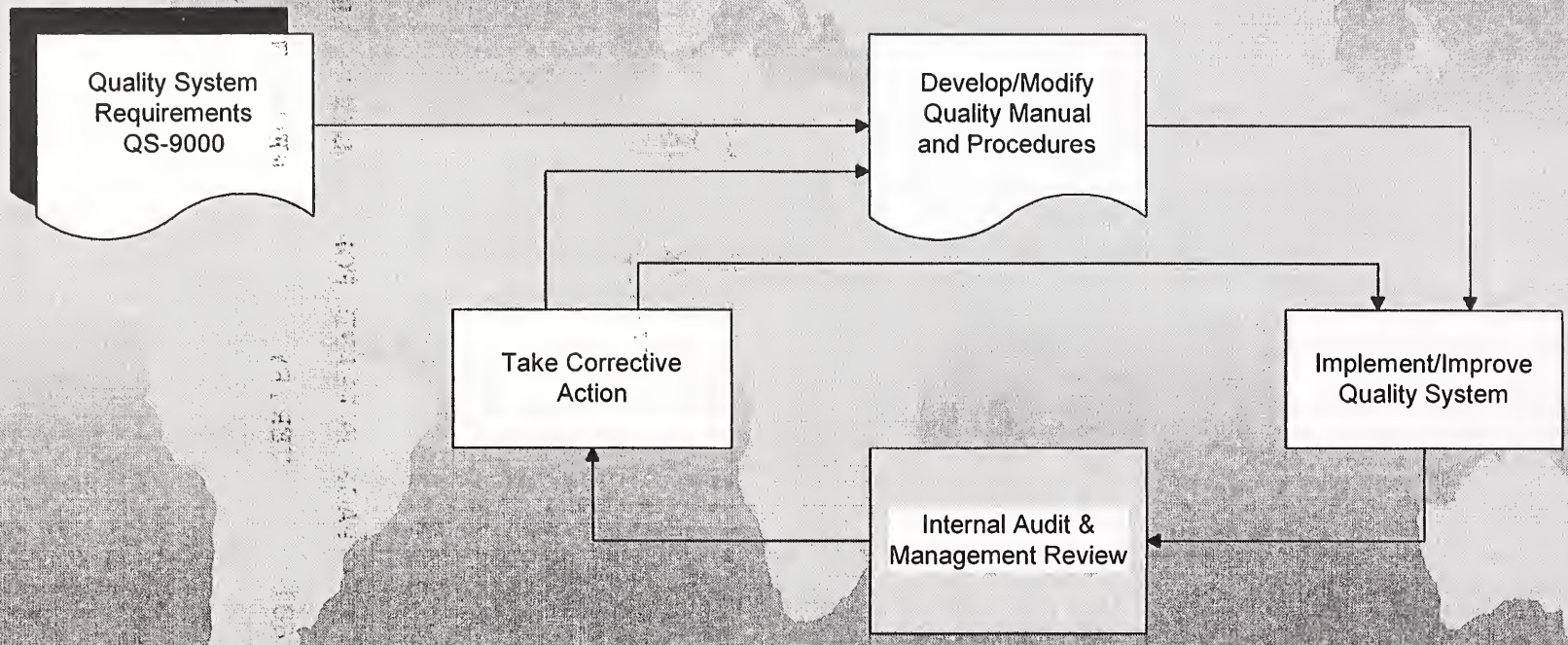
Customer Performance Requirements

- Supplier internal key indicators must be established to meet customer performance requirements, e.g. 4.1.5, 4.1.6, 4.15.6
- Quality system effectiveness must be measured and tracked using these indicators
- Continued surveillance of poor trends will jeopardize *QS-9000* registration

Management Responsibility

- Quality Policy
  - Defines/documents objectives and commitment to quality
  - Understood, implemented, and maintained at all levels of the supplier's organization
- Organization
  - Responsibility and authority of personnel affecting quality defined and documented
  - Provide Adequate Resources/Trained Personnel
- Organizational Interface
  - Must ensure management of appropriate activities:
  - Must use multi-disciplinary decision-making
  - Must be able to communicate data in customer-prescribed format

The Quality System Development/Implementation Process



Quality System

- General
  - Establish, document, and maintain a quality system
  - Document in a **quality manual (level 1)**
  - Manual to reference procedures (level 2) and outline structure of documentation

- Quality System Procedures
  - Documented procedures/effectively implemented
  - Degree of documentation depends on:
    - Methods used
    - Skills needed
    - Training acquired by personnel involved

Quality System

Quality Planning

- Define/document how requirements will be met
- Quality planning culminating in a control plan
  - Controls, equipment, resources, skills needed
  - Compatibility of design and production processes
  - Updating of techniques, instrumentation
  - Updating of measurement systems capability
  - Suitable verification activities at appropriate stages
  - Clarification of standards of acceptability
  - Preparation of quality records (See 4.16)
  - Feasibility studies
  - FMEAs
- Suppliers must use the APQP manual

Quality System

Quality Planning

- Use of Cross-Functional Teams to:
  - Develop and review FMEAs &PFMEAs
  - Develop/finalize special characteristics
  - Establish actions to reduce potential failure modes
  - Develop and review Control Plans
- Feasibility Reviews
- Control Plans (system, subsystem, component)
  - must include all special characteristics (Appendix C)
  - for prototype, pre-launch, production phases
- Use of appropriate APQP Manual techniques

Control Plans

- Detailed listing of all tests to be conducted on each part
- Document includes
  - Characteristics inspected/tested
  - Test method
  - Sample size
  - Test Frequency
  - Reaction Plan

Document and Data Control

- General
  - Procedures to control all documents/data including reference documents
  - *Documents and data can be in the form of any type of media:*
    - *Hard Copy*
    - *Electronic*
- Document and Data Approval and Issue
  - Must be reviewed/approved for adequacy
  - Master list or equivalent control procedure
    - Must identify current revision status of documents
    - Must be readily available
  - Pertinent issues to be available at "all locations"
  - Invalid/obsolete documents must be removed

Purchasing

- General
  - Procedures to ensure purchased product conformance
  - Use of customer-approved subcontractors
  - Approved Materials - Ongoing Production
    - Materials must comply with government regulations:
      - e.g. restricted, toxic, or hazardous materials
- Evaluation of Subcontractors
  - Selection based upon ability to meet requirements
  - Type/extent of subcontractor control to be defined
    - Based on type of product
    - Criticality of subcontracted product/service
    - Quality audit reports/past performance
    - Records of acceptable subcontractors

Product Identification/Traceability

- Supplier shall establish/maintain procedures
- To identify product by suitable means
- From receipt and during all stages of production
- Including delivery and installation as appropriate
- Where traceability is a specified requirement:
  - Procedures for unique identification of product
  - Records shall be kept

Process Control

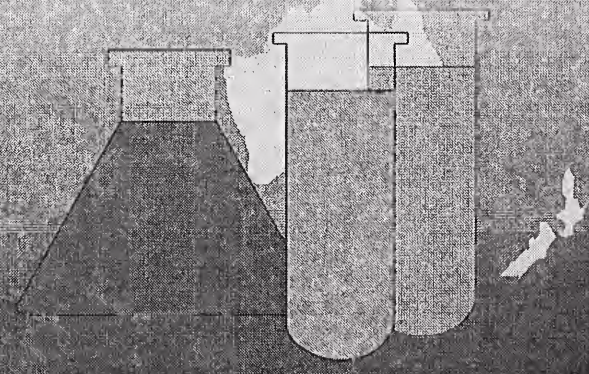
- Processes must be under controlled conditions:
  - Documented procedures defining work
  - Suitable equipment and work environment
  - Compliance with standards, quality plans, Control Plans, procedures
  - Monitoring key process parameters/product characteristics
  - Approval of processes and equipment
  - Criteria for workmanship shall be stipulated
  - Suitable maintenance of equipment
    - Identification of key process equipment
    - Provide appropriate resources
    - Develop an effective, planned total maintenance system

Process Control

- Process Monitoring/Operator Instructions
  - Understandable instructions for operators, at work station
  - Derived from sources listed in the APQP Manual
- Preliminary Process Capability Requirements
  - Preliminary studies required for each special characteristic for new processes.
  - Ppk targets set by customer (defaults to Ppk=1.67)
  - Reviewed with customer during APQP Process
- Ongoing Process Performance Requirements
  - Ppk/Cpk targets set by customer
    - Cpk=1.33 stable, normally distributed data
    - Ppk=1.67 unstable, but predictable pattern
  - Other methods, e.g. PPM, for non-normal data
  - Significant events must be noted on control chart

Inspection and Testing

- General
  - Procedures to verify that product requirements are met
  - The required inspection/testing shall be documented in the Control Plan and/or supporting documentation.
  - Accredited Laboratories must be used if required by customer.
- Acceptance Criteria
  - Zero defects to be used for attributes data
  - Appropriate criteria for other situations:
    - Documented by the supplier
    - Approved by customer, e.g. visual standards



Inspection and Testing

Receiving Inspection/Testing

- Incoming product to be verified before use
- Verification to be in accordance with control plan
- If product is released prior to verification, it must be:
  - Positively identified and recorded
  - Recalled or replaced if found nonconforming
- Incoming quality system must use one or more of:
  - Receipt of statistical data
  - Receiving inspection and/or testing
  - Second or third party audits of subcontractor locations
  - Part evaluation by accredited 3rd parties
  - Subcontractor warrants/certifications

Inspection and Testing

- In-Process Inspection/Testing
  - Inspect/test product according to Control Plan and/or supporting documentation.
  - Hold product until verification is completed
  - Emphasis should be on prevention, not detection
- Final Inspection/Testing
  - Conduct as required by control plan and/or supporting documentation
  - To complete evidence of product conformance
  - Must require all specified activities be completed
  - Results must be authorized prior to product dispatch
- Layout Inspection/Functional Testing
  - At a customer-prescribed frequency

Inspection and Testing

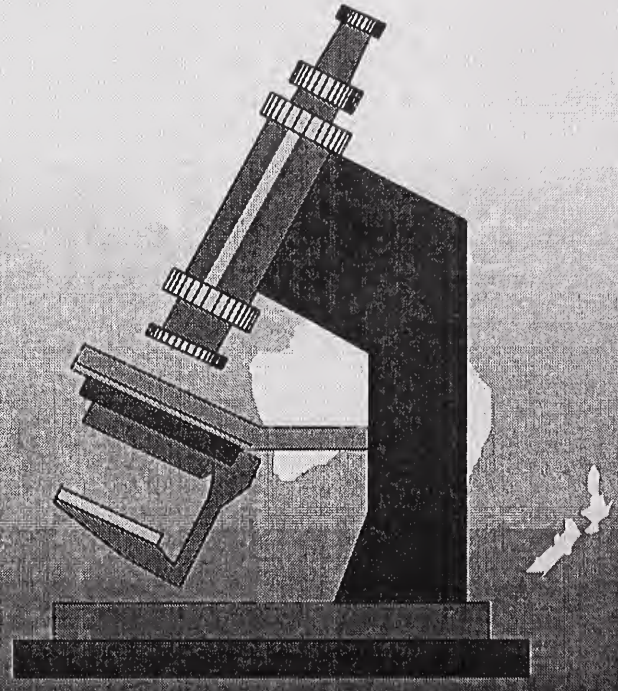
Inspection and Test Records

- Supplier to establish/maintain records
- Provide evidence that inspection/tests were done
- Records must clearly show that product has:
  - Passed or failed the inspections/tests
  - According to defined acceptance criteria
- Where product fails, procedures for control of nonconforming product shall apply
- Records shall identify the inspection authority responsible for the release of the product.

Inspection, Measuring and Test Equipment

General

- Procedures to control, calibrate, maintain equipment
  - Used to demonstrate conformance of product
- Measurement uncertainty must be known
- Equipment must meet required capability
- Software must be capable of verifying acceptability of product
  - Extent/frequency of rechecks and results to be recorded
- Technical data may be required for verification



Inspection, Measuring and Test Equipment

- Inspection, Measuring, and Test Equipment Records
  - Records must include:
    - Revisions following engineering changes
    - Gage conditions and actual readings taken
    - Notification to customer if suspect material shipped
  - Must include employee-owned gages
- Measurement Systems Analysis
  - Appropriate statistical studies must be conducted
  - Applies to all measurements referenced in Control Plan
  - Methods/criteria should conform to Measurement Systems Analysis manual

Inspection and Test Status

- General
  - Status must be identified by suitable means
- Status must be maintained through production process
  - To ensure only verified product is used
  - Or released under authorized concession
- Location of parts in normal production flow is insufficient indication of status where not inherently obvious
- Supplemental Verification
  - Additional requirements may need to be met
    - e.g. early launch controls

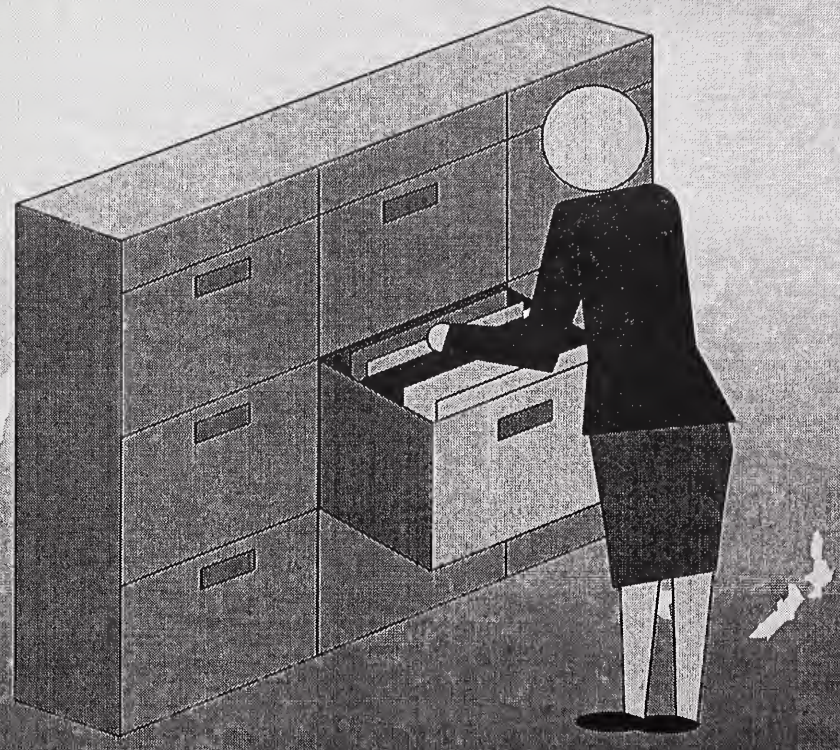
Control of Nonconforming Product

- General
  - Use of nonconforming/suspect product must be prevented
  - Procedures shall provide for:
    - Identification, Documentation, Evaluation, Segregation (when practical)
    - Disposition of nonconforming product
    - Notification to functions concerned
- Engineering Approved Product Authorization
  - Prior written customer authorization required when:
    - Product/process differs from PPAP approval this applies equally to subcontractor products/services
  - Supplier must concur with subcontractor requests before submission to customer
  - Supplier must record expiration date or quantity
  - Ensure compliance with requirements after expiration
  - Material must be identified on each container

Control of Quality Records

Supplier to establish/maintain quality records procedures for:

- Identification
- Collection
- Indexing
- Access
- Filing
- Storage
- Maintenance
- Disposal



Internal Quality Audits

- Establish/maintain documented procedures
- Plan/implement internal quality audits
- Verify that activities comply with quality plan
- Determine effectiveness of the quality system
- Schedule based on status/importance of activities
- Done by independent personnel
- Results to be recorded, reported to audited department
- Management responsible to take timely corrective action
- Next audits to record the effectiveness of the C/A
- *Internal audit is integral part of management review*
- Suitable work environment must be audited

Statistical Techniques

- Identification of Need
  - Supplier shall identify the need for techniques for establishing, controlling, verifying:
    - Process capability
    - Product characteristics
- Procedures
  - Establish/maintain documented procedures
  - To implement/control the application of techniques
- Statistical Tools
  - Selection should be done during quality planning
  - Must be included in the Control Plan

Statistical Techniques

- These Basic Statistical Concepts should be understood throughout the supplier's organization:
  - Variation
  - Control (stability)
  - Capability
  - Overadjustment
- Consult Fundamental SPC Reference Manual

Production Part Approval Process (PPAP)

- Supplier must comply with all PPAP requirements
- Production part approval is granted for a:
  - Part number
  - Engineering change level
  - Manufacturing location
  - Material/component subcontractor (s)
  - Production process environment
- Change to any requires a review of PPAP for direction

Continuous Improvement

- Comprehensive Continuous Improvement philosophy must be fully deployed
- Supplier must show continuous improvement in quality, service, price
- Supplier shall develop specific action plans for continuous improvement in processes, that are most important to the customer, once those processes have demonstrated stability and acceptable capability
- Attribute data: perfection of process methods
- *Variable data: reducing variation around target*
- *Continuous improvement philosophy should extend to all processes/services.*

QS-9000 & Third Party Registration

- Why We Did It
  - *QS-9000*:
    - ISO 9001 - not at current automotive level
    - "interpretations" supplement ISO 9001
  - *Registration process*
    - wanted the current 3rd party methodology
    - variation in practice was unacceptable
  - *CUSTOMER ASSURANCE is key*
    - consistency and integrity

INTRODUCTION

I am Max Dorflinger, President & Chairman, Nylok Fastener Corporation.

Nylok is a supplier of self-locking, sealing, and other specialty fasteners.

This year I am serving as IFI Chairman. The IFI represents the fastener manufacturing industry throughout North America and its suppliers from many countries of the world.

Currently IFI represents:

- 104 fastener manufacturers
- 48 suppliers of material, tooling and engineered services

IFI members pool their resources to further fastener application engineering.

PURPOSE OF THIS PRESENTATION

- Make clear that IFI fully supports its largest customers which are the automotive and aerospace industries.

- Support the need for change to prevent industry technology from stagnating in an obsolete law and its regulations.

- Express support for those seeking to correct legislative oversight.

GENERAL COMMENTS

Every fastener has three basic characteristics which collectively give the fastener its service capability. These include:

- **Physical Characteristics -** Inherent in the raw material and remain unchanged or only slightly altered in manufacturing, such as electrical resistance and thermal expansion.

- **Mechanical Characteristics** - Are those which identify the reaction of a fastener to an applied load. These characteristics are achieved in processing, and include properties such as hardness and tensile strength.

- **Performance Characteristics** - Design features which are manufactured into a fastener to meet a service application, such as a paint removing slot.

Standards have been written which outline the mechanical and performance requirements for many geometric configurations which are described in dimensional standards.

To evaluate these and establish conformance, standards have also been written which describe testing procedures and inspection procedures including frequency.

Standards are living, breathing documents which are constantly being reviewed and modified to reflect evolving technology and experience.

It is historically correct that the special of today becomes the standard of tomorrow. It is never the reverse. New ideas and technology continue to fuel this evolution.

Unfortunately, the Law, which has become known as the "Fastener Quality Act," is actually the opposite. It fixes in time and space requirements which have become obsolete because of evolving fastener technology.

Unless a solution is found, the fastener industry will suffer under intense foreign competition which is not bound by such requirements in their own countries.

Far worse, it will place our largest consumers of fasteners in North America in an unacceptable global position.

IFI sees the auto and aerospace industries faced with two serious and unresolved issues which need the collective "best thinking" of all present at today's session.

1. A need to assure evolving technology will be reasonably and assuredly accommodated by the Law and its Regulations.

2. A need to assure no disruption in supply will occur or that present just-in-time delivery practices may continue without interruption.

IFI has met with numerous customers and fastener manufacturers. It fully supports the need for major revision and change which should be carried out to meet the needs of the North American fastener industry and its most important customers.

~ OTHER CONCERNS ~

While today's meeting is focused on the need to accept and accommodate modern in-process control procedures, it must be noted that IFI has continuing concerns related to other issues as well. They include:

- No definite or defined plan to develop an orderly procedure to implement the Law to assure that by the effective date the pipeline is filled with raw material which is qualified for use.

- The Law's encouragement of the importation of subassemblies which will include billions of fasteners moving outside the spirit and intent of the Law and economically could be devastating to USA component manufacturers.

IFI CONTINUING CONCERNS

- A strong feeling that the economic impact has not considered the costs of the raw material manufacturer's laboratory accreditation and the routine practice of overnight or premium shipments to assembly plants.

IFI RECOMMENDATIONS

- NIST should amend or revise existing regulations to reflect the spirit and concepts reflected in ASME drafts B18.18.5M, B18.18.6M and ASME B18.18.7M in addition to B18.18.1M thru .4M.

These same concepts will inevitably be introduced into existing and new ASTM and SAE standards as well.

- NIST should prepare and submit recommendations to revise the Public Law and/or its Regulations to assure that industry technology is not stymied and shipments for just-in-time delivery are not disrupted. Revisions should account for global parity of all parties.

- A delay should be immediately issued based on:

  - → inadequate raw material laboratory and fastener laboratory accreditation.
  - → the need for significant clarifications required to assure orderly implementation.
  - → manufacturers' concerns regarding compliance and their fears of shutdown to prevent violations.
  - → expressed major user concerns regarding in-process inspection and just-in-time issues, including premium shipments.

"Quickest way through is often the longest way round."

Good Morning, my name is Jack McCarthy. I have spent the last 37 years of my life working in the fastener industry in both the United States and Europe. I am President of Kamax-G.B. Dupont, a Limited Partnership located in Troy MI. Kamax-G.B. Dupont is a manufacturer of M6 through M18 diameter (1/4" - 3/4") fasteners, 100% of which go to the Automotive Industry.

I am here today as the current chairman of I.F.I. Division 7. Division 7 consists of 36 companies within the Industrial Fastener Institute who have a substantial portion of their production being delivered to the automotive industry. In fact, we also call ourselves AIFG or Automotive Industrial Fastener Group. Our group represents over $2 billion in sales revenue and we produce in excess 40 billion parts per year and employ over 10,000 people. We meet periodically, usually in the Detroit area, to discuss issues of common concern between our members and our customers. We address subjects such as quality, where we monitor our parts per million performance as a group and address improvements or

enhancements to standards or specifications; issues connected with packaging, where we address returnable containers and just in time delivery concepts; finishes, where we work to improve corrosion resistance at the same time reduce environmental impacts of these hostile processes, all in concert with our customers and with a mandate which we all share to continuously improve our performance by reducing our costs and adding value to our products.

What we wish to address today is how the current regulations associated with the recently enacted Fastener Quality Act impact our group.

Let me say first that no member of our division opposes the original concepts or spirit of the Fastener Quality Act, at least the concepts as we understand them which is essentially truth in selling. The turn around in the U.S. automotive industry in terms of quality, in terms of value, and in terms of performance is well documented. Certainly Ford, General Motors, and Chrysler get the headlines, but behind these great companies

are thousands of suppliers, and their employees, like the 36 members of Division 7 who for the past decade have reduced prices, yes reduced prices, improved quality and embarked on a journey of continuous improvement unparalleled in our's or any other industry. Today we are delivering on a just in time basis millions of parts with quality levels none of us would have believed possible just 10 years ago. And, I might add, we are not only doing it for the Big 3, but we are also supplying the Japanese transplants as well as the recent German start-up operations in the U.S.A. How did we do it? We did it by aligning ourselves with our customers and working together to take cost out of our processes and to build quality into our products, not inspect defects out. Together we realized that old A.Q.L. (Acceptance Quality Level) final inspection techniques were not only costly, they were ineffective. We have achieved the above improvements by process controls including S.P.C and T.Q.M. concepts that deliver quality products on time every time. We constantly look at everything we are doing to examine how we can improve.

Our customers have introduced a quality system called QS9000. This is a further step towards insuring quality performance throughout the entire process. It also attacks costs in so much as it is an industry system and moves us away from costly duplications of multiple quality systems. Again, improving quality decreasing costs.

As I stated earlier, the membership of Division 7, the Automotive Industrial Fastener Group, is in complete agreement with the spirit and intent of the Fastener Quality Act. In fact, we believe today that each and every one of our members comply with the spirit of the law; shipping parts that 100% conform to our customers requirement, over 8,000,000 times every day. Our problem, gentlemen, is that in order to conform to the current regulations when the FQA goes into effect, we will need to introduce a significant amount of final inspection as well as needless and useless duplication in documentation that will represent a significant set back on our journey to excellence. In other words, a step backward in our efforts to compete in a global economy and to lead the world in

quality and productivity. We are also concerned about our ability under the inspection requirements in the current regulations to react to our customers' schedule changes in today's just in time environment. This situation could lead to costly and non value added inventory investments, and/or costly plant shut downs.

How can we prevent this from happening? Some of the membership of Division 7 would suggest the entire law needs to be re-examined and ask if we, our industry, our customers, and our government do not need to ask ourselves if we are making some drastic mistake here that will only add significant cost, unnecessary regulation and a bureaucratic nightmare to an industry that was almost annihilated by the off shore competition in the 1960's and 1970's. And is only today beginning to get back on its feet and provide a real contribution to the American economy.

Most of our members realize that a total "re-think" of the F.Q.A. at this point in time is probably unrealistic. We do believe however that at a

minimum, we must modify the regulations to recognize in process controls which focus on defect prevention as a replacement for final inspection procedures, which focus on defect detection.

How can this be done? We would suggest that an amendment to the regulation that first, accepts major end user quality systems such as QS9000 as meeting the inspection, testing, and certification requirements of the law, utilizing certified laboratories.

Second, by endorsing in the regulations concepts reflected in current and proposed ASME, SAE and other quality standards organizations which emphasize process control as a means to insure product quality. Such as ASME B 18.18.5, .6 and .7M.

In summary, I am sure everyone in this room wants a fastener industry that delivers quality parts that meet customer expectations.
No member of Division 7 is opposed to that concept. In fact we do just

that every business day.

Let's work together, as users, as producers, and as government to not only insure the integrity of the products we provide, but to do so in an atmosphere that recognizes the needs for productivity and global competitiveness and that allows our factories to utilize the tools of modern manufacturing technology.

Good morning/afternoon Ladies and Gentlemen. Thank you for the opportunity to address you on the Fastener Quality Act.

My name is Patrick Meade. I am Chairman of Division VI, the Aerospace Fastener Division of the Industrial Fasteners Institute. I am also President and Chief Operating Officer of Hi-Shear Corporation, a major manufacturer and designer of aerospace fastening systems; and a subsidiary of GFI Industries, a world leader in fastener manufacturing.

With regard to Statistical Process Control, or Statistical Quality Control, the Aerospace fastener industry uses this method to control its manufacturing

process and key characteristics of its products. The industry uses Process Capability Studies, Process Control Charts in our factories, Statistical sampling inspection, and Statistical design of experiments to compare variables and determine their significance. A process, by the way, is any set of conditions which work together to produce a result, and in this case an aerospace fastener.

SPC or SQC is not limited to manufacturing, it is a method which is used in our industry to solve problems in Accounting, Engineering, Management and virtually all fields of activity. SPC is mandated on the suppliers of aerospace fasteners by the end users – the builders of aerospace structure (Boeing's Advanced Quality

System D1-9000A). The Aerospace industry specifies control of key characteristics and key processes, either by direct reference on product standard drawings or in related specifications. Fastener manufacturers are required in most instances to provide the SPC data in hard copy format on each lot of fasteners produced and shipped to the end user.

The ultimate intent of the aerospace vehicle manufacturer is to eliminate final inspection which is redundant and therefore unnecessary added cost. This plan to eliminate final inspection by using in-process controls, is in fact approved by the Federal Aviation Administration. The elimination of final inspection

justified by demonstrated in-process controls is in effect at a substantial number of producers.

I invite you to visit aerospace manufacturers to see SPC at work. Names and addresses are available through the Industrial Fasteners Institute.

Ladies and Gentlemen, the pressure of time necessitates brevity in our comments, so I will briefly hit on a few of the many concerns we have with regard to the FQA.

Aerospace fastener manufacturers are currently subjected to government audits and certification to military specifications such as MIL-I-45208 and MIL-Q-

9858. Our quality systems and product performance are audited and qualified by our customers such as Boeing, General Electric, Lockheed, and so on -- not just once, but annually or bi-annually. Some of us are subjected to as many as 50 audits per year. The FQA does not replace these audits, it is an additive.

This current audit of our systems is not limited to manufacturers, but is extended to our Authorized Distributors.

When The Act goes into effect, what happens to the hundreds of millions of dollars of fasteners in inventories at fastener manufacturers and authorized distributors? They cannot be certified as in compliance

with the FQA. Will they be discounted or scrapped at substantial economic hardship to the industry? This is perfectly good hardware -- May 27 or any other date does not change this hardware.

With regard to raw material certification, under The Act, all raw material will have to be recertified. Why? This material has already been certified to the acceptability of the Aerospace end users. Who is going to recertify the material? Have enough material labs been accredited? How many must be accredited to meet the industry needs? It has been estimated that 300 to 400 labs will have to be accredited to meet the needs for material and product testing. I believe this number is low. However, how many labs will be

accredited by May 27, 1997? How many are accredited today -- with only 4 months left until implementation date?

I submit this added certification is bureaucratic – adding nothing but cost. If we are to comply with this requirement, a delay in fastener shipments will occur and will result in disruptions to aircraft production at a significant cost to aircraft builders, and potentially a delay in aircraft shipments to domestic and foreign customers, with a potential negative effect on our foreign trade dollars.

The record keeping by our quality departments required by the FQA is an unnecessary burden.

Recording on the certifications the name of each quality insurance department employee who has any input on the certification of the product has no added value. Our internal documents register the identification of Quality Assurance personnel involved in testing and inspection. Listing these on a certification is bureaucratic, provides no added value to the customer, and results in added cost.

Finally, The Act does not apply to fasteners produced overseas and installed overseas in an airframe subassemblies. Aren't subassemblies built overseas subject to the same safety concerns as subassemblies built in the USA? If you argue that the aerospace

OEM's control the quality of their systems, then why is domestic production any different?

Ladies and Gentlemen, the aerospace fastener industry subscribes -- without question -- to the production of high quality hardware to the high standards required by the aerospace users with the object of the highest level of safety. The FQA adds only paper and bureaucracy to products already produced to the highest standards consistent with their use. There is no added value -- in fact, the implementation of this Law will reduce the competitiveness of the United States.

Respectively submitted,

Patrick Meade

PREPARED REMARKS OF WILLIAM TUDOR
ON BEHALF OF THE AAMA
FOR THE NIST PUBLIC MEETING
FEBRUARY 4, 1997

The draft paper on statistical process control provides a good explanation of QS-9000 and some good proposals. We heard a good overview of QS-9000 earlier, so I will only briefly highlight a few points about it. Then I will discuss features of a quality assurance plan and statistical process control and how they might be used to develop parallel requirements under the Act.

QS-9000

Under QS-9000, there are four separate things that a fastener supplier must do:

- The supplier must establish its qualifications by obtaining registration through a third party registrar or customer approval.
- The supplier must maintain that registration through periodic inspections by the registrar or customer.
- The supplier must provide a satisfactory control plan for a specific fastener and meet the other requirements for the Production Part Approval Process.
- The supplier's performance must be satisfactory when it is audited by the customer.

Each of these steps helps to assure quality. The Fastener Quality Act's requirements are, on the one hand, much less demanding in assuring part quality, and, on the other hand, can force costly and redundant work and documentation.

Comparison of traditional lot inspection and quality assurance plans using SPC

We think that examining the parallels between traditional lot inspection and quality assurance plans using SPC will help to decide what is necessary and appropriate to accommodate quality assurance plans and SPC under the law.

Whichever one is using, the beginning point is product characteristics specified by a consensus standard [see Chart 1].

Under a traditional lot control system, operators are given instructions on how to do each job. Under a quality assurance plan, there must be a control plan that covers each step and specifies the equipment used, the criteria that apply, the steps to take when there are nonconformities, and who is responsible for the step. QS-9000 and its related documents describe what must be in a control plan.

The quality assurance in lot inspection is based on sampling from each lot to determine if the specified characteristics have been met. The criteria for sampling may be based on a consensus standard. Under a quality assurance plan, lot inspection may be used for some characteristics. Process controls are also used and are based on establishing a controllable process that will produce the desired characteristics and validating that the system produces quality products. Error proofing, the use of equipment that can detect and reject non-conforming parts, represents the ultimate form of control.

With traditional lot inspection, the verification is the testing and inspection results. This once was mainly the responsibility of the laboratory, but now some testing and inspection has shifted to the plant floor. In process control systems, the equivalent form of verification is the systematic monitoring of the process. If temperature is a factor to be controlled, then the temperature may be checked and noted on a regular schedule or it may be recorded continuously. Dimensional checks may be required following setup changes, at the beginning of shifts, lots, and batches, and on a periodic basis.

The monitoring of the process controls system produces data that is or can be recorded. That data may be as simple as a signature or initials showing that a required inspection was made. Operators may be required to sign a control sheet showing that required inspections were made during their shift or for a lot or batch. Equipment must be calibrated at least once a year and be traceable to NIST standards. Under QS-9000, process control charts and records must be kept for at least one calendar year after the year in which they were created.

Proposals

With this background, we now turn to the proposals that have been outlined.

We support changing the requirements so that they can be satisfied using quality assurance plan and statistical process control methods.

We share the concern that the Act's inspection and testing requirements are so inflexible that just changing the regulations will not be sufficient to accommodate fasteners made under a quality assurance plan and avoid redundant testing and documentation.

What we have tried to look at is how some of the features of a quality control plan might be used to develop parallel requirements under the Act. In doing so, we are not addressing the many other issues and concerns about the Act. That is for another day.

Our analysis is shown in this chart [see Chart 2]. On the left we show the current requirements and on the right we show how that requirement might be modified. This is the basic idea: If using statistical process control is part of the manufacturing process, then the certification of conformance should be based on either (1) conformance to specifications shown through lab test results or in-process test results or (2) conformance to the control plan shown through the process control sheets and monitoring data. Registration to ISO 9000 or QS-9000 or an equivalent would provide an independent verification, much like that supplied by the accreditation of laboratories.

Here are some thoughts about this:

- The third party registration and auditing system would provide an independent determination of a firm's ability to implement quality practices and whether it does so.

- The focus remains on the capabilities and actions of the fastener manufacturer, not those of the customer.

- NIST would not have to accredit manufacturing processes.

- We want to make sure that we don't increase paperwork costs.

- I mentioned earlier that QS-9000 requirements are much broader than those of the Fastener Quality Act. It makes sense to recognize that compliance with QS-9000 meets the Act's intent. But I want to be clear that we are not suggesting that QS-9000 should be imposed by law on the entire industry.

- ISO 9000 and QS-9000 must be able to change as technology and systems change. We do not want them to become government regulations.

We will be listening closely to hear the thoughts of the other speakers today and to the discussion that will follow.

Thank you.

Chart 1

System	Traditional Lot Inspection	Quality Assurance Plan
Specifications	Often includes fastener characteristics established by a consensus standard.	
Implementation	Job instructions to operators	Control plan
Measurement	Lot inspection and testing, sometimes with sampling criteria established by a consensus standard.	Combination of: (1) Lot inspection (2) Statistical process controls (3) Error-proofing
Verification	Laboratory testing and inspection reports	Combination of: (1) Laboratory testing and inspection (2) Continuous or periodic monitoring and data recording

Bill Tudor (GM)

Chart 2

Current requirement	Potential requirement for quality assurance plans and SPC
Certification of conformance to standards and specifications based on laboratory test reports.	Certification of conformance to standards, specifications, and the control plan, according to the quality assurance plan, based on laboratory test reports, in-process inspection and testing, or process control sheets and monitoring data.
Accreditation of laboratories.	(1) Accreditation of laboratories. (2) When certification of conformance is based in part on use of process controls, the processor is registered under ISO 9000, a more stringent standard such as QS-9000, or another consensus standard NIST finds to be appropriate.
Laboratory report on compliance with specifications.	(1) For characteristics verified by inspection and testing: laboratory report based on in-process and end of process inspection and testing. (2) For characteristics verified by process controls: control sheets and monitoring data.
Retention of laboratory test reports and test records.	Retention of (1) laboratory test reports and records and in-process inspection and test records and (2) process control sheets and monitoring data.

STATEMENT OF THE
ASSOCIATION OF INTERNATIONAL AUTOMOBILE MANUFACTURERS, INC.
BEFORE THE DEPARTMENT OF COMMERCE
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
PUBLIC MEETING ON ACCOMMODATING STATISTICAL PROCESS CONTROL
IN THE FINAL RULE IMPLEMENTING THE FASTENER QUALITY ACT

February 4, 1997

Good afternoon, I'm George Parker, Vice President for Engineering Affairs of the Association of International Automobile Manufacturers (AIAM). AIAM is a trade association that represents companies which sell passenger cars and light trucks in the United States that are manufactured both here and abroad.[1]

I appreciate the opportunity to appear before the National Institute for Standards and Technology, or NIST, today on behalf of AIAM's members to address the concerns we have about the burden the Final Rule in its current form imposes on motor vehicle manufacturers without any commensurate safety benefits. Specifically, I will address the questions posed by NIST related to how statistical process control, or SPC, might be accommodated through a modification to the Final Rule. I must point out, however, that the Final Rule includes a definition of "fastener" that is not justified by the statute or by its legislative history. We still strongly believe that there are no safety benefits to be derived from applying the Fastener Quality Act, or FQA, to motor vehicle manufacturers and, given the cost of compliance, reiterate the request of our recent petition for reconsideration to exclude motor vehicle manufacturers, which we believe NIST has the authority to do under the FQA.

In its current form, the Final Rule would require motor vehicle manufacturers to change their current practices of purchasing fasteners from suppliers which use motor vehicle manufacturers' specifications to produce fasteners using manufacturer-approved quality

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[1] AIAM represents: American Honda Motor Co., Inc.; American Suzuki Motor Corporation; BMW North America Inc.; Fiat Auto U.S.A., Inc.; Hyundai Motor America; Isuzu Motors of America, Inc.; Kia Motors America, Inc.; Land Rover North America.; Mazda Motor of America, Inc.; Mercedes-Benz North America, Inc.; Mitsubishi Motor Sales of America, Inc.; Nissan North America, Inc.; Porsche Cars North America, Inc.; Rolls-Royce Motor Cars Inc.; Subaru of America, Inc.; Toyota Motor Sales, U.S.A., Inc.; Volkswagen of America, Inc.; and Volvo North America Corporation.

AIAM members' U.S. auto manufacturing plants include: AutoAlliance International, Inc., Flat Rock, MI; BMW Manufacturing Corp., Spartanburg, SC; Honda of America Mfg., Inc., Marysville, OH, East Liberty, OH; Mercedes-Benz U.S. International, Vance, AL; Mitsubishi Motor Manufacturing of America, Inc., Normal, IL; Nissan Motor Manufacturing Corp. U.S.A., Smyrna, TN; Subaru-Isuzu Automotive, Inc., Lafayette, IN; Toyota Motor Manufacturing Kentucky, Inc., Georgetown, KY

assurance systems, including SPC-type systems, and require fastener suppliers to add redundant and expensive end-of-process testing or revert back to the previous system of only conducting production lot testing, which resulted in a lower level of quality. Even if the Final Rule is modified to accommodate SPC, the extra administrative costs associated with record-keeping, certification, and lot control would remain, again without safety benefits.

Recognition of Statistical Process Control

We are pleased NIST recognizes that SPC represents the highest level of the current state-of-the-art system in fastener production for motor vehicle manufacturers and in other advanced industries. Actually, SPC is the standard by which most components used in manufacturing motor vehicles are produced, which is the reason for the rapid advancement in product quality in the last few years. Unfortunately, the provisions of the FQA were written with reference to an obsolete method of assuring fastener quality. While the end-of-production testing called for by the FQA was the norm in the 1970s, modern principles of total quality management have revealed better methods of quality assurance. Experience has shown that such total quality management is far more effective in ensuring compliance with requirements than end-of-production testing.

A method for accommodating SPC that NIST has suggested in the preamble to the Final Rule implementing the FQA is to change the appropriate fastener standards to include SPC as a means of assuring that specifications are met. This suggestion is not practical for a number of reasons. First, and most important, any change to consensus standards would take a long time relative to the effective date of May 27, 1997.

Further, we are concerned with the level of specificity needed in a consensus standard to allow certification that the process was followed and production was in control. With greater specificity comes less flexibility to change the process for whatever reason - to reduce costs, raise quality, or both. A high level of specificity also increases the difficulty of getting agreement among all the motor vehicle manufacturers plus other fastener users and suppliers on a single SPC protocol that could be incorporated into a consensus fastener standard.

AIAM Recommendations for an Alternative Approach for Accommodating SPC

We would like to propose a different approach by which SPC can be accommodated. We suggest that NIST recognize the fastener specification and quality assurance standards of major end users, and the quality assurance systems imposed as a result of these standards on the fastener suppliers for major end users. The requirements in the current Final Rule would remain in effect for generic fasteners held out as meeting consensus standards organization or government agency standards and offered in the general stream of commerce, as envisioned by Congress. The reason for this is that,

for fasteners entering the general stream of commerce, there is no major end user specification or manufacturer quality assurance-approval system in place that would be enforced by the major end user.

Manufacturers' quality assurance standards and related quality assurance systems imposed as a result of those standards on suppliers would be allowed to form the basis of compliance with the Final Rule. NIST would require that the major end user quality assurance standard is published and that the quality assurance system developed and imposed on a fastener supplier as a result of the standard would include the specific control attributes to be monitored, the level of control needed, the system for monitoring the attributes, and any other features to be included in the major end user-approved plan that NIST would find necessary to ensure that the quality assurance system would, in fact, result in fasteners meeting the applicable specifications with a very high probability (or conversely, a very low defect rate).

We recommend that whatever criteria NIST would set up be performance based so as not to restrict the adoption of more advanced quality assurance systems in the future. We stand ready to assist NIST in such an effort to develop the SPC eligibility criteria. There would be no review by NIST or an independent party of the major end user quality assurance standards or the quality assurance systems imposed on their fastener suppliers. Major end users would essentially "self certify" that their quality assurance standards and the quality assurance systems developed and imposed on each supplier by the standard for each type of fastener procured complied with the eligibility requirements in the Final Rule.

Since production of fasteners under a major end user-approved quality assurance system would not require "test reports" as in the current Final Rule, the system just described has an element of self certification similar to the self certification to Federal Motor Vehicle Safety Standards under the National Traffic and Motor Vehicle Safety Act of 1966, referred to as the Safety Act. Therefore, we recommend that NIST recognize the motor vehicle industry's long history of producing vehicles under a self-certification system and accommodate SPC by allowing their fastener suppliers to self-certify that fasteners they supply to the motor vehicle industry for producing assemblies and for spares were manufactured under a quality assurance system approved by the motor vehicle manufacturer and that the requirements in the quality assurance system were met. Given the excellent fastener-related safety record of the motor vehicle industry, this would not create any safety hazards. Under this system, fastener suppliers operating under an approved quality assurance system could be required to keep records of the control charts and other data records required by the quality assurance system for fasteners produced. These records could be subject to periodic audits by NIST or an independent entity that would be accredited by NIST. Since this provision would only be available for fasteners produced in closed-loop systems for production of assemblies and for spares for those assemblies, no certification to purchasers would be

needed, whether the fastener supplier was domestic or off shore. We recognize that some sort of entry notification that a shipment of fasteners was produced in accordance with a major end user-approved quality assurance system might be needed for imported fasteners. Finally, since all motor vehicle manufacturers must be able to conduct defect recalls under the Safety Act, no lot traceability requirements need be specified for end users that would obsolete or hinder modifications to existing systems that allow motor vehicle manufacturers to identify components needing recall. End users are generally exempt from commingling restrictions under the FQA in any case. This self-certification system of compliance would greatly reduce the administrative burden of compliance.

The recommendations just described cover ideas on how SPC could be incorporated into a modified Final Rule. I have not addressed whether the changes outlined could be accommodated under the FQA as presently codified. We leave that to the expertise of NIST. We stand ready to assist NIST in seeking any changes it feels are necessary to accommodate SPC into the Final Rule or any other change to the FQA that will substantially reduce or eliminate the burden of compliance for motor vehicle manufacturers.

The changes in the Final Rule to incorporate SPC, whether they be based on incorporating SPC into consensus standards organization or government agency standards, or the recommendations AIAM has offered, or some other approach will take some time to accomplish, especially if the FQA must be modified. Even without these changes, there is considerable uncertainty regarding many provisions in the Final Rule regarding coverage issues and how compliance can be achieved, as indicated by the large number of clarifying questions submitted to NIST. Meanwhile, the compliance date is rapidly approaching. We urge NIST to announce immediately a delay of the compliance effective date for at least one year, and preferably two years, in order to make the changes to the Final Rule. Our members and their fastener suppliers remain uncertain about major aspects of the Final Rule and are spending substantial amounts in preparing for compliance and need to know very soon if the requirements may change to less burdensome ones.

The 1996 Amendments to the FQA Effectively Excluded Motor Vehicle Manufacturers from Coverage

As I stated at the start of my comments, AIAM believes that there are no safety benefits of applying the FQA to the motor vehicle industry, and the Final Rule therefore unnecessarily imposes a cost burden on motor vehicle manufacturers and consumers. Congress intended the FQA to apply to the 1 percent of fasteners that are used in critical high strength fastener applications with a potential for significant safety problems. It was meant to apply to generic fasteners that are held out as meeting

consensus standard organization or government agency standards and that are offered in the general stream of commerce. This was clear when Congress expressly excluded fasteners produced to the requirements of "major end users" from coverage under the FQA. Fasteners used in the motor vehicle industry are not held out as meeting any but the manufacturer's specifications and do not enter the general stream of commerce. They are produced to a manufacturers own specifications and in a closed loop system involving a limited number of suppliers, their own assembly plants, and their dealers for distribution of spare parts. Furthermore, there is no safety problem to address. Motor vehicles have an excellent safety record related to fastener quality. From a regulatory standpoint, the safety of fasteners used by motor vehicle manufacturers is assured and monitored pursuant to the provisions of the Safety Act administered by the National Highway Traffic Safety Administration. All of these points and others were made in our recent petition for reconsideration. Thus, we urge NIST to modify the Final Rule to recognize that fasteners produced to the requirements of motor vehicle manufacturers are not covered.

Thank you for the opportunity to present these views. I will try to answer any questions you may have.

Comments of Robert Brunner, ITW Shakeproof

February 4, 1997

Before the National Institute of Standards and Technology

Re: Implementation of the Fastener Qualtiy Act

Illinois Tool Works, through its several separate fastener divisions, is one of the largest suppliers of fasteners to North American industry. As a leader in fastener design, development, manufacture and quality for over seventy-five years, we feel compelled, having reviewed the effect of PL 101-592 on our businesses, to respond to your request for comment.

In its written comments to the National Institute of Standards and Technology of May 22, 1996, following the agency's preliminary publication of its final fastener rule, ITW drew the agency's attention to its definition of a fastener.

Therein, fasteners, manufactured to a major end user's specification, where such specification references a consensus standard, would be subject to the Act.

ITW objected to this definition, not to exclude its fasteners from the Act, but to relieve it of the need to revert its production and quality assurance to antiquated practices prescribed in outdated standards which existed when the Congress first proposed the legislation in the mid-1980's, and, which allowed up to 65,000 defective parts-per-million (PPM), per lot of fasteners.

In the ensuing months, in our discussions with the office of Management and Budget, the office of the Secretary, representatives of the office of technology, NIST, and the Bureau of Export Administration, one theme has been consistent in the government's position relative to application of the Act -- each lot

of covered fasteners must be inspected and tested such that associated documentation evidences conformance to the Standards to which they are made. Therein lies the "rub".

Throughout the history of our nation, technology has always preceded the construction of standards. As products, processes, and technologies are developed, the need for a "common language" in the form of standards, which describe things like dimensions, materials, processing, performance and inspection methods, has become necessary.

Peculiar to the United States, is the fact that these standards are developed through a process that reflects a consensus of opinion rather than that of a simple majority. The application of an innovation created today, is unlikely to become a component of a

standard for some years to come.

In practice, once a change is offered to a standard, at least two years pass before consensus is reached and the standard is amended. Hence, process controls that are being developed and deployed in our plants today, will likely not find their way into standards for many years to come. By that time, we believe quality control methods will have further evolved and will employ yet more advanced forms of process control.

The Act was written at a time when every manufacturer had as its primary quality assurance strategy, end-of-line testing and inspection. This strategy yielded defect levels in the thousands and even tens of thousands of parts-per-million. Our customers' demand for higher levels of quality and lower costs, compelled us to continue the evolutionary process. Today, process controls and

automated inspection methods have largely replaced the in-process and end of line inspections of the past. The result has been, significantly improved levels of quality, (i.e. hundreds of part-per-million vs. tens of thousands of parts-per-million) and lowered costs. And the challenge to "continuously improve" our processes and quality remains just as compelling as ever.

As stated in earlier communications with the agency, reversion to the quality control methods of the last decade will cost ITW alone millions of dollars per year, with positively no increase in product value to our customers, or safety to the public at large.

Clearly, Congress did not intend to hamstring industry in this manner. It was with the understanding that approximately 1% of fasteners consumed in the United States would be covered by the Act, that Congress enacted P.L. 101-592.

Yet today it appears, after the rule goes into effect, that more than half the fasteners produced in this country will be subject to the Law.

For the agency to write regulations, which have the effect of stifling the advancement of fastener industry process technology to ensure ongoing compliance with lagging standards, is problematic. So how can the rule be fixed?

As a result of visits to several ITW operations, as well as the operations of a number of our competitors, agency personnel gained insight into how the quality assurance practices of the fastener industry have evolved well beyond the outdated consensus standards that the Act prescribes adherence to. In the course of these visits and in subsequent discussions, several ideas which

would serve to bring the rule back in line with the intent of Congress, were put forward.

It's a fact that every reputable fastener manufacturer operates within the confines of a well defined and documented internal quality system. In fact, those of us that supply the automotive industry are required to attain third party registration to the quality system standards known as ISO/QS 9000. As you heard in Mr. Reid's presentation, the "Big 3" automakers have built upon the ISO 9000 foundation by adding additional requirements from the predecessor quality system standards known as General Motors' Targets for Excellence, Ford's Q-101 Quality System Standard, and Chrysler's Quality System Standard. It is within these major end user quality system standards that I believe the gap between quality assurance standards and practices can be "bridged".

A good example of this "bridge" can be found in QS 9000. Within QS 9000, there is a requirement that a rigorous process of quality planning be performed for each part prior to first production. This Advanced Quality Planning Process (APQP) ultimately results in a quality "control plan". This "control plan" represents the distillation of standards based requirements, manufacturing workmanship and know how, past quality history, and available manufacturing and quality control technology, into a concise set of quality control strategies from raw material to finished product for each part produced.

"Control Plans" are unique documents. The beauty of the "control plan" is that it harmonizes the standards to which a part is manufactured with the capabilities and technologies available to the manufacturer.

In effect, the "control plan" becomes the standard to which automotive fasteners are manufactured. The "control plan" defines what's to be inspected/tested, how it is to be inspected/tested, and how that inspecting/testing is to be documented. The "control plan" bridges the gap between antiquated standards and modern manufacturing practices resulting in better quality at lower cost. Beyond the "control plan", QS 9000 and perhaps other major end user quality system standards, offer a better solution to the problems we see with the Act and its implementing regulations.

To directly address the concerns of Congress related to public safety, we suggest the Agency consider the long standing practice of the automotive industry and other major end users of designating fasteners used in "safety critical" applications as "safety parts." Examples of this include seat belt and steering column bolts. In our experience, these fasteners account for

between 1% and 2% of the fasteners supplied to automotive. To the extent that there are major end users with quality systems that identify and establish special inspection requirements for safety critical fasteners, and, to the extent that fastener manufacturers are registered to major end user - published quality assurance programs such as QS 9000, the agency should consider an amendment to the regulations which would limit coverage of parts to those designated as "safety" critical by the major end user.

ITW strongly urges the Department of Commerce to find the authority they require to permit the fastener industry to use current technologies and methods, as well as those awaiting us on the other side of this administrations "Bridge", to comply with the intent of the act. To that end, we continue to offer our cooperation and support.

While the issue of recognition of major end user quality system standards is of primary concern to us and others here today, we do not want the agencies present or the Congress to feel that such recognition will solve all of the problems with the Act. There are several other long term problems imposed by the Act of which you have and will continue to hear today which will add far more cost than value, especially, but not limited to, Just-In-Time inventory control and increasing the number of wasteful premium shipments. ITW recognizes that these issues are not the subject of today's meeting, however, we offer our cooperation and support in attempting to find solutions.

ITW appreciates this opportunity for comment. However, with an effective date only four months hence, we strongly urge the Department to respond to these comments in a timely fashion.

SPC UNDER QS9000 AND THE FQA

Christopher B. Wackrow
MNP Corporation

NIST
February 4th 1997

Good afternoon,

1. Intro.

   My name is Chris Wackrow, and I represent the MNP Corporation as the VP of Quality and Reliability. MNP is headquartered in Utica Michigan. I have been involved in the fastener business for the past 27 years, in aerospace, automotive, and commercial fastener manufacture both here and in the UK. 20 of those years have been at MNP. I am also chairperson of the Quality committee of the AIFG that Jack McCarthy spoke of earlier, and recently became chairperson of ASME subcommittee 18, on quality.

2. MNP

   i) MNP is in the steel purchasing, steel processing, fastener manufacturing, and fastener importing business. Almost everything we do, is impacted in some way by the Fastener Quality Act. Our customers are automobile manufacturers, distributors, and other fastener manufacturers.

   ii) While not trying to sound like sales literature, MNP has a mission to be the best in whatever we do. In this there are pro's and con's. The pro, of

this concept is that we work hard at anticipating what the needs of our customers will be in the future; the con is that within the fastener industry the competition will be fierce. Like our customers, and others, we have benchmarked off of the best fastener manufacturers in the US, Orient, Europe, and Canada.

iii) We are applying QS9000 to all of our plants and the products they make, which incidentally are not all automotive. Every product line benefits from this singular system, and the QS accredited company is in our view at an advantage over those that have anything less.

We believe in IIIrd party accreditation, as a means for making it easier for our customers to discern those suppliers who have a recognized quality system, that includes internationally and nationally recognized system elements, while making it less arduous on the manufacturer in having to host numerous redundant audits. We are all reading from the same sheet of music, variations and redundancy are removed, and we can understand each other.

b) The law

i) Although things needed to be done to address the practices that caused the law to come into being, the law unfortunately penalizes the good supplier and those sections of industry that have well regulated and implemented supplier quality

management systems, and which were not the original cause of the problem.

I doubt that many would argue that the law would be improved if it were to accommodate the means whereby quality sources could be differentiated from non-quality sources, and permit these companies a process that gives them the freedom to satisfy quality standards and expectations in their own way, without having to resort to restrictive and prescriptive means.

ii) We at MNP consider that we are satisfying the intent of the law already, with a system that NIST has seen in practice, but feel that the changes that will be needed to address the regulations requirements, will be at certain, but undetermined cost, and be the tip of the iceberg.

b) Option 3

i) Although we appreciate the dilemma NIST has in establishing regulations from the prescriptive nature of the law, the so-called "third option" provides what is probably the best avenue to explore, and the laws institution date would have to be extended to enable the conditions for such a system to be developed.

ii) We would hope that this option be extended in some way to those consumers who, although not qualifying as OEM/major end users, could purchase parts from an OEM approved manufacturer without forcing the manufacturer to abide by non OEM

regulation requirements just because the customer is not an OEM.

2. Customers and QS9000

Without a doubt the differences between suppliers will be less obvious as our customers remove the lowest quality supplier and the highest priced suppliers. More product will be supplied by fewer sources, and a proven quality track record is the price of admission.

Because of this focus, the car companies have been at the forefront of quality system development, and QS 9000, as an example, is a standard that many industries would do well to examine, addressing as it does,

i) an orderly approach on the origins of variation
ii) the concept of prevention and continuous improvement
iii) a standardized toolbox of methods

all intended to "zero in" on processes, develop control plans custom fit by the manufacturer to his business and his product, control and reduce cost, while satisfying ever-tightening quality standards.

QS9000 emphasizes the importance of process reproducibility with the built in ability to recognize, approve, and incorporate improvements in a controlled fashion. The QS system has accountability in it, and provides a means for the customer and manufacturer to work more effectively together to get the job done. QS 9000 addresses the intent of the law, and is a means to provide regulation and order to the quality system.

b) The control plan

i) At the core of the manufacturing process is the control plan, containing the who, why, what, when and where of the details essential to the production of parts. It is the result of advanced quality planning, and relies heavily on anticipating causes of variation, and the errors that might arise, so that they can be handled appropriately and their effects minimized.

ii) The plan capitalizes heavily on the application of experience, knowledge and adherence to specified techniques and approaches. It is, in a sense, a standard that is the result of consensus, since it utilizes the input and agreement from the people from the various departments that have a part in its implementation.

iii) Once developed, the plan is deployed, parts made, and the results evaluated, during production and upon completion, to confirm that the plan produces the desired results.

c) Process Control

i) In the construction of the control plan, the advanced quality planning process can suggest one or more of the SPC methods, as a means of control, along with others. Once finalized the control plan deploys a blend of these, forming a custom fit approach to the production of parts.

ii) For many automotive suppliers, SPC was applied to fastener manufacture in the very early 80's, to study the

capability of processes and to find and remove the special causes that caused incapability and non conforming parts. Many processes have been well developed as a result, so much so that in many cases, the SPC has been discontinued, and a modest but regular checking of parts in-process, or at significant times or points in the process, is all that is required.

iii) In addition, statistical methods enable the manufacturer to assess errors in the gages and measuring equipment being used to check the parts.

iv) Also, improvements in micro-processor technology and equipment design, has enabled many fastener manufacturers and their suppliers to automate process controls such as;

a) the metering of parts onto heat treat belts;
b) management of furnace temperatures and gas composition;
c) recording and crunching of data;
d) the increasing use of sensors;
e) etc.

and in general enabling the industry to manage the process in ways unthinkable in the not-to-distant past.

The result is better control and better quality.

3. Discussion

a) This progressive approach has brought many desired benefits, such as the reduction in wasted time and material and parts, and reduced redundant work and testing. It has enabled cycle times to be lowered, and has permitted just-in-time delivery to become a daily reality in these competitive times. We believe that we have a system that works.

b) It is clear though, that without the processing methods mentioned, and continuous improvement, we will all regress, and lose ground. The inclusion of any activity that is redundant, no matter how inexpensive it might seem, puts the manufacturer at an immediate disadvantage with no ability to recover the costs involved. We do not think that this is what the law had in mind, but inadvertently it does. The law seems to be requiring final inspection, a concept that to us is outdated and unnecessary, having been negated by the preventative activities mentioned earlier.

c) Of further concern is the sheer number of incidental specifications that are involved in parts standards, many of which are addressed simultaneously by a single physical property or a single process control element, long since stabilized, and no longer requiring constant scrutiny or final verification. Many features are unchanged by subsequent processes, so in-process data can be utilized.

In closing, I am concerned about the number of inconsistencies we have heard regarding regulations interpretation. On 5/27, there will probably be a lot of people who still won't

know for sure whether they are in compliance or not. Also, many steel suppliers who have A2LA accreditation already, have indicated that they will wait for A2LA to become NIST accredited, before hosting an A2LA FQA audit. Although they have been advised that they can begin the proceedings with A2LA during this pending period, those of us who use A2LA, hope that NIST can complete its approval process soon.

We all have our own private feelings and opinions about the law and the events that have gotten us this far, but what we do from now on is what counts. This is a somewhat belated opportunity for government, industry segments, and the fastener manufacturers to work together on this issue to establish systems that do not impede American productivity or impede domestic and global competitiveness.

Thank you

Chris Wackrow MVP

PLAN FOR: UTICA WASHERS MANUFACTURING CONTROL PLAN
USS FLATS AND SAE WASHERS
PLATED

SIGN OFF APPROVALS

CHRIS WACKROW / VPQR | TOM KLEIN / EXECUTIVE V.P. | AL ANSTIE / ENGINEERING

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BRUCE JURGELEWICZ / PLANT MGR. | BRENDA OSSOWSKI / Q. A. MGR. | BRUCE KOWAL / P.A. MGR.

PROCESS FLOW

FAB	MOVE	STORE	INSPECTION	STEP OR STAGE	PROCESS OR FUNCTION	MACHINE / EQUIPMENT NAME & GAGE ITEMS FOR MFG.	CHARACTERISTICS: SIGNIFICANT ASPECTS	CHARACTERISTICS: PRODUCT CHARACTERISTICS	METHODS: PRODUCT SPECIFICATION	METHODS: EVALUATION METHOD	METHODS: SAMPLE SIZE FREQUENCY	RECORDS AND PROCESS ANALYSIS METHODS	REACTION IF NONCONFORMING CONDITIONS ARISE	RESPONSIBLE PERSON	AUDIT RESULTS
				25	MOVE PARTS TO WASHER STAGING AREA	HILO	TUB TICKET	PROPER STAGING PER ROUTING	PER ROUTING	VISUAL	PER TUB	TUB TICKET SOP 149 DO NOT STACK UNLIKE PARTS OR LOTS. SOP 138	CONTACT UW PRODUCTION CONTROL	HILO DRIVER	
				26	TUMBLER STAGING	TUMBLER STAGING AREA	PROPER STAGING	PROPER STAGING	NEAT AND ORGANIZED. DO NOT MIX LOTS OR HEATS IN STACK.	VISUAL	PER TUB	TUB TICKET SOP 149	CONTACT UW PRODUCTION CONTROL OR QUALITY CONTROL	HILO DRIVER	
				27A	TUMBLE PARTS	TUMBLER KORN KOB WATER / RUST INHIBITOR ROUTING	REMOVE SHARP EDGES FROM WASHERS	APPEARANCE	PER CUSTOMER REQUIREMENTS AND BLUE PRINT	VISUAL	25 PIECES PER TUB	UW TUMBLER INSPECTION SHEET SOP 149 SOP 287 SOP 182 SOP 177 - UW DAILY TUMBLER REPORT	FOLLOW PROCEDURE AS STATED IN SOP 101	TUMBLER OPERATOR	
				27B	PART INSPECTION	BLUE PRINT MICROMETER CALIPER ROUTING TUMBLER INSPECTION LOGSHEET DAILY TUMBLER REPORT TUB TICKET	CONFORMANCE TO CUSTOMER REQUIREMENTS	APPEARANCE OUTSIDE DIAMETER INSIDE DIAMETER THICKNESS CROWN HGT FLATNESS	PER CUSTOMER REQUIREMENTS PER BLUE PRINT	VISUAL DIMENSIONAL	25 PIECES PER TUB PER # OUT OF DIE	UW TUMBLER INSPECTION SHEET SOP 103 / GCP 13 SPO 139 / GCP 9 SOP 12 / SOP 149 SOP 182 / 290 297 SOP 177 - UW DAILY TUMBLER REPORT SOP 138	FOLLOW PROCEDURE AS STATED IN SOP 101	TUMBLER OPERATOR	
				28	MOVEMENT OF PARTS TO ADDITIONAL PROCESS STAGING AREA	HILO	PROPER STAGING PER ROUTING	PROPER STAGING PER ROUTING	PER ROUTING	VISUAL	PER TUB	TUB TICKET SOP 149 - DO NOT STACK UNLIKE PARTS OR LOTS. SOP 138	CONTACT UW PRODUCTION CONTROL OR QUALITY ASSURANCE.	TUMBLER OPERATOR	
				29	STAGING OF PARTS IN ADDITIONAL PROCESS STAGING AREA	ADDITIONAL PROCESS STAGING AREA	PROPER STAGING	PROPER STAGING	NEAT AND ORGANIZED. DO NOT MIX LOTS OR HEATS IN STACK.	VISUAL	PER TUB	TUB TICKET SOP 149 SOP 138	CONTACT UW PRODUCTION CONTROL OR QUALITY ASSURANCE	TUMBLER OPERATOR	

1 ☐ TEXTRON/NIST PRESENTATION 2/5/97 (TIM MCGUIRE)

2 ☐ We are here today representing several Divisions of Textron.

Textron is a multinational company with world wide sales of $9.3 Billion.

World wide sales of fasteners are $1.5 Billion.

US. sales of fasteners are in excess of $700 Million.

Represented here today are the Camcar, Elco, and Rocknell Divisions. Other US divisions include Avdel and Cherry Aerospace

Our business breaks down into approximately 50 % automotive and 50% commercial business.

The US. based fastener divisions of Textron represent over 150 years of experience and leadership in the industry.

3 ☐ Surviving in today's market is a challenge.

- All the major players have survived, in a very competitive world, because we know what we are doing and have accepted the responsibility to make quality product. This is also true for the majority of the manufacturers in the US.
- We a leaders in meeting and exceeding our customer's expectations.
- We know, and practice, the proper engineering and application of fastener and fastening technology.

4 ☐ Our point

- All of this brings me to a very specific point that needs to be made here today. That is the importance of the "contract" between the purchaser and the seller.
- We believe strongly that the customer should be able to define, with the supplier partner, what constitutes the customer's needs and what meets those needs. This truly is the power of defined quality systems like QS and ISO family of systems.
- We also understand that there are organizations who's

only motivation may be to make profit, regardless of the recognition of the need for the best quality possible.

5 ☐ Our recommendation

- Our recommendation today is that the Fastener Quality Act require that both the "buyer" and the "seller" of fasteners define in writing, or name, the quality system with which they choose to work.
- This definition should be required as part of the contract that both parties agree to prior to doing any business.
- The quality systems must be able to be approved and monitored by an outside third party.
- And finally, the microdetails of the systems should be negotiated, as part of the contract, by both parties based on "best industry practice".

6 ☐ This preserves the "contract".

- This concept both preserves the ability of both the buyer to divine his needs and the supplier to contract for those needs.
- This concept protects the American consumer by requiring that the companies defining their fastener needs, and those supplying fasteners to meet those needs, are working under a recognized quality system, required by a written contract.
- The Fastener Quality Act should move toward this type of system and away from the micromanagement approach.

January 31, 1997

From: Jeff Easter, Director of Technical Services, Elco Textron Inc.
Subject: Speaker notes for presentation during the February 4, 1997 FQA Public Meeting
Use of Statistical Process Control in the Fastener Industry

♦ **Opening**

A number of open issues still exist which interfere with the cost effective implementation of compliance with the FQA. These issues exist as a result of a conflict between the FQA regulations, the standards and specifications which are used to manufacture fasteners and the existing Quality Systems in-place at many fastener manufacturers. A great deal of discussion has taken place relative to the effective incorporation of Quality Systems into the FQA regulations. I will attempt to highlight some of the specific issues which exist and offer insights or approaches as to how these issues might be addressed.

♦ **Identification of Items to be included in the FQA Test Report**

The "FQA Test Report" serves as the "proof of compliance" of a given lot of fasteners with the customers requirements and is required by the Law. Identification of the key elements of a given standard or specification which must be tested and documented on the test report is to be defined according to the standard or specification. The current practices of many manufacturers use the techniques of Advanced Quality Planning, technical knowledge and past experience to develop a "contract" with the customer in the form of a "control plan". Portions of this control plan identify the elements which are included in current documentation systems. Every element of a given standard or specification does not necessarily have a documented test result to prove conformance. The documented elements are determined by a combination of specific customer requirements and the suppliers knowledge of his products and processes. It would be extremely difficult to document every element of a control plan in a test report. Those elements identified in the control plan as being documented in a test report are the suppliers commitment to "prove conformance".

♦ **SPC as a Tool**

SPC is not the savior which guarantees a products' conformance to a standard or specification. SPC is a tool to be utilized in the efforts to assure that a product feature or process characteristic is in control and capable of meeting requirements. SPC is just one of the many elements of an effective Quality System. The key to success is in the effective utilization of SPC techniques. Product features are generally identified on drawings or in standards and specifications, while process characteristics such as temperature, pH, %concentration, loading rate, time, forming pressure etc are not generally defined by standards and specifications, but through the suppliers' knowledge of the process. This makes it extremely difficult to present data to certify that a product is in conformance, however it can be stated that the process was in control during the

manufacture of a given product. Often times it is difficult to statistically connect a process characteristic such as pH or temperature to a product feature such as hardness or salt spray.

- **Process Testing for Finishing Processes**

A significant issue exists with respect to the fastener industries ability to cost effectively comply with the law regarding salt spray test requirements contained in the majority of finishing standards. There has been significant discussion regarding the use of process control data. Some Textron divisions currently use process testing as a means of assuring conformance to salt spray requirements. Bath parameters are monitored using individual moving range charts and weekly representative samples are taken for salt spray testing of each process. We have had limited success showing statistically valid relationships between process parameters (i.e. pH, temperature) and performance (i.e. salt spray). However, if all salt spray tests are conducted to failure, the process capability shows that our processes far surpass the standard requirements in most cases. The ANSI B18.18.2 Appendix recommends 2 samples per line per shift as a salt spray monitoring sampling plan. We submit that this sampling frequency is excessive based on our data. The sampling plan for each process should be based on the capability of the process. Process standards are generally developed by the processor and/or the chemical supplier. There may or may not be customer input into the process standard.

- **Standards and Specifications**

Most standards and specifications currently used in fastener manufacturing are product standards. There are very few process based standards in existence. Many of the product standards as currently written do not identify testing requirements to assure conformance. We do not expect that it be the responsibility of the federal government to effectively change or control the standards and specifications. However, we do expect the federal government to understand the situation that exists with respect to the inadequacy of the current standards and specifications to address process control. These process controls are identified within the quality systems of the suppliers.

- **Closing**

In closing, we understand that it is not the direct responsibility of NIST or the federal government to address these issues in their entirety as many of the issues are specification based. In general, our customers are currently satisfied with our products. In order to be to be competitive in todays' global marketplace we must allow the currents systems and tools to be utilized towards compliance with the FQA. The FQA regulations need to recognize the supplier/customer developed control plan and the specific existing documentation specified in that plan as the acceptable FQA Test Report. Our recommendation is to allow suppliers and customers to continue towards their long term goals of continuous improvement through the development of quality systems and process control to assure conformance to specifications and standards.

Steve Engleman

SPS TECHNOLOGIES, INC.

PRESENTATION TO NIST

TUESDAY, FEB. 4, 1997

GAITHERSBURG, MD.

SPS TECHNOLOGIES, INC.
BACKGROUND

- MAJOR FASTENER PRODUCER WITH GLOBAL OPERATIONS IN 11 COUNTRIES
- PARTICIPATE IN AEROSPACE, AUTOMOTIVE, GENERAL INDUSTRIAL AND COMMERCIAL SEGMENTS
- TECHNICAL LEADER - 150 PATENTS & HIGH TEMPERATURE ALLOY DEVELOPMENTS

NORTH AMERICAN OPERATIONS

- AEROSPACE PLANTS IN PA., UTAH & CALIF.
- AUTOMOTIVE PLANT IN OHIO
- UNBRAKO PLANT IN OHIO
- IMPORTS FROM BRAZIL, CANADA, IRELAND, U.K.& CHINA

AUTOMOTIVE OPERATIONS

- MAJOR CUSTOMERS - FORD, G.M., CATERPILLAR, NAVISTAR, JOHN DEERE
- MANUFACTURE CRITICAL ENGINE FASTENERS TO CUSTOMER SPECIFICATION (SPECIALS)
- QS9000 CERTIFIED, FORD Q1 APPROVED
- CUSTOMER QUALITY RATINGS HIGH

CURRENT QUALITY SYSTEMS

- MAJOR CUSTOMERS HAVE QUALITY PROGRAMS WHICH QUALIFY FASTENER MANUFACTURERS
- QS9000 WILL BECOME THE STANDARD
- QS9000 REQUIRES APQP APPROACH - CONTROL PLAN IS KEY
- QS9000 REQUIRES INSPECTION & TESTING IAW DOCUMENTED PROCEDURES(4.10)

PROBLEM WITH THE FQA

- ASSUME OUR PARTS ARE COVERED BECAUSE ALL CUSTOMER SPECS. REFER TO CONSENSUS STANDARDS
- FQA MOUSETRAPS FASTENER PRODUCER INTO STRICT COMPLIANCE WITH CONSENSUS STANDARD INSPECTION REQUIREMENTS, EVEN WHEN CUSTOMER DOES NOT REQUIRE IT.
- RESULT WILL BE REDUNDANT AND UN-NECESSARY TESTING

EXAMPLE #1

- A CUSTOMER SPEC. REQUIRES PROOF LOAD, TENSILE AND HARDNESS BE CHECKED (6 PCS PER LOT). WE INCORPORATE THIS INTO OUR CONTROL PLAN FOR THIS CUSTOMER.
- CUSTOMER PRINT REFERS TO PROPERTY CLASS 10.9. WE INTERPRET THAT THIS REFERENCE WILL REQUIRE TESTING TO SAE J429 WHICH CALLS FOR 8 PCS PER LOT (33% INCREASE IN THIS TEST).

EXAMPLE #2

- A CUSTOMER SAMPLING PLAN REQUIRES THAT 50 PCS PER LOT BE INSPECTED FOR SURFACE DISCONTINUITIES.
- THE CUSTOMER PRINT REFERENCE TO SAE J123 WILL REQUIRE THAT 100 PCS PER LOT BE CHECKED
- 100% INCREASE IN THIS TEST.

IMPACT OF FQA

- INCREASED COST (MIN 1/2% SALES)
- DISRUPTION IN JIT SUPPLY - IN OPPOSITION TO CUSTOMERS' INCREASED DEMANDS FOR JIT
- INCREASE FASTENER MANUFACTURERS' INVENTORY INVESTMENT
- DOES NOT IMPROVE QUALITY - MAKES IT MORE DIFFICULT TO IMPLEMENT PREVENTION BASED SYSTEMS

POSSIBLE SOLUTIONS

- CHANGE THE REGULATIONS TO REQUIRE THAT A FASTENER MANUFACTURER SELLING TO A MAJOR END USER FOLLOW MAJOR END USERS QUALITY PROGRAM, WHICH MEETS DEFINED MINIMUM REQUIREMENTS
- FURTHER, CHANGE THE REGS TO REQUIRE DEMONSTRATION OF CONFORMANCE TO CONTROL PLANS RATHER THAN INSPECTION & TESTING TO DEMONSTRATE CONFORMANCE TO SPECIFICATIONS.

SOLUTIONS, CONT'D.

- OTHER PARTS OF THE REGULATIONS COULD STILL APPLY, I.E. LOT TRACEABILITY, HEAD MARKINGS, LAB ACCREDITATION, ETC.
- DEFINITION IS NEEDED OF HOW CONFORMANCE TO CONTROL PLANS WOULD BE DEMONSTRATED.
  - BASED ON AUDIT
  - CERTIFIED WITH EACH LOT

February 4, 1997

Statement of Mr. Y. Imai
on behalf of
The Fasteners Institute of Japan

I. Introduction

A. Self-introduction

Good Afternoon. My name is Yoshio Imai. I am Chairman of the Technology Committee of the Fasteners Institute of Japan and a director of Sannohashi Corporation, which manufactures fasteners for automobiles. I am very grateful for this opportunity to address you today. This is the first time for me to give a speech in English, so I hope you will be especially patient with me. I would like to discuss the SPC and the impact of the FQA on the Japanese fastener industry.

B. Introduction to FIJ

First, I would like to give you a brief introduction to the Fasteners Institute of Japan ("FIJ"). Please refer to Figure 1 of your hand-outs. FIJ was established in December 1960. It has 200 member companies. The fasteners manufactured by the Japanese fastener industry are shipped to a variety of customers. Sales to automotive-related customers account for 31.6% of our fasteners. Fastener trading companies account for another 23.6% and electronics or electrical equipment companies account for 7.2%. In 1995, the total production output of the

Japanese fastener industry was about 2,646,883 tons, which amounted to sales of approximately $6.8 billion.[1/]

II. SPC and Japan

In order to explain the SPC issue from our view, I would like to cover the following five points outlined in Figure 2 of your hand-out. First, I would like to discuss the role of SPC in Japan today. Second, I will discuss how SPC works. Third, I would like to emphasize the importance of SPC to Japanese fastener companies, in particular, companies which sell to automobile manufacturers. Fourth, I will address the issue of whether or not it is possible to replace SPC with the proposed FQA regimen. Fifth, I will discuss the status of Japanese fastener companies' preparation for FQA compliance. Finally, I will suggest a framework for resolving the SPC/FQA issue.

A. The Role of SPC in Japan Today

Regarding the first point -- the current role of SPC in Japan -- please refer to Figure 3 of your hand-out.

Automobile-related fastener manufacturing companies use the various techniques shown in Figure 3, including SPC, in order to meet the respective quality requirements of their customers.

[1/] Based on Dow Jones 1995 annual average ¥/$ ratio

Customer quality control requirements are based on the following objectives: (1) to secure lot traceability; (2) to control changes in manufacturing conditions (such as conditions related to manpower, machines, process control methods, and material) in order to keep them fixed; (3) to confirm the process capabilities of the manufacturing equipment; and (4) to produce reliable, high quality products which are continuously improved during the manufacturing process, rather than relying on final inspections.

B. How SPC Works

Regarding my second point -- how SPC works -- please refer to Figure 4 of your hand-out. SPC techniques emphasize quality control during the manufacturing process, rather than in final inspections. The specific techniques used by each manufacturer are based on the particular customer's requirements. In general terms, Japanese Industrial Standard actively supports the development of the SPC techniques used in our industry. This point will be further developed by the following speaker, Mr. Fukuda of MITI.

The following Australian example demonstrates the diversity of SPC techniques. Please refer to Figure 5 of your hand-out.

This example is taken from Section 2.17 of the "Guide for Preparing Quality Control Manuals" published by the Australian Standards Association. It states as follows:

> Where statistical procedures are used by the supplier to demonstrate conformance, the quality manual should indicate the extent to which they are used, and the type and origin of the procedures. Typically, the following are examples of aspects which should be covered where these are relevant:
>
> (a) Time, place and method of drawing a sample
>
> (b) Batch acceptance and rejection criteria
>
> (c) Use of tightened and reduced inspection
>
> (d) Use of statistical procedures to establish process capability
>
> (e) Statistical procedures demanded by customers
>
> (f) Records of statistical quality control results . . . .
>
> Statistical quality control procedures, however, can embrace far more than the areas indicated above, and all such procedures used by the supplier should be covered in this section of the quality manual.
>
> [end of quotation]

A major reason for the variety of SPC techniques is that, in cases where normal distribution is expected, it is difficult to treat statistical quantities which are being processed in order to meet the lower range (or upper range) of tolerances. This is particularly the case with cold forging work using dies.

C. The Importance of SPC to the Japanese Fastener Industry

My next point concerns the importance of SPC to the Japanese fastener industry.

As Chairman of the Technology Committee of FIJ, I estimate that 70 to 80% of our fastener companies are using SPC techniques in their manufacturing operations. In most of these cases, the fasteners are manufactured for automotive applications. The degree of importance of SPC to these Japanese fastener companies varies according to the specific SPC technique used. Generally, however, SPC is a key component of quality control operations in the Japanese fastener industry, and its importance is widely recognized.

D. Is it Possible to Replace SPC with the FQA System?

Regarding my next point -- whether it is possible to replace SPC with the FQA system -- please refer to Figure 6 of your hand-out.

First of all, I would like to point out that the quality control regimen prescribed by the FQA regulations is still at the conceptual stage, whereas SPC consists of actual techniques. Therefore, it is somewhat contradictory to discuss these two as comparable.

Based on my own personal experience, I believe it would be very burdensome for many companies who are currently using SPC to return to the end-of-production inspection methods required by FQA regulations. There are costs associated with the changeover itself, and the cost benefits gained from the use of SPC techniques would be lost.

Based on many years of practical application of SPC techniques, it is broadly recognized in the fastener industry that SPC is superior to end-of-production inspection methods for purposes of quality control. Thus, in my opinion, it may be theoretically possible to replace SPC with the FQA system, but it would be unnecessarily costly.

E. The Status of Preparation by Japanese Fastener Companies for FQA Compliance

Regarding my next point -- the status of preparation of Japanese fastener companies for FQA compliance -- please refer to Figure 7 of your hand-out.

FIJ estimates that 20 in-house test laboratories will have to be accredited for fastener testing. The metal processing companies which supply us with the processed metal will require a similar number of test laboratories.

The practical preparations for FQA compliance are progressing, but it will not be possible for our industry to meet

the May 27, 1997 deadline. Moreover, it is difficult to move manufacturers to make costly changes to business practices already in place and working, and it takes time to build a consensus for this.

III. Towards a Solution to the SPC/FQA Issue

I would now like to propose a general framework for resolution of the SPC/FQA issue. Please refer to Figures 8-10 of your hand-out.

In order to verify that fasteners are manufactured in accordance with "standards and specifications," the FQA regulations currently require a quality control system based on final inspections. On the other hand, we believe that the FQA's goal can be met by maintaining an in-process quality control system. This can be accomplished by a program which addresses the following four points:

1. Is it possible to verify product traceability?

2. Is it possible to verify that the SPC techniques are being correctly applied?

3. Is it possible to verify that the technical skill levels of the workers are being maintained and taught to successors?

4. Is it possible to verify material composition and prevent the introduction of non-conforming materials?

With respect to traceability, Japanese fastener manufacturers and their fastener users have jointly developed a system which identifies fastener manufacturers and lots. We can apply this same system to all types of fasteners upon the request of our customers.

With respect to verifying the correct application of SPC techniques, I would like to say as follows. If the FQA regulations were amended to allow for accreditation of SPC verification systems as a means of determining that fasteners are being manufactured in accordance with the pertinent "standards and specifications," we would consider developing such a verification system for the Japanese fastener industry. We already have developed methods for verifying the correct calibration of the testing equipment.

As to the third point, the technical skill levels of workers will be maintained and transferred by conducting training activities according to the guidelines of an existing training program.

Regarding the final point of establishing control methods for confirming material composition and for preventing the introduction of non-conforming materials, we would rely on the existing system of mill sheets provided by steel makers. This system is recognized throughout all Japanese industries,

including the fastener industry, as accomplishing this very purpose.

It is our sincere hope that a viable program can be established based on this framework which will permit the retention of in-process quality control techniques by fastener manufacturers.

In conclusion, I would like to say that we technical people consider that our mission is to offer safe and reliable products to our customers. No matter how much companies and society may change, this mission will remain the same. I sincerely believe that in-process quality control meets this overriding goal.

If you have any questions regarding the content of my presentation, please address them in written form to the FIJ address which appears at the end of the hand-out. We will give them our careful consideration.

Thank you very much for your kind attention.

405167-01 / DOCSDC1

Fig. 1/10

INTRODUCTION TO THE FASTENERS INSTITUTE OF JAPAN

Established . . . December 1960

No. of Member Companies . . . 200 companies

Fastener Shipment Destinations . . .

Automotive-related	31.6%
Fastener trading companies	23.6%
Electronics/electrical equipment	7.2%

Production output (1995) . . . 2,646,883 tons
728,024 million yen ($6.8 billion)

The Fasteners Institute of Japan

Fig. 2/10

MAIN TOPICS

A. The Role of SPC in Japan Today

B. How SPC Works

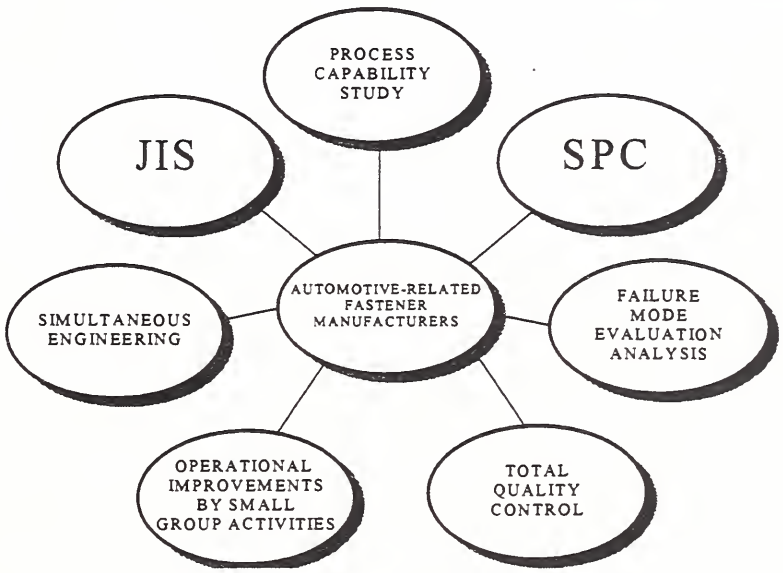
C. The importance of SPC to the Japanese Fastener Industry (particularly automobile-related companies)

D. Is it possible to replace SPC with the FQA?

E. The status of preparation by Japanese Fastener Companies for FQA Compliance

Fig. 3/10

Japanese fastener manufacturing companies utilize various control techniques including SPC in order to supply quality products to customers based on the quality requirements of these customers



Customer Quality Requirements

Fig. 4/10

THESE SPC TECHNIQUES EMPHASIZE QUALITY CONTROL DURING THE MANUFACTURING PROCESS, RATHER THAN IN FINAL INSPECTIONS

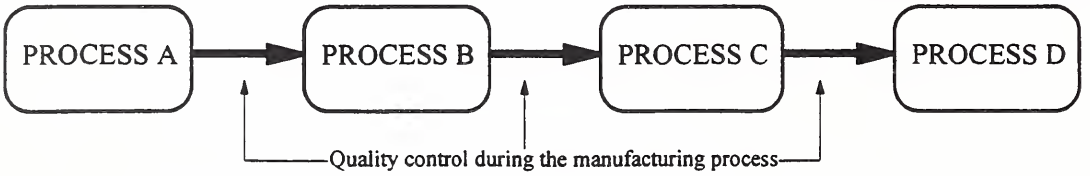


Fig. 5/10

Statistical Process Control

In statistical process control,
there are numerous and wide-ranging techniques

Guide for Preparing Quality Control Manuals
SAA QS1-1988

Australian Standards Association
Standards House, 80 Arthur St., North Sydney, N.S.W.

Fig. 6/10

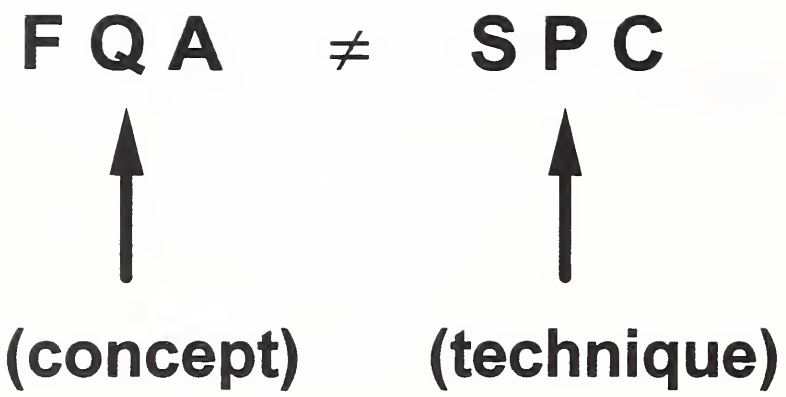
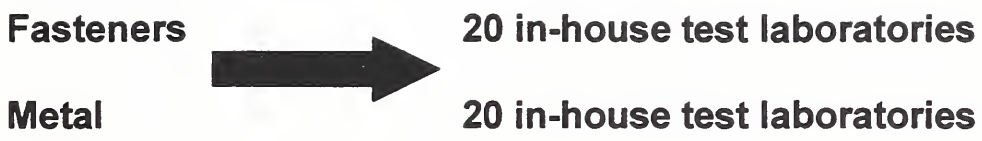


Fig. 7/10



Preparing certification procedures for test laboratories

Fig. 8/10

PROPOSAL

Conduct quality control during the manufacturing process, rather than in final inspections

The four points of a minimum proposal

1. A system which enables product traceability

2. A system which verifies that SPC techniques are being correctly applied

3. A system which maintains and teaches to successors the technical skills of its workers

4. A system which establishes methods for verifying material composition and preventing the introduction of non-conforming materials

Fig. 9/10

PROPOSAL (CONT.)

1. **A system which enables product traceability**
   - Japanese fastener manufacturers and users have jointly developed a system which identifies fastener manufacturers and lots

2. **A system which verifies that SPC techniques are being correctly applied**
   - The measurement accuracy of the testing instrumentation is being correctly maintained

3. **A system which maintains and teaches to successors the technical skills of its workers**
   - There is a training system, and training is being executed according to its guidelines

4. **A system which establishes methods for verifying material composition and for preventing the introduction of nonconforming materials**
   - Mill sheets issued by steelmakers accomplish this purpose

Fig. 10/10

CONCLUSION

The Mission of We Technologists

Regardless of the Corporate or Social Environment,
We Will Offer Safe, Reliable Products to Customers

Please address any questions to the below address:

Mr. Yoshio Imai
Technical Advisor
The Fasteners Institute of Japan
Kikai Shinko Building
3-5-8 Shibakoen Minato-Ku
Tokyo
JAPAN

JIS Marking System
and
Statistical Quality Control

presented by

Yasukazu Fukuda

Deputy Director
Management System Standards Division
Standards Department
AIST, MITI, JAPAN

What is JIS?

- **Japanese Industrial Standards (JIS) are**

  - voluntary national standards
  for industrial and mineral products

  - established or revised
  based on a consensus of producers, consumers and related parties.

- **JIS describe**

  - category, type, from, dimension, structure, performance, and grade and packaging method of mineral and industrial products;

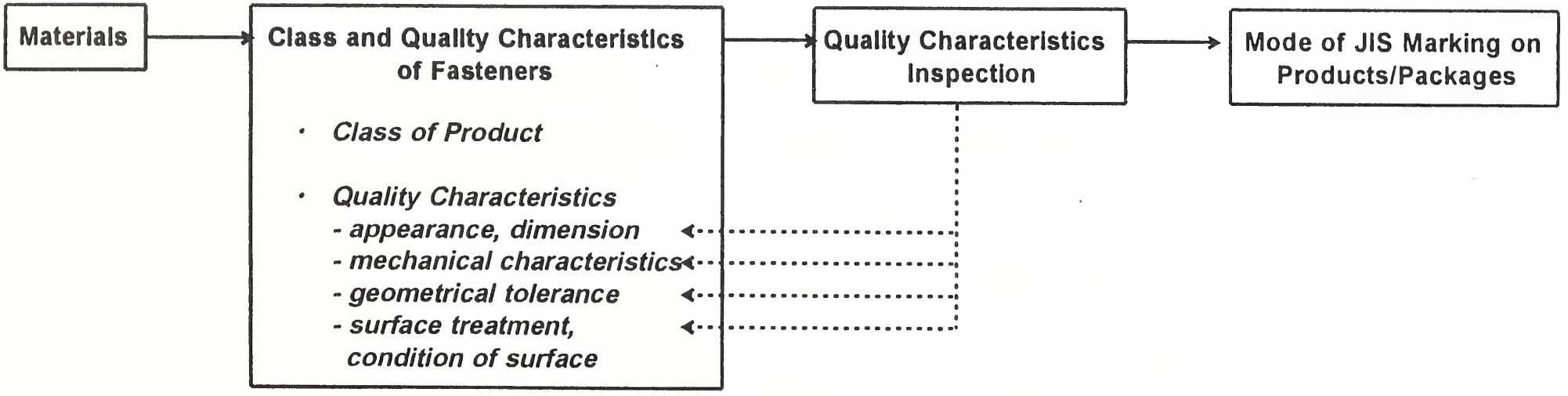
  - method of test, analysis, appraisal, inspection, verification or measurement of mineral and industrial products;

  etc.

- JIS consist of over 8000 standards.

- Among them, there are 12 standards for fasteners within the scope of FQA.

Requirements of JIS for Fasteners



What is JIS Marking System?

JIS Marking System is that

- *the factory certified as having the technical capability to produce continuously and stably the product conforming to JIS based on factory examination can affix JIS Marking.*
- *the products within the scope of JIS Marking System are designated by Minister in charge.*

Note: The "factory examination system" in JIS Marking System considers a factory as one system as a whole and examines its technical capability to produce continuously and stably products conforming to JIS rather than only checks produced commodities whether or not they conform JIS as "product inspection system" does.

Characteristics of JIS Marking System

In order to certify factories' technical capability of producing continuously and stably the products conforming to JIS, the factory examination under JIS Marking System examines;

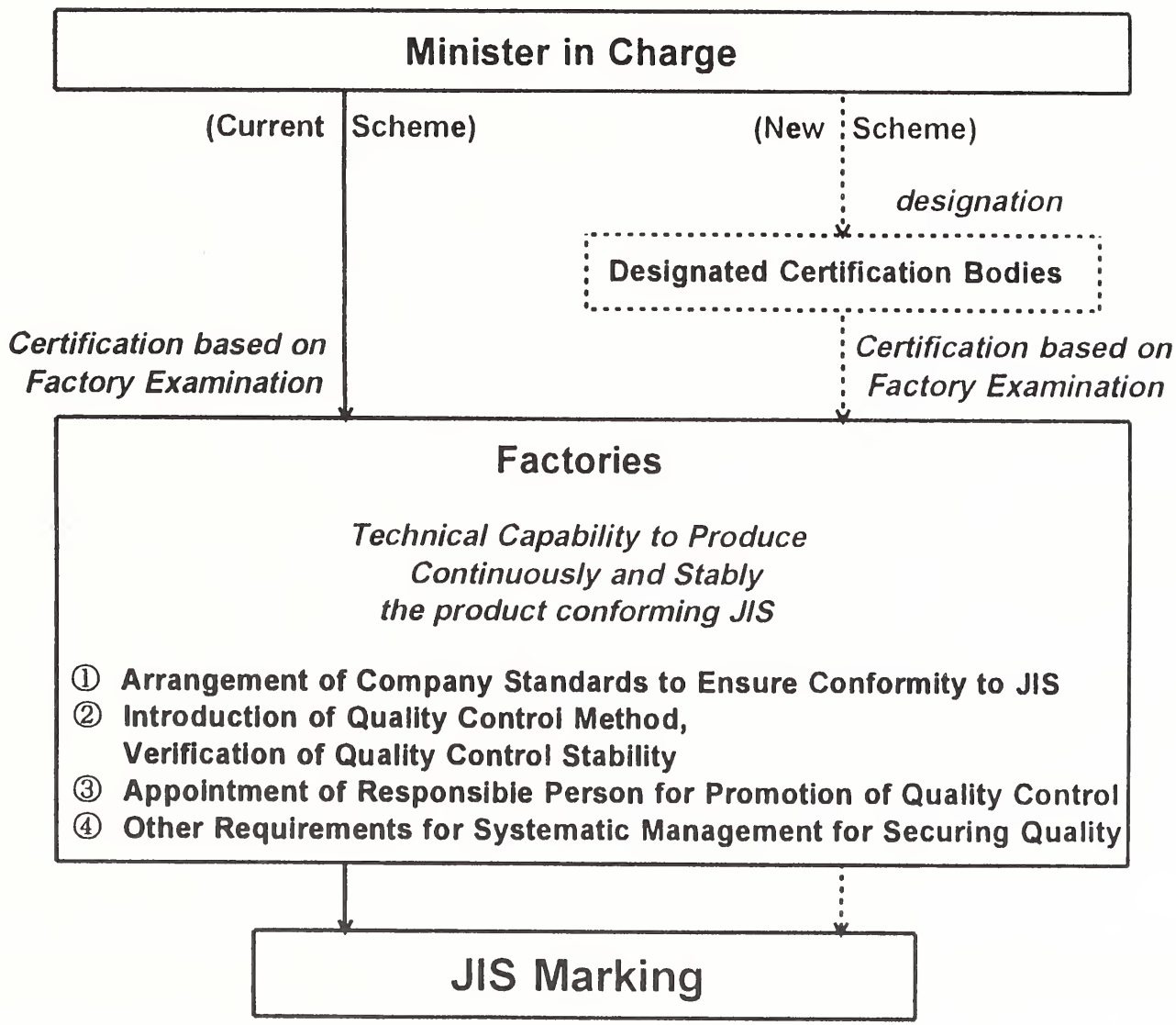
① Arrangement of Company Standards to Ensure Conformity to JIS

② Introduction of Quality Control Methods,
Verification of Quality Control Stability

③ Appointment of Responsible Person for Promotion of Quality Control

④ Other Requirements for Systematic Management for Securing Quality

JIS Marking System



JIS Marking System Examination Criteria

- There are two equivalent examination criteria (examination criteria Ⅰ and Ⅱ).

- Examination criteria Ⅱ utilize ISO 9002 (JIS Z 9902) as the requirements for quality control from the viewpoints of these quality control systems to ensure produce commodity with the quality specified in JIS.

JIS Marking System Examination Criteria II

ISO 9002 (JIS Z 9902)

Quality System

Requirents

+

JIS Marking System-specific requirements

① Arrangement of Company Standards to Ensure Conformity to JIS

- Purchasing/Process/Product Control
- Maintenance of Manufacturing/Test and Inspection Equipment
- Subcontract Control
- Complaint Handling

② Introduction of Quality Control Methods

- Receiving Inspection and Testing of Materials, Parts, etc.
- In-Process Inspection and Testing
- Final Inspection and Testing

Verification of Quality Control Stability

③ Appointment of Responsible Person for Promotion of Quality Control

↓

Continuous and Stable Production Conforming to JIS

① Arrangement of Company Standards to Ensure Conformity to JIS

Purchasing Control (for Ensuring Quality of Materials Required in JIS)
- Methods of Receiving Inspection and Testing of Materials, Parts, etc
- Methods of Storage of Materials

Process Control
- Control Points (process condition, heat treatment condition, surface treatment condition, etc.)
- Control Methods
- In-Process Inspection and Testing

Product Control (for ensuring Quality Characteristics of Product required in JIS)
- Methods of Final Inspection and Testing of Products described in JIS
- Methods of Storage of Products

Maintenance of Manufacturing / Test and Inspection Equipment
- Methods / Frequency of Checking or Inspection of Equipment
- Methods of Calibration of Equipment

Subcontract Control

Complaint Handling

② -1 Introduction of Quality Control Methods

Receiving Inspection and Testing of Materials, Parts, etc.

- Accept Materials, Parts, etc. which have pass Receiving Inspection and Testing Methds described in Company Standards (100 % or Sampling Inspection or Testing)

- In the case of sampling methds, Company Standards shall describe lot size (N), Sampling Size (n), Criteria for Judgment of Lots, Treatment of Unacceptable Lot, etc.

In-Process Inspection and Testing

- Go to the next process stage only when a process has passed the in-process inspection and testing described in Company Standards (100 % or Sampling Inspection or Testing)

- In the case of sampling methds, Company Standards shall describe lot size (N), Sampling Size (n), Criteria for Judgment of Lots, Treatment of Unacceptable Lot, etc.

Final Inspection and Testing

- Ship Products which have passed Final Inspection and Testing required in JIS
(Final Inspection and Tesing Method (100 % or Sampling Inspection or Testing)are described in Company Standards

- In the case of sampling methds, Company Standards shall describe lot size (N), Sampling Size (n), Criteria for Judgment of Lots, Treatment of Unacceptable Lot, etc.

② -2 Verification of Quality Control Stability

- Verify stability of Quality Control by cecking continuously HIstogram and Fraction Defective, etc. for every Quality Characteristics of Products required by JIS

③ Appointment of Responsible Person for Promotion of Quality Control

JIS Marking Factory shall appoint a Responsible Person for Promoting Quality Control who has the ability of managing quality control, technical competence and experience of relevant production

Responsible Person for Promoting Quality Control shall be responsible for;

- *Planning and promotion of the program concerning company standardization and quality control*
- *integration of development, revision of the company standards*
- *assessment of quality level of the commodity*
- *instruction and advice as to the action and measure to be taken against the abnormality arising in the process and the complaint*
- *promotion of education and training on the company standardization and quality control for employees*
- *instruction and advice with regard to the subcontract*

ATTACHMENTS

Attachment A

MEETING AGENDA

PUBLIC MEETING
USE OF STATISTICAL PROCESS CONTROL IN THE FASTENER INDUSTRY
February 4, 1997
Green Auditorium
Administration Building (Bldg. 101)
National Institute of Standards and Technology
Gaithersburg, Maryland

Agenda

9:00 - 9:30	Welcome and Purpose of Meeting	Dave Edgerly, NIST
9:30 - 10:00	QS 9000 Overview	Dan Reid, General Motors Corp.
10:00 - 10:30	ARD 9000 Overview	Chuck Vohsen, McDonnell-Douglas
10:30 - 11:00	Break	
11:00 - 3:30	Presentations from Public	(See List of Presenters Below)
	(12:30 - 1:30 Lunch Break)	
	(2:45 - 3:00 Break)	
3:30 - 4:30	General Discussion by All	
4:30 - 5:00	Wrap-Up (Next Steps)	Dave Edgerly, NIST

Presentations from Public

11:00 - 11:15	Max Dorflinger, Chairman, Industrial Fasteners Institute (IFI), Chairman, Nylok Fastener Corporation
11:15 - 11:30	Jack McCarthy, Chairman, IFI Division VII (Automotive), President, Kamax-G.B. Dupont L.P.
11:30 - 11:45	Pat Meade, Chairman, IFI Division VI (Aerospace), President, Hi-Shear Corporation
11:45 - 12:00	Jeff Bobeck, Senior Congressional Liaison, American Automobile Manufacturers Association (AAMA) Bill Tudor, General Motors Corporation
12:00 - 12:15	George Parker, Vice President, Engineering Affairs, Association of International Automobile Manufacturers, Inc. (AIAM)
12:15 - 12:30	Bob Brunner, General Manager, Shakeproof Automotive Division, ITW Corporation

1:30 - 1:45 Christopher Wackrow, Vice President, Quality Assurance and Product Reliability, MNP Corporation
1:45 - 2:00 Tim McGuire, Director of Product Engineering, Camcar Textron Corporation, and Jeff Easter, Director of Technical Services, Elco Textron Corporation
2:15 - 2:30 Steve Engleman, President, Industrial Products Group, SPS Technologies, Inc.
2:30 - 2:45 Kenneth Van Hook, Manager, Product Safety, Standards Engineering, Mitsubishi Caterpillar Forklift America, Inc.
3:00 - 3:15 Y. Imai, Director, Sannohashi Corporation (Speaking in behalf of the Fastener Institute of Japan)
3:15 - 3:30 Yasukazu Fukuda, Deputy Director, Management System Standards Division, Standards Department, Agency of Industrial Science and Technology, MITI

Department of Commerce Panel

Daniel Cohen, Office of the General Counsel
Thomas Barbour, Senior Counsel, Office of the Chief Counsel for Export Administration, BXA
Bill Arvin, Special Assistant to the Deputy Assistant Secretary for Export Enforcement, BXA
Mark Bohannon, Chief Counsel, Technology Administration
Michael Rubin, Deputy Chief Counsel, NIST
David Edgerly, Deputy Director, Technology Services, NIST
Subhas Malghan, Program Manager, FQA, Technology Services, NIST
David Alderman, Deputy Chief, NVLAP, Technology Services, NIST
Lynne Hare, Chief, Statistical Engineering Division, Information Technology Laboratory, NIST
Ralph Veale (Retired), Manufacturing Engineering Laboratory, NIST

Billing Code:

U.S. DEPARTMENT OF COMMERCE
National Institute of Standards and Technology

NOTICE OF PUBLIC MEETING ON THE FASTENER QUALITY ACT

AGENCY: National Institute of Standards and Technology(NIST), Commerce.

ACTION: Notice of Open Meeting.

SUMMARY: NIST will hold an open meeting on February 4, 1997, to solicit industry views on the use of statistical process control (SPC) in the manufacture of fasteners under the Fastener Quality Act (P.L. 101-592, as amended by P.L. 104-113)(The Act). The purposes of the meeting are to determine what impact, if any, the inspection, testing, and certification requirements of the Act and regulations may have on fastener manufacturers who use statistical process control and to identify ways in which the requirements of the Act and regulations might be met by SPC. Fastener manufacturers, Major End Users of fasteners (Automobile, Aerospace, Heavy Machinery, and others), representatives of Consensus Standards Bodies and Laboratory Accreditation Organizations, and academics with appropriate engineering expertise are invited to make presentations not exceeding 15 minutes each during the meeting.

DATES: The meeting will be held on February 4, 1997, from 9:00 a.m. until 5:00 p.m. Individuals and organizations wishing to present information orally during the meeting must contact NIST not later than January 24, 1997, to request time, not to exceed 15 minutes, on the program.

ADDRESS: The meeting will take place in the Green Auditorium, Administration Building (Bldg. 101), at NIST in Gaithersburg, Maryland.

FOR FURTHER INFORMATION CONTACT: Individuals and organizations wishing to present information orally during the meeting should contact Mr. David Edgerly, Deputy Director, Technology Services, NIST, telephone 301-975-4510, telefax 301-975-2183. All other questions should be directed to Dr. Subhas Malghan, Program Manager, Fastener Quality Act, Building 820, Room 306, National Institute of Standards and Technology, Gaithersburg, Maryland 20899; telephone 301-975-6101, telefax 301-975-2183.

SUPPLEMENTARY INFORMATION:

The agenda for the meeting is:

1. Welcome and opening remarks.
2. NIST overview of SPC issues raised by industry.
3. Statements by members of the public on the issues.
4. Discussion of potential solutions.
5. Next Steps (NIST).

Various industries, including automobile, aerospace, and heavy machinery industries have established quality assurance programs as a means of assuring quality parts and materials from large networks of suppliers, and have invested considerable energy and expense in developing such systems. Companies supplying fasteners under quality assurance systems (such as QS9000), have also invested considerable energy and expense in putting quality systems in place and in getting registered to them as a condition of supplying fasteners to major end users. NIST has heard from some representatives of industry that the Fastener Quality Act's reliance on lot control and final inspection of fasteners may be inconsistent with and may not meet the standards of modern mass production using statistical process control.

The proposed meeting is for the purpose of addressing these issues and to provide a forum for discussion of possible solutions under the Act and regulations. NIST would like to hear from a variety of sources including the aerospace, automobile and heavy machinery industries, fastener manufacturers who supply such industries on the use of statistical process control under quality assurance plans similar to QS9000, and interested academics. Also, because reliance upon existing consensus standards and specifications is a cornerstone of the Fastener Quality Act, representatives of consensus standards organizations are invited to discuss efforts underway to recognize statistical process control in fastener standards and specifications. Similarly, some fastener manufacturers rely on in-process measurements of critical fastener parameters by manufacturing personnel rather than upon final testing of such parameters by an accredited laboratory. Because SPC may implicate laboratory accreditations under the Act and regulations, laboratory accreditation bodies are also invited to present their views.

/s/Elaine Bunten-Mines
Elaine Bunten-Mines
Acting Associate Director

Jan 8, 1997
Date