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QS-9000 and Its Legal Implications

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ALFONSO G. CHAN*

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I. INTRODUCTION

QUALITY ISSUES are conclusively among the top concerns in the aviation industry today. Specifically, the ISO 9000 series of quality assurance standards is becoming increasingly the standard throughout the aviation and aircraft manufacturing industries. For example, industry-leader Boeing recently obtained ISO 9000 certification at its Modification Center in Wichita, Kansas, which specializes in wide-bodied airplane modification and maintenance.1 Boeing regularly boasts of its ISO 9000 certification, stating:

By earning ISO-9000 certification, the Boeing commercial Modification Center is further demonstrating its commitment to quality. By formalizing its documentation and using ISO-9000 as an extra set of eyes, Boeing Wichita will be able to continue to improve quality and remain at the cutting edge of industry. The company has committed employees and well-organized processes—ISO-9000 certification can only serve to improve an already top-of-the-line business.2

Another example is Raytheon. Raytheon Aircraft, manufacturer of aircraft such as the Beech Baron 58 and the Bonanza A36 and B36TC, has adopted ISO 9000 in its Wichita, Kansas

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2 Id. (quoting John Rodgers, Client Manager for BSI, Inc., the North American division of the British Standards Institution).
manufacturing facility and other subsidiary locations. In addition, Raytheon Aerospace is ISO 9002 certified. A further example is Dassault Aviation, which is currently in the process of achieving ISO 9000 certification by 2000. Dassault proudly states that "[w]e sought ISO 9002 registration because it is globally recognized, and we have customers and vendors in many different countries." Furthermore, those in the aviation support and servicing sector of the industry are similarly adopting ISO 9000 standards. For example, China Airlines, TransAsia Airways, and Far Eastern Air Transport Service entered into a joint venture in the commercial air transport industry, and plan to use their ISO 9001 and ISO 9002 quality systems in the joint venture. AEI has implemented ISO 9002 in its aviation-related information technology and security programs. "UTFLIGHT, the aviation department of United Technologies Corp., claims to be 'the first corporate aircraft operator in the world to become registered to ISO 9002.'" Dallas Airmotive's ten overhaul and repair facilities received ISO 9002 certification. Air Navigation Services of the Czech Republic aims to achieve ISO 9000 certification, and Aeronautical Radio, Inc. will achieve company-wide ISO 9000 certification by 2000.

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Even the United States and foreign governments are adopting ISO 9000 and QS-9000 in their procurement and maintenance of aircraft. For example, the U.S. Federal Acquisition Regulations specify ISO 9000 and QS-9000 as examples of quality standards that may be required for compliance with higher-level contract quality requirements. The National Aeronautical and Space Administration's (NASA) Jet Propulsion Laboratory is contemplating using ISO 9000 in its commercialization of space transportation initiatives. The Naval Aviation Depot in Cherry Point, North Carolina, is seeking ISO 9000 certification. The U.S. Army Aviation and Missile Command requires ISO 9000 compliance for its contracts. And, since 1993, the Canadian government has required suppliers of aviation-related products to comply with ISO 9000 quality standards.

Two major forces drove quality to the forefront of industrial thinking. The first force driving quality was the Japanese revolution in quality. Previously, a "Made in Japan" label was an indicator of inferiority; now it is a hallmark of quality. After World War II, Japanese industry shocked the industrial world by implementing revolutionary, yet common-sense, quality initiatives, such as ensuring that upper management takes responsibility for quality, training all levels of personnel in quality concepts, and striving to continuously improve.

The second major force driving quality was increased public awareness of how quality directly affects consumers on a personal level. Contributing factors to this awareness include an increasing number of products liability lawsuits, enhanced public awareness of the environment and limited natural resources, media attention given to major disasters caused by engineering

21 See id.
failures, pressure from consumer organizations, and increased international competition.\textsuperscript{22}

To help achieve these quality goals, in 1994 the giants of American industry—Chrysler (now Daimler Chrysler but hereinafter “Chrysler”), Ford, and General Motors—cooperatively promulgated a standard quality-related specification titled \textit{Quality System Requirements QS-9000}.\textsuperscript{23} Now, to do business with any of the “Big Three,” suppliers \textbf{must} conform and be certified to QS-9000.\textsuperscript{24} By mandate, QS-9000 is incorporated into all component supplier contracts in the automotive industry as part of the standard terms and agreements.

Following the lead of the “Big Three” in the automotive industry, many other industries, including the aviation and aerospace industries, jumped on the QS-9000 bandwagon to capitalize on the quality movement in the supplier base. However, QS-9000 and quality concepts in general still remain somewhat of an enigma to lawyers and nontechnical personnel. What exactly is quality? How is quality achieved? What is the connection between QS-9000 and quality? Furthermore, what are the legal issues arising from quality systems and QS-9000? Unfortunately, little has been written to explain and discuss QS-9000 in a nontechnical context.

This document provides an overview of QS-9000 quality principles in a manner specifically tailored for legal practitioners and persons without a technical background in quality control and quality assurance. First, the general concepts of quality and a quality system are explained in Part II. Next, Part III provides an overview of ISO 9000, the progenitor of QS-9000. Afterwards, this article provides a general overview of QS-9000 in Part IV, followed by a detailed discussion of its provisions in plain language in Part V. Ten significant legal issues raised by QS-9000 are discussed in Part VI. Finally, Part VII provides a comprehensive summary of QS-9000.

\textsuperscript{22} See \textit{id}.

\textsuperscript{23} \textit{Chrysler Corp., Ford Motor Co. and General Motors Corp., Quality System Requirements QS-9000} (2d ed. 1996) [hereinafter citations to particular QS-9000 sections will be cited as QS-9000.] (e.g., \textit{Chrysler Corp., Ford Motor Co., and General Motors Corp., Quality System Requirements QS-9000} § 4.14.1 (2d ed. 1996) is simply QS-9000.4.14.1), and citations to particular pages of the QS-9000 document will be cited, e.g., QS-9000 at 41].

\textsuperscript{24} See Kendall Slee, \textit{Revving Up For QS-9000, Export Today Online} 1, ¶ 3 (July 1996) <http://www.exporttoday.com/archive/july96/article7.html>.
II. WHAT IS A QUALITY SYSTEM?

Although industry frequently talks about quality and seeks to achieve quality, the actual definitions of "quality" and "quality system" are usually not well understood. "Quality is an unusually slippery concept, easy to visualize and yet exasperatingly difficult to define. It remains a source of great confusion to managers, leading to the frequent but empty claim, 'I know it when I see it.'"25

Basically, quality can be defined simply as "customer satisfaction"—satisfying the needs of the buyer as well as those within the organization who rely on the actors' role in the design and manufacturing process.26 Customer satisfaction is largely achieved through two components: (1) product features, i.e., ensuring that the product satisfies the customer's performance needs, and (2) freedom from deficiencies, i.e., satisfying the customer's performance needs in an efficient manner that minimizes or eliminates scrap, rework, and complaints.27 Quality is achieved through three major "quality process" steps: (1) quality planning, i.e., designing quality into the production process; (2) quality control, i.e., instilling quality during production; and (3) quality improvement, i.e., feedback, critical self-review, and corrective actions.28

A quality system is simply the administrative framework for implementing these quality processes.29 In other words, a quality system provides a common context from which a designer or manufacturer can exercise initiatives related to quality.

III. ISO 9000: PREDECESSOR OF QS-9000

Understanding ISO 9000 is key to understanding QS-9000, because QS-9000 is fundamentally based on ISO 9000. In fact, QS-9000 incorporates verbatim almost all of the ISO 9000 quality elements.30

ISO 9000 is a set of international standards on quality management and quality assurance. ISO 9000 was developed by the International Organization for Standardization (ISO) with the
cooperation of industry and numerous technical societies.\textsuperscript{31} The idea of developing an international standard for quality was conceived in 1979.\textsuperscript{32} The first drafts of ISO 9000 were derived from the British Standards Institute (BSI) standard BS 5750, which was derived from North American Treaty Organization (NATO) and U.S. military standards.\textsuperscript{33} In addition, quality management systems procedures developed by the NASA for the Apollo missions were factored into the ISO 9000 drafting process.\textsuperscript{34}

The purpose of ISO 9000 is to provide an effective means for documenting essential elements of a quality system; the ISO 9000 standards, however, do not themselves specify how to implement or maintain a quality system.\textsuperscript{35} Hence, ISO 9000 is focused not on actual product quality or quality control, but on developing customer satisfaction by ensuring that a documentation system exists for measuring quality-related attributes.\textsuperscript{36}

ISO 9000 is actually a series of five individual, but related, standards. They are generic standards that are not specifically designed for a particular industry, product, or service.\textsuperscript{37} Due to its generic nature, ISO 9000 is intended to serve as a "baseline" from which more tailored, industry-specific requirements may be derived.\textsuperscript{38}

The five documents comprising the ISO 9000 series are:

1. ISO 9000: Quality Management and Quality Assurance Standards—Guidelines for Selection and Use.\textsuperscript{39}


\textsuperscript{33} See id.

\textsuperscript{34} See id.


\textsuperscript{37} See id.

\textsuperscript{38} See id. See also Adams, supra note 32, at 605.

\textsuperscript{39} See \textit{INTERNATIONAL ORGANIZATION FOR STANDARDIZATION}, ISO 9000 (1994) [hereinafter all ISO 9000 series standards and their sections will be cited in short form; e.g., the citation \textit{INTERNATIONAL ORGANIZATION FOR STANDARDIZATION}, ISO 9001 § 8.5.1 is simply ISO 9001.8.5.1].


In the United States ISO 9000-9004 are also referred to as ANSI/ASQ Q9000-9004. Both ISO 9000 and ANSI/ASQ Q9000 are identical.  

ISO 9000 is the base document that provides the fundamental requirements of a quality system and guidance for selection and use of its companion standards ISO 9001, ISO 9002, ISO 9003, and ISO 9004. ISO 9001, ISO 9002, and ISO 9003 provide the detailed quality system requirements in varying levels of stringency and are actually successive subsets of one another.  

ISO 9001 is the most stringent and comprehensive level of quality system requirements. ISO 9001 consists of twenty clauses directly addressing: research and design; product manufacturing, inspection and testing; storage, distribution, installation, and post-sale servicing; and indirectly address marketing.  

ISO 9002 is the second most stringent and comprehensive level of quality system requirements. ISO 9002 comprises eighteen of the twenty ISO 9001 clauses, deleting the research and design and post-sales servicing clauses. In general, ISO 9002 covers production and installation.  

ISO 9003 is the least stringent of the three ISO 9000 levels of quality system requirements. ISO 9003 is far more limited in scope than ISO 9001 and ISO 9002—it focuses on only three of  

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40 See ISO 9001, supra note 39.  
41 See ISO 9002, supra note 39.  
42 See ISO 9003, supra note 39.  
43 See ISO 9004, supra note 39.  
44 See ANSI ASC Z-1 Committee on Quality Assurance, supra note 36.  
45 See id.  
46 See id.  
47 See id.  
48 See Adams, supra note 32, at 605.  
49 See id.  
50 See ANSI ASC Z-1 Committee on Quality Assurance, supra note 36.
ISO 9000's twenty clauses and covers only final product inspection, testing, storage, and delivery.  

ISO 9004 provides quality management guidance and is intended for internal use within an activity. It addresses an activity's own efforts to improve its internal operations and to anticipate emergent business opportunities. ISO 9004 also provides general guidance and assistance in interpreting ISO 9000-9003.

To become “ISO 9000 Certified,” an activity must first determine whether ISO 9001, ISO 9002, or ISO 9003 is the appropriate level of quality system certification. ISO 9001 is applicable to activities that perform research/design and manufacturing. ISO 9002 is applicable to manufacturing facilities and installation activities that do not engage in design. ISO 9003 is applicable to warehousing and distribution activities.

Second, an activity must document their processes and, if necessary, modify their procedures to comply with the desired level of ISO 9000 certification. This can be achieved in-house or through the use of management consultants specializing in ISO 9000 certification.

Third, the activity must contract an ISO 9000 “third-party registrar” to perform an on-site audit to ensure compliance with the appropriate ISO 9000 standard. The registrar actually spends a significant amount of time at the activity’s site reviewing quality documentation and observing processes. Registrars are intended to be external, independent, and impartial organizations, such as the American Bureau of Shipping (ABS) or Underwriters Laboratories (UL), which usually service a specific industry sector. Registrars must be certified by a national

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51 See Adams, supra note 32, at 605.
52 See ANSI ASC Z-1 Committee on Quality Assurance, supra note 36.
53 See Adams, supra note 32, at 605.
54 See id.
55 See id.
56 See id.
60 See J. Eric Reed et al., Introduction to QS 9000 (visited Dec. 12, 1997) <http://et.nmsu.edu/-etti/summer97/manufacturing/qs9000.html>.
or international accreditation board, such as the Registrar Accreditation Board (RAB), which is administered by the American National Standards Institute (ANSI) and the American Society for Quality (ASQ).  

Finally, upon successful completion of the third-party registrar audit, the activity will receive certification that its quality system is in compliance with the appropriate ISO 9000 standard. The activity will be listed in a register maintained by the third-party registrar. Certified activities may publicize their registration and use the third-party registrar’s certification mark and the accreditation board’s mark on its advertising and business correspondence, but not on the product itself. Follow-up audits by the certifying registrar are required to maintain ISO 9000 certification.

IV. QS-9000: AN OVERVIEW

A. HISTORY AND BACKGROUND

Prior to QS-9000, Chrysler, Ford, and General Motors each promulgated their own supplier quality system standards, namely Chrysler’s Supplier Quality Assurance Manual, Ford’s Q-101 Quality System Standard, General Motors’ North American Operations (NAO) Targets for Excellence, and General Motors’ Europe General Quality Standard for Purchased Materials. These standards were generally incompatible with one another, used different terminology, and contained substantially different requirements. As a result, Chrysler, Ford, General Motors, and their suppliers bore significant additional costs associated with having such disparate customer-specific requirements.

In 1988, the Purchasing and Supply Vice Presidents of Chrysler, Ford, and General Motors established the Supplier Quality Requirements Task Force to “standardize reference

61 See ANSI ASC Z-1 Committee on Quality Assurance, supra note 36.
62 See id.
63 See id.
64 See id.
66 See QS-9000 at 2; see also Peter B. Lake et al., QS-9000 and Automotive Quality (visited Dec. 16, 1997) <http://www.asq.org/standcert/qs-9000 qs9000a.html>.
67 See Lake et al., supra note 66; QS-9000 at ii.
The Task Force, organized by the Automotive Division of the American Society for Quality Control (ASQC), focused on harmonizing existing supplier documents and procedures and created five manuals from 1990 to 1994. These standardized manuals were the Initial Sample Warrant Form, the Measurement System Analysis Reference Manual, the Fundamental Statistical Process Control Reference Manual, the Production Part Approval Process, the Potential Failure Modes & Effects Analysis Reference Manual, and the Advanced Product Quality Planning & Control Plan Reference Manual. These manuals significantly reduced unnecessary variation. The supplier community, as well as Chrysler, Ford, and General Motors, considered the manuals a success.

Based on this initial success, in December 1992, the Purchasing and Supply Vice Presidents of Chrysler, Ford, and General Motors directed the Task Force to undertake a more comprehensive project and “harmonize the fundamental supplier quality systems manuals and assessment tools.” Although it was understood that each automobile manufacturer would continue to separately require company-specific, division-specific, and product-specific requirements, it was recognized that industry-wide standardization on a fundamental level would enhance quality, eliminate redundant requirements, and reduce costs.

In August 1994, the Task Force issued Quality System Requirements QS-9000, better known simply as QS-9000. Response to QS-9000 was “overwhelming and positive” and created a substantial demand worldwide for QS-9000 certification. Numerous activities have pursued and obtained compliance with QS-9000, and many ISO 9000 registrars began to support certification to QS-9000. Furthermore, activities implementing QS-9000 provided the Task Force with constructive
suggestions to clarify and update requirements.\textsuperscript{78} As a result, in February 1995, the Task Force issued the second edition of QS-9000,\textsuperscript{79} consisting of forty updates, revisions, clarifications, corrections, and additions to the original QS-9000.\textsuperscript{80} The second edition, which became fully effective in January 1996, is the current version of QS-9000.\textsuperscript{81}

\section*{B. Purpose of QS-9000}

The purpose of QS-9000 is to define the fundamental quality system expectations of Chrysler, Ford, and General Motors for internal and external suppliers of production, service parts, and materials.\textsuperscript{82} QS-9000 is intended to serve as a common ground among suppliers and manufacturers in the automotive industry from which to build quality initiatives, such as continuous improvement, defect prevention, reduction of variation and waste in the supply chain, and cost reduction.\textsuperscript{83} In summary, QS-9000 is the standard set of quality system requirements common to the automotive industry which can be expanded upon on a customer-by-customer or product-by-product basis.

\section*{C. Relationship Between QS-9000 and ISO 9000}

QS-9000 is based on ISO 9000 and ISO 9001 and embraces much of the actual text of ISO 9001.\textsuperscript{84} QS-9000, however, modifies ISO 9001 in many respects—in fact, "QS-9000 changes ISO 9000 by over 76 percent."\textsuperscript{85} QS-9000 expands upon ISO 9000, is more comprehensive in scope than ISO 9000 and ISO 9001, and is specifically tailored to the needs of the automotive industry.\textsuperscript{86} QS-9000 takes many of the ISO 9001 non-mandatory guidelines and turns them into requirements.\textsuperscript{87} In addition, QS-9000 contains many requirements not based on either ISO 9000 or ISO 9001, including: (1) production part approval process; (2) re-

\begin{itemize}
\item \textsuperscript{78} See id.
\item \textsuperscript{79} See id.
\item \textsuperscript{80} See id. at 89.
\item \textsuperscript{81} See id. at i.
\item \textsuperscript{82} See QS-9000 Info Center (visited Dec. 12, 1997) <http://home.sprynet.com/sprynet/crawfo03/quality6.html>.
\item \textsuperscript{83} See id.
\item \textsuperscript{84} See Perry Johnson, Inc., \textit{supra} note 58.
\item \textsuperscript{85} See Dennis Hughey & Marek Piatkowski, \textit{What is QS-9000?} (visited Dec. 12, 1997) <http://www.newsteel.com/features/0996zu.html> (emphasis added).
\item \textsuperscript{86} See Reed et al., \textit{supra} note 60.
\item \textsuperscript{87} See Amy Zuckerman, \textit{Meeting QS 9000 Requirements} (visited Dec. 12, 1997) <http://www.newsteel.com/features/0996zu.html>.
\end{itemize}
quiring customer approval to run a new or altered part through the process; (3) continuous improvement; (4) requiring suppliers to adopt systems to ensure that organized improvement activities take place which can be quantitatively measured; (5) requiring planning for equipment, facility, and process maintenance; and (6) requiring tooling management and manufacturing error safeguards. Accordingly, QS-9000 should be thought of as a standard completely separate from and substantially more stringent than ISO 9001.

D. APPLICABILITY OF QS-9000

In general, QS-9000 applies to all internal and external suppliers of production materials, parts, and services to Chrysler, Ford, and General Motors, as well as the truck manufacturers Freightliner, Mack Trucks, Navistar International, PACCAR, and Volvo GM Heavy Truck. Specifically:

QS-9000 applies to all internal and external suppliers of: a) production materials, b) production or service parts, or c) heat treating, painting, plating, or other finishing services directly to Chrysler, Ford, General Motors or other OEM [original equipment manufacturers] subscribing to this document.

QS-9000 is imposed primarily on “Tier 1” suppliers (i.e., suppliers who provide materials and/or services directly to automobile or truck manufacturers). QS-9000 is not currently imposed upon Tier 2 or Tier 3 suppliers (i.e., suppliers who provide materials and/or services indirectly to automobile or truck manufacturers through a Tier 1 or Tier 2 supplier). However, it is very likely that Tier 1 suppliers will eventually impose QS-9000 on their subcontractors, the Tier 2 and Tier 3 suppliers, to satisfy the subcontractor quality requirements of QS-9000.4.6

Although each of the “Big Three” requires compliance to QS-9000, each differs with respect to third-party registration requirements. “All [p]roduction and [s]ervice [p]art [s]uppliers to Chrysler must be ... [r]egistered to QS-9000 by July 31,

E. IMPLEMENTATION OF QS-9000

Although the implementation process of QS-9000 is very similar to ISO 9000, QS-9000 is generally considered much more difficult to implement than ISO 9000. QS-9000 registration is achieved through a registrar specifically qualified to QS-9000. A list of QS-9000 registrars is maintained by the International Automotive Sector Group.

Many activities pursuing QS-9000 certification first obtain ISO 9001 or ISO 9002 certification as a “work up” toward QS-9000. After completing the process, two quality managers advise:

Start with the ISO 9000 startup process before embarking on the prescriptive, industry-specific elements that QS-9000 requires. Set up work teams, establish a documentation system, and then roll into the QS 9000 process. “Having achieved ISO 9002, we were able to move directly into QS 9000” . . . “ISO 9000 is an easier process . . . . Once you have it right, you can plug in anything because the structure is right.”

To ensure correct and consistent application of QS-9000 through the registrars’ initial on-site inspection and periodic surveillance audits, Chrysler, Ford, and General Motors have established a set of requirements that registrars performing QS-9000 certification must follow. The registrar must be certified

94 QS-9000, supra note 23, at 58; QS-9000 Info Center, supra note 82.
95 QS-9000, supra note 23, at 70; QS-9000 Info Center, supra note 82.
96 QS-9000, supra note 23, at 62; QS-9000 Info Center, supra note 82.
98 See QS-9000 Info Center, supra note 82.
100 See INTERNATIONAL AUTOMOTIVE SECTOR GROUP, supra note 97.
101 Zuckerman, supra note 87.
by an accreditation organization approved by the Big Three.103 The registrar must also be accredited to service the particular industry sector in question.104 Although currently the registrar may be part of the same organization that assisted the supplier in implementing QS-9000, "it is very likely that third party certification may be mandatory in the near future."105 Registrar audits and assessments must ensure both implementation and continued practice of QS-9000 requirements.106 Registrar surveillance audits must be performed periodically and must include a review of customer complaints, supplier responses, suppliers' internal auditing systems, and corrective actions taken by management to ensure continuous improvement.107

V. TECHNICAL REQUIREMENTS OF QS-9000

QS-9000 requirements are organized into three major sections: (1) Section I: ISO 9000-Based Requirements; (2) Section II: Sector-specific Requirements; and (3) Section III: Customer-specific Requirements.108 Relevant QS-9000 requirements are also contained in an appendix, glossary, five supplementary documents, and official interpretive guidance.

A. SECTION I OF QS-9000

Section I contains twenty requirements taken nearly verbatim from ISO 9001.4, which are designated using the same numbering scheme from ISO 9001 and printed in italics.109 Interpretations of the ISO 9001 requirements and supplementary QS-9000-specific requirements are also included in Section I and printed in normal text.110 Section I alone is nearly twice the size of the original ISO 9001 document and constitutes the biggest section of QS-9000. The twenty requirements, in a nutshell, are:

1. Management Responsibility. The supplier’s management must “define and document its policy for quality[,] ... ensure that this policy is understood, implemented and maintained at

103 See id.
104 See id.
105 See id.
106 See id.
107 See id.
108 See generally QS-9000, supra note 23.
109 See QS-9000, supra note 23, at 5-49.
110 See id.
all levels of the organization,” and dedicate adequate resources and responsibilities to achieve this requirement.\textsuperscript{111}

2. Quality System. The supplier’s system to ensure quality must be documented and include a detailed implementation plan that involves “cross-functional teams” (i.e., groups comprised of persons from diverse divisions within a supplier), feasibility reviews (i.e., “an assessment... of a particular design... or process”), Process Failure Mode and Effects Analysis (Process FMEA; an analysis focused on preventing defects rather than detecting defects), and a master control plan (i.e., a plan that covers the entire process from prototyping to pre-launch testing to actual production).\textsuperscript{112}

3. Contract Review. The supplier must establish a documented procedure for coordinating the review of proposed contracts and amendments to contracts.\textsuperscript{113}

4. Design Control. The supplier must establish a documented procedure to ensure that the customer’s specifications are met.\textsuperscript{114} This involves obtaining design input, measuring design output, reviewing the design, verifying the design for accuracy, validating the design against customer specifications, and incorporating design changes.\textsuperscript{115}

5. Document and Data Control. The supplier must establish documented procedures to control all documents used during design and manufacturing.\textsuperscript{116} This involves engineering review, approval, and controlled issuance of all documents and changes to documents.\textsuperscript{117}

6. Purchasing. The supplier must establish documented procedures to ensure quality among Tier 2 and Tier 3 suppliers.\textsuperscript{118}

7. Control of Customer-Supplied Product. “The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided [to the supplier for processing].”\textsuperscript{119}

\textsuperscript{111} QS-9000.4.1.1-4.1.2.2, supra note 23; see also QS-9000.4.1.1-4.1.6, supra note 23.

\textsuperscript{112} See QS-9000.4.2, supra note 23. A more complete discussion of FMEA is provided in Part VI.G.

\textsuperscript{113} See QS-9000.4.3.1-4.3.4, supra note 23.

\textsuperscript{114} See QS-9000.4.4.1, supra note 23.

\textsuperscript{115} See QS-9000.4.1.4.4.9, supra note 23.

\textsuperscript{116} See QS-9000.4.5.1, supra note 23.

\textsuperscript{117} See QS-9000.4.5.2, QS-9000.4.5.3, supra note 23.

\textsuperscript{118} See QS-9000.4.6, supra note 23.

\textsuperscript{119} QS-9000.4.7, supra note 23 (emphasis omitted).
8. Product Identification and Traceability. "[T]he supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation."\textsuperscript{120}

9. Process Control. The supplier must document its process in enough detail to permit recreation and auditing of the manufacturing process.\textsuperscript{121} This involves process monitoring, providing written instructions to operators, performing preliminary process capability studies to ensure production feasibility for a new process, auditing the existing process continuously, and ensuring changes to the process are approved and documented.\textsuperscript{122}

10. Inspection and Testing. "The supplier shall . . . verify that the specified requirements for the product are met."\textsuperscript{123} This involves documentation of receipt inspection of raw or input materials, in-process inspection, and final inspection.\textsuperscript{124}

11. Control of Inspection, Measuring, and Test Equipment. The supplier must document and maintain the calibration of inspection equipment to ensure consistency and accuracy of measurements.\textsuperscript{125}

12. Inspection and Test Status. The supplier must document whether each product has failed or passed inspection.\textsuperscript{126}

13. Control of Nonconforming Product. The supplier must specifically identify, segregate, and evaluate a product that fails testing and inspection.\textsuperscript{127} Reworked product must be controlled.\textsuperscript{128} Customer approval is required to accept any product that deviates from customer specifications.\textsuperscript{129}

14. Corrective and Preventive Action. The supplier must establish documented procedures for implementing actions to correct deficiencies and prevent them from recurring.\textsuperscript{130}

15. Handling, Storage, Packaging, Preservation, and Delivery. The supplier must document and maintain procedures for, and the

\textsuperscript{120} QS-9000.4.8, supra note 23 (emphasis omitted).
\textsuperscript{121} See QS-9000.4.9, supra note 23.
\textsuperscript{122} See QS-9000.4.9.1-4.9.7, supra note 23.
\textsuperscript{123} QS-9000.4.10.1, supra note 23 (emphasis omitted).
\textsuperscript{124} See QS-9000.4.10.2-4.10.5, supra note 23.
\textsuperscript{125} See QS-9000.4.11.1-4.11.4, supra note 23.
\textsuperscript{126} See QS-9000.4.12, supra note 23.
\textsuperscript{127} See QS-9000.4.13.1, supra note 23.
\textsuperscript{128} See QS-9000.4.13.2, QS-9000.4.13.3, supra note 23.
\textsuperscript{129} See QS-9000.4.13.3, supra note 23.
\textsuperscript{130} See QS-9000.4.14.1, supra note 23.
performance of, product handling, storage, packaging, preservation, and delivery.  

16. **Control of Quality Records.** Records associated with production part approvals, tooling records, purchase orders, and amendments must be retained throughout the production run plus one year. Quality performance records must be retained for one year after creation. Records for internal audits and management review must be retained for three years.  

17. **Internal Quality Audits.** "The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system."  

18. **Training.** The supplier must document and maintain training procedures and ensure that its personnel must be qualified to perform their tasks.  

19. **Servicing.** The supplier must document servicing procedures and ensure that feedback is communicated.  

20. **Statistical Techniques.** The supplier must document and maintain statistical quality control methods, ensure that the proper statistical tool is used to quantify quality, and ensure that personnel understand statistical concepts.  

**B. Section II of QS-9000**  

Section II contains requirements specific to the automotive industry not included in Section I, including Production Part Approval Process, the Continuous Improvement program, and the Manufacturing Capabilities program. The Production Part Approval Process (PPAP) requires compliance with the PPAP manual, as well as customer notification and possibly re-approval, if any of the following are changed: part number, engineering change level, manufacturing location, material subcontractors, or production process environ-

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131 See QS-9000.4.15.1, *supra* note 23.  
132 See QS-9000.4.16, *supra* note 23.  
133 See id.  
134 See id.  
135 QS-9000.4.17, *supra* note 23 (emphasis omitted).  
136 See QS-9000.4.18, *supra* note 23.  
137 See QS-9000.4.19, *supra* note 23.  
138 See QS-9000.4.20.1, QS-9000.4.20.2, *supra* note 23.  
139 See generally QS-9000, *supra* note 23.
The PPAP manual provides the administrative framework for implementing the methodology for organizing the stages of planning, product design and development, process design and development, product and process validation, and production. PPAP requires that "[s]uppliers are responsible for subcontracted material and services" and that suppliers are responsible "to verify that [engineering] changes are properly validated."

Continuous Improvement requires suppliers to fully implement a continuous improvement "philosophy" throughout their organization to improve "quality, service (including timing, delivery) and price for all customers." Cited examples of improvements to be made on a continuous basis include:

- unscheduled machine downtime
- machine set-up die change and machine changeover times
- excessive cycle time
- scrap, rework and repair
- non value-added use of floor space
- excessive variation
- less than 100% first run capability
- process averages not centered on target values (bilateral specifications)
- testing requirements not justified by accumulated results
- waste of labor and materials
- excessive cost of non-quality
- difficult assembly or installation of the project
- excessive handling and storage
- new target values to optimize customer processes
- marginal measurement system capability
- customer dissatisfaction, e.g. complaints, repairs, returns, misshipments, incomplete orders, customer plant concerns, warranty, etc.

Suppliers are also required to know the following methods for measuring continuous improvement, and use them, if appropriate:

- Capability Indices (Cp, Cpk)
- Control Charts (Variables, Attributes)
- Cumulative Sum Charting (CUSUM)

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140 See QS-9000, supra note 23, at 52.
141 See generally CHRYSLER CORP., FORD MOTOR CO., & GENERAL MOTORS CORP., PRODUCTION PART APPROVAL PROCESS (1995) [hereinafter PPAP].
142 QS-9000, supra note 23, at 52 (emphasis omitted).
143 Id. at 53.
144 Id. at 53-54.
The Manufacturing Capabilities program consists of four major requirements. First, suppliers must "use a cross-functional team approach for developing facilities, processes and equipment plans in conjunction with the advanced quality planning process." This requirement prescribes a number of considerations to ensure that a supplier's facilities, equipment, and processes are coordinated for optimum effectiveness. Second, suppliers must use a methodology called "mistake proofing" to "prevent manufacture of nonconforming product." Third, suppliers must control tool and gage design, fabrication, and inspection, whether performed in-house or subcontracted, and permanently mark all customer-owned tools and gages. Fourth and finally, suppliers must "establish and implement a system for tooling management . . . ."

C. SECTION III OF QS-9000

Section III contains requirements specific to Chrysler, Ford, and General Motors. Chrysler-specific requirements cover: part identification; annual layout inspection; annual supplier internal quality audits; annual design validation/product verification; corrective action plans in accordance with the "Chrysler 7D" format; standard Chrysler packaging, shipping and labeling formats; defect criteria; acceptance criteria; and sampling schedules.
Ford-specific requirements cover unique requirements applicable to control item parts (a.k.a. "V" parts, i.e., parts with "Critical Characteristics that may affect safe vehicle operation and/or compliance with government regulations"), heat treating, engineering specification (ES) testing, process monitoring, compliance with the Ford *QOS Assessment & Rating Procedure*, acceptance criteria, product qualification, and sampling schedules.\(^\text{158}\)

General Motors-specific requirements cover customer approval of control plans, UPC labeling, and 17 additional General Motors standards.\(^\text{154}\)

No customer-specific requirements are included in QS-9000 for the truck manufacturers Mack Trucks, Navistar International, PACCAR, and Volvo GM Heavy Truck.\(^\text{155}\) QS-9000 states only that customer-specific requirements are available directly from the truck manufacturer.\(^\text{156}\)

D. **Appendices and Glossary of QS-9000**

QS-9000 also contains eight appendices and a glossary that provide relevant information.\(^\text{157}\) The appendices are summarized as follows:

1. *Appendix A: The Quality System Assessment Process.* Determines compliance with QS-9000.\(^\text{158}\)
2. *Appendix B: Code of Practice for Quality System Registrars.* Requirements applicable to registrars.\(^\text{159}\)
3. *Appendix C: Special Characteristics and Symbols.* A summary of symbols used on special parts by Chrysler, Ford, and General Motors.\(^\text{160}\)
4. *Appendix D: Local Equivalents for ISO 9001 and 9002 Specifications.* Country-by-country designations of ISO 9001 and 9002 and appropriate controlling body (e.g., in New Zealand ISO 9001 is designated as NZS 9001-1987 and controlled by Standards New Zealand).\(^\text{161}\)

\(^\text{155}\) See id. at 62-67.
\(^\text{154}\) See id. at 70-72.
\(^\text{155}\) See id. at 73.
\(^\text{156}\) See id.
\(^\text{157}\) See generally id. at 75-100.
\(^\text{158}\) See id. at 75-77.
\(^\text{159}\) See id. at 79-81.
\(^\text{160}\) See id. at 82.
\(^\text{161}\) See id. at 83-86.
5. Appendix E: Acronyms and Their Meanings.\textsuperscript{162}

6. Appendix F: Change Summary. A listing of changes between the 1994 and 1995 versions of QS-9000.\textsuperscript{163}

7. Appendix G: November 21, 1994 QS-9000 Accreditation Body Implementation Requirements. Covers criteria for registrar qualification, registrar auditor qualifications, certificates, and upgrading of registrar accreditation from ISO 9000 to include QS-9000.\textsuperscript{164}

8. Appendix H: Survey Audit Days Table. A schedule for determining the minimum number of man-days that a registrar should spend on performing initial and surveillance QS-9000 audits.\textsuperscript{165}

E. Supplementary Documents Referenced in QS-9000

Throughout QS-9000 several non-customer-specific supplementary manuals are referenced that contain important requirements. These manuals are based on existing standards within the automotive industry and the standards initially created by the Supplier Quality Requirements Task Force.\textsuperscript{166} Five of these manuals are of particular importance, and are summarized as follows:

1. Advanced Product Quality Planning and Control Plan.\textsuperscript{167} Used in conjunction with the Production Part Approval Process manual, this manual provides a comprehensive methodology for organizing the stages of planning, product design and development, process design and development, product and process validation, and production.\textsuperscript{168}

2. Production Part Approval Process.\textsuperscript{169} This manual provides the administrative framework for implementing the methodology in the Advanced Product Quality Planning and Control manual.\textsuperscript{170}

\textsuperscript{162} Id. at 87-88.

\textsuperscript{163} See id. at 89.

\textsuperscript{164} See id. at 90-92.

\textsuperscript{165} See id. at 93.

\textsuperscript{166} See infra Part VI.A.

\textsuperscript{167} See CHRYSLER CORPORATION, FORD MOTOR COMPANY, AND GENERAL MOTORS CORPORATION, ADVANCED PRODUCT QUALITY PLANNING AND CONTROL PLAN (1995).


\textsuperscript{169} See PPAP, supra note 141.

\textsuperscript{170} See id.
3. **Failure Mode and Effects Analysis.** This manual provides a methodology for finding weaknesses in designs before the design is ever realized, either in prototype or production. FMEA provides a record of the design development process and helps prevent mistakes by recognizing past design experiences.

4. **Measurement System Analysis.** Used in conjunction with the Fundamental Statistical Process Control manual, this manual covers methods to ensure the reliability of inspection and test personnel and measurement gauges.

5. **Fundamental Statistical Process Control.** This manual outlines methods of using statistical process control to assess quality and process capabilities, and solve problems. It focuses on defect prevention, rather than defect detection, and covers statistical concepts, including the central limit theorem, normal distributions, sampling, control chart construction, and moving average/moving range charts. The manual is used in conjunction with the Measurement System Analysis manual.

**F. Official QS-9000 Interpretive Guidance**

The International Automotive Sector Group (IASG) provides users of QS-9000 with "official" guidance in interpreting QS-9000. Such guidance is promulgated in a document titled IASG Sanctioned QS-9000 Interpretations. The IASG is an international ad hoc working group that consists of members from: (1) registrar accreditation bodies recognized by Chrysler, Ford and General Motors; (2) QS-9000 registrars; (3) the Supplier Quality

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171 See CHRYSLER CORPORATION, FORD MOTOR COMPANY AND GENERAL MOTORS CORPORATION, POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (1995) [hereinafter FMEA].
176 See CHRYSLER CORPORATION, FORD MOTOR COMPANY, AND GENERAL MOTORS CORPORATION, FUNDAMENTAL STATISTICAL PROCESS CONTROL (1997).
178 See INTERNATIONAL AUTOMOTIVE SECTOR GROUP, supra note 97.
Requirements Task Force; and (4) Tier 1 suppliers.\textsuperscript{179} Chrysler, Ford, and General Motors sanctioned the interpretations promulgated by IASG and considers them binding, unless indicated otherwise.\textsuperscript{180} Anyone can submit questions for consideration by faxing the IASG at 412-940-1004.\textsuperscript{181}

VI. LEGAL ISSUES RAISED BY QS-9000

There has been little, if any, attention given to quality standards such as ISO 9000 and QS-9000 by the law in the United States.\textsuperscript{182} On the other hand, the European community has given quality assurance standards, particularly ISO 9000, substantially greater attention. Specifically, in 1992, the European Council of Ministers issued the General Product Safety Directive that imposed a duty, \textit{inter alia}, upon product manufacturers to ensure that consumer products marketed in the European Union are safe.\textsuperscript{183} If a country has not legislatively specified what constitutes “safe,” compliance with technical manufacturing standards, including ISO 9000, might be considered “safe” \textit{per se}.\textsuperscript{184}

Accordingly, the United States’s lack of attention should not be taken as indicative of a lack of legal issues raised by quality standard systems such as QS-9000. This examination raises thirteen issues of legal importance that both litigators and transactional lawyers should consider when dealing with Chrysler, Ford, General Motors, or their Tier 1 suppliers.

A. CONSUMERS CAN USE QS-9000 TO ESTABLISH LIABILITY OF A NONCONFORMING SUPPLIER

The scope of QS-9000 applicability clearly includes Chrysler, Ford, General Motors, and their Tier 1 suppliers, because QS-9000 compliance is expressly and explicitly mandatory.\textsuperscript{185} The scope of QS-9000 applicability will also extend to encompass Tier 2 and Tier 3 suppliers, because QS-9000 will likely be re-

\textsuperscript{179} See id.
\textsuperscript{180} See id.
\textsuperscript{181} See id.
\textsuperscript{184} See id. at 159.
\textsuperscript{185} See QS-9000 Info Center, supra note 81.
quired to satisfy the subcontractor quality requirements of QS-9000.4.6.186 Such scope is consistent with the intent of the drafters of QS-9000 to make the document applicable only within the American automobile industry.187 Accordingly, breaches of QS-9000 requirements could probably be used to establish liability between players in the automotive industry.

However, the scope of QS-9000 may also include general public consumers, especially if the promotion or advertisement of the product alleges compliance with QS-9000.188 Therefore, QS-9000 could potentially be used by parties outside of the automotive industry to establish liability of a party who did not comply with QS-9000 requirements. For example, the Michigan Court of Appeals opinion in Baker v. Arbor Drugs, Inc. indicated that statements made in the promotion and advertising of Arbortech Plus, a drug interaction detection system could establish the duty of a pharmacy to its customers.189

The Baker plaintiff had been prescribed the drug Parnate (an anti-depressant) to be taken on a long-term, periodic basis. Plaintiff regularly filled his Parnate prescription at Arbor Drugs.190 Nearly three years later, Plaintiff was prescribed the decongestant Tavist-D to relieve a cold.191 Plaintiff filled the Tavist-D prescription at Arbor Drugs.192 The combination of Parnate and Tavist-D is known to cause severe complications.193 As a result, plaintiff suffered a stroke.194

Plaintiff’s suit against Arbor Drugs alleged that Arbor Drugs assumed a duty of care to the plaintiff by implementing, advertising, and using its Arbortech Plus system.195 The Arbortech Plus system is a computer system that is ISO 9000 certified and is designed to detect drug interactions.196 Although Arbor Drugs won its motion for summary judgment in the trial court, the Michigan Court of Appeals reversed, stating that “[d]efendant has advertised that its Arbortech Plus computer system was designed in part to detect harmful drug interactions. There-

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186 See Smith, supra note 92.
187 See generally, INTERNATIONAL AUTOMOTIVE SECTOR GROUP, supra note 95.
188 See Bruno & Pynnonen, supra note 179, at 1076.
190 See id. at 729.
191 See id.
192 See id.
193 See id.
194 See id.
195 See id.
196 See Bruno & Pynnonen, supra note 179, at 1076.
fore, defendant voluntarily assumed a duty of care when it im-
plemented the Arbortech Plus system and then advertised that
this system would detect harmful drug interactions for its
customers."197

Accordingly, promoting, advertising, or selling a product that
meets QS-9000 could establish a binding contractual duty
among consumers that the production process and finished
product meets QS-9000 specifications.198

B. QS-9000 DUTIES LIMITED TO AUTOMOBILE MANUFACTURER AND TIER 1 SUPPLIER

Duties derived from QS-9000 requirements might be limited
only to the automobile manufacturer and the Tier 1 supplier, not Tier 2 and lower tier suppliers. The duty of an automobile
manufacturer or supplier derived from QS-9000 requirements is
established by the level of involvement exercised.199 Tier 1 sup-
pliers and the automobile manufacturers are the primary parties
who bear QS-9000 requirements, and therefore, who bear any
duties resulting from QS-9000. In particular, QS-9000 expressly
states that the supplier’s management and production person-
nel bear a duty to ensure compliance with quality require-
ments.200 QS-9000 requires that “management . . . shall have
defined authority for ensuring that a quality system is estab-
lished, implemented and maintained in accordance with this In-
ternational Standard . . . .”201 QS-9000 requires that personnel
involved throughout the manufacturing process, from designers
to inspectors to salespersons, become involved in decision-mak-
ing to ensure quality.202 Furthermore, the automobile manufac-
turers also share a duty derived from QS-9000 because of their
active role in QS-9000 implementation. For example, the auto-
mobile manufacturers review and approve procedures as re-

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197 Baker, 544 N.W.2d at 205-06.
198 See Bruno & Pynninen, supra note 182, at 1076.
199 See generally Amstadt v. United States Brass Corp., 919 S.W.2d 644 (Tex. 1996).
200 See QS-9000.4.1, supra note 23.
201 QS-9000.4.1.2.3, supra note 23.
202 See QS-9000, supra note 23, at 7. The following personnel must be incorpo-
rated in management’s multi-disciplinary decision process: (1) engineering/tech-
nical; (2) manufacturing/production; (3) industrial engineering; (4) purchasing/materials management; (5) quality/reliability; (6) cost estimating;
(7) product service; (8) management information systems/data processing; (9) packaging engineering; (10) tooling engineering/maintenance; (11) marketing and sales; and (12) subcontractors. See id.
quired by the Production Part Approval Process manual. Prior to production, Chrysler approves suppliers’ written processes, Ford approves initial material qualification and acceptance criteria, and General Motors approves the procedures to produce specific critical parts.

Responsibility, however, might not flow to the Tier 2 and lower tier suppliers. QS-9000 expressly states in bold that “[s]uppliers are responsible for subcontracted material and services” per the Production Part Approval Process manual. On the other hand, this appears to contravene another requirement that Tier 2 and lower tier suppliers, i.e., “subcontractors,” are considered members of the “multidisciplinary” party who must be involved in decision-making. Furthermore, QS-9000 never expressly states that lower tier suppliers are not responsible.

C. Supplier Cannot Escape Enforcement of Any Contract Term

It is a basic principle of the law of contracts that “a party who signs an instrument manifests assent to it and may not later complain that he did not read the instrument or that he did not understand its contents.” This principle is also known as the “duty to read.” However, “[t]here is a growing body of case law which subverts the traditional duty to read concept . . . upon a theory that there was not true assent to a particular term . . . .” Furthermore, the Restatement (Second) of Contracts states that “[w]here the other party has reason to believe that the party manifesting such assent would not do so if he knew that the writing contained a particular term, the term is not part of the agreement.” Accordingly, it is possible that a contract term might not be enforceable if one party did not realize the magnitude and importance of the term.

This possibility could very well be extinguished by the contract review requirements of QS-9000 which require a complete

203 See PPAP, supra note 141, at 2, 48.
204 See generally QS-9000, supra note 23, at 57-74.
205 QS-9000, supra note 23, at 52 (emphasis omitted).
206 Id. at 7.
208 See id.
209 Id. § 9-44.
and documented procedure for suppliers to review contracts.\textsuperscript{211} QS-9000 explicitly adds that "all customer requirements, including those in Section III of this document [i.e., the Customer-Specific Requirements for Chrysler, Ford, and General Motors], can be met."\textsuperscript{212} These terms, which are incorporated into the contract when QS-9000 is imposed, could be interpreted as indicative that the supplier recognizes and agrees to all contract requirements. As a result, QS-9000 provides assurance that the supplier cannot escape enforcement of any contract terms imposed by the automobile manufacturer.

D. Design Responsibility Placed on Supplier

According to generally accepted industry practice, suppliers usually request the automobile manufacturers to "sign-off" on the design, thereby potentially relieving the supplier of liability associated with design defects.\textsuperscript{213} Nonetheless, it is still possible that the supplier, in addition to the automobile manufacturer, could bear design responsibility.\textsuperscript{214} QS-9000 contains strong language that places full responsibility for design control on the supplier. For example, the Design Control section states that "[t]he supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met."\textsuperscript{215} Accordingly, suppliers should ensure that their contracts expressly place design responsibility with the automobile manufacturer after "sign-off."

E. Implied Warranties of Fitness Become Express Warranties That Cannot be DISCLAIMED

Industry generally believes that quality standards apply only to the production process and not to the product itself; however, legal commentators have seriously questioned this premise.\textsuperscript{216} It has been argued that if a quality standard like ISO 9000 or QS-9000 is adopted, then the U.C.C.'s implied warranty of fitness for a particular purpose is transformed into an express warranty of fitness.\textsuperscript{217} Commentators state that customers "have a reason-

\begin{footnotes}
\footnote{211} See QS-9000.4.3.1, \textit{supra} note 23.
\footnote{212} QS-9000.4.3.2(d), \textit{supra} note 23 (emphasis added).
\footnote{213} See Bruno & Pynnonen, \textit{supra} note 182, at 1079.
\footnote{214} See id.
\footnote{215} QS-9000.4.4.1, \textit{supra} note 23.
\footnote{216} See Bruno & Pynnonen, \textit{supra} note 182, at 1080.
\footnote{217} See id.
\end{footnotes}
able argument that a specific, separate product warranty is superfluous to a warranty that [the supplier's] procedure will produce a product [that meets contract specifications].”\textsuperscript{218} QS-9000 states that the supplier's quality system will effectively satisfy “the expectations and needs of its customers.”\textsuperscript{219} Therefore, the supplier's guarantee that the process used to design and manufacture the product in accordance with QS-9000 can be easily transformed into an express warranty that the product itself meets QS-9000 standards.\textsuperscript{220} Although this is inconsistent with the purpose of a quality system, such an argument is certainly plausible given QS-9000's detailed requirements which, upon first glance, look like product requirements.\textsuperscript{221}

Furthermore, suppliers may not be able to disclaim any warranties of fitness, whether implied or express, derived from QS-9000. “One significant result of the transmogrification of implied warranties into an express warranty of fitness is that the standard boilerplate language disclaiming implied warranties may be ineffective because disclaimers of express warranties may be considered unreasonable.”\textsuperscript{222}

F. Extent of Documentation—Limited to Scope of Supplier's Role

Another issue of legal concern is the extent to which quality records must be maintained by the supplier to comply with QS-9000. For example, assume a supplier makes widgets and also uses subcontractors in the widget-production process. Must quality records be maintained only for steps performed by the supplier? Must quality records also include records from the subcontractors? Must the quality records track all of the design steps and the production steps? In other words, what is the scope of each widget's traceability through the production process?

There are four major QS-9000 sections addressing the extent to which quality records must be maintained. First, the section

\begin{footnotesize}
\begin{enumerate}
\item Id.
\item QS-9000.4.1.1, supra note 23 (emphasis omitted).
\item See generally Bruno & Pynnonen, supra note 182, at 1080-81.
\item See, e.g., QS-9000, supra note 23, at 66 (Ford's sampling plan requirements for inspecting product and ensuring that the testing conforms with statistical process control).
\item Bruno & Pynnonen, supra note 182, at 1081 (citing UCC § 2-316, "negation or limitation [of express warranties] is inoperative to the extent that such construction is unreasonable.").
\end{enumerate}
\end{footnotesize}
titled "Product Identification and Traceability" requires that, "the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation" where the product identity is not inherently obvious.223 Furthermore, "[w]here and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches" which shall be recorded.224 Second, the section titled "Control of Quality Records" generally requires that "[q]uality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data."225 Third, the section titled "Process Control" requires that "[t]he supplier . . . shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include . . . documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality . . . ."226 Fourth, the subsection titled "Purchasing Data" requires that "[p]urchasing documents shall contain data clearly describing the product ordered, including where applicable . . . the type, class, grade or other precise identification . . . ."227 Finally, in addition to the four major QS-9000 sections, Ford requires lot traceability of control item fasteners.228

Interpreted as a whole, these sections require the supplier to maintain enough documentation to recreate its role in the quality process. In other words, the documentation should permit the customer to track the supplier's processes from: (1) receipt inspection of incoming materials and subcontracted parts, to (2) processing by the supplier, to (3) final inspection and delivery.

The supplier need not maintain a complete record of its incoming material supplier's or subcontractor's quality documentation.229 The supplier must only document the results of its

223 QS-9000.4.8, supra note 23 (emphasis omitted).
224 QS-9000.4.8, supra note 23 (emphasis omitted).
225 QS-9000.4.16, supra note 23 (emphasis omitted).
226 QS-9000.4.9, supra note 23 (emphasis omitted).
227 QS-9000.4.6.3, supra note 23 (emphasis omitted).
228 See QS-9000, supra note 23, at 63.
229 See QS-9000.4.6, supra note 23.
receipt inspection that the incoming material or subcontracted parts have been verified to conform to specifications, as required by QS-9000.4.10.2.230

Documentation does not necessarily need to accompany every individual item produced. Documentation on a batch-by-batch basis is acceptable, provided that the batches are defined on a scale that permits quality to be controlled. For example, if widgets are made on a daily basis by three shifts of different personnel, then widgets made on a particular day by a particular shift could constitute a batch for documentation purposes. On the other hand, if the widget is particularly complex, such that quality could be substantially different on a widget-by-widget basis (e.g., automobile assembly), then batch documentation may be inappropriate and individual documentation may be required.

Documentation of supplier processing should be able to certify that all factors determined to significantly affect product quality and warrant control can be tracked. For example, suppliers to Ford must, as a minimum, be able to document its processing of Control Item Parts as designated by a "V" preceding the part or material number.231 Types of processing that must be documented for Control Item Parts include, inter alia, verification of machine set-up, material analysis to ensure conformation to specifications, and control of heat treatment.232 Furthermore, documentation must provide certification indicating "whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria."233

In summary, the supplier must document its processing of each item or batch from receipt inspection to delivery. The supplier must document each of its processing steps determined to have a significant affect on quality.

G. Failure Mode and Effects Analysis—"Damned If You Do and Damned If You Don't"

Perhaps the most significant legal impact of QS-9000 is the effect of its potential Failure Mode and Effects Analysis (FMEA) program on the products liability of designers and manufacturers. FMEA is outlined in a separate document titled Potential

230 See QS-9000.4.10.2, supra note 23.
231 See QS-9000 at 62, supra note 23.
232 See, e.g., QS-9000, supra note 23, at 63-64.
233 QS-9000.4.10.5, supra note 23.
Failure Mode and Effects Analysis\textsuperscript{234} and is incorporated in QS-9000 by reference.\textsuperscript{235} Chrysler, Ford and General Motors describe FMEA as "a systemized group of activities intended to: 1) recognize and evaluate the potential failure of a product/process and its effects, 2) identify actions which could eliminate or reduce the chance of the potential failure occurring, and 3) document the process."\textsuperscript{236} The purpose of FMEA is to predict possible failure modes, identify the effects of such failures, and determine further actions "to the Team's level of knowledge."\textsuperscript{237}

FMEA can be applied to suppliers who provide either design services, or processing, or both. FMEA is intended to be performed before production begins as part of the product and manufacturing design process. "It is meant to be a 'before-the-event' action, not an 'after-the-fact' exercise... the FMEA must be done before a design or process failure mode has been unknowingly designed into the product."\textsuperscript{238} Generally, FMEA consists of three stages, namely: (1) failure identification; (2) evaluation; and (3) corrective action.

During the first stage of FMEA, all potential failure modes are identified to the greatest extent practicable. A potential failure mode is defined as:

[T]he manner in which a component, subsystem, or system could potentially fail to meet the design intent. The potential failure mode may also be the cause of a potential failure mode in a higher level subsystem, or system, or be the effect of one in a lower level component.\textsuperscript{239}

Potential failure modes should be evaluated under normal as well as atypical operating and usage conditions.\textsuperscript{240} For design FMEAs, the manual provides a partial list of potential failure modes:

\textsuperscript{234} FMEA, supra note 171.
\textsuperscript{235} See QS-9000.4.2, supra note 23; supra Part VI.F.
\textsuperscript{236} FMEA, supra note 171, at 1.
\textsuperscript{237} Id. at 11.
\textsuperscript{238} Id. at 1.
\textsuperscript{239} Id. at 11.
\textsuperscript{240} See id. Atypical conditions listed include hot, cold, dry, or dusty operating conditions, and above average mileage, rough terrain, and only city driving usage conditions. See id.
Cracked
Deformed
Loosened
Leaking

Sticking
Short Circuited (electrical)
Oxidized
Fractured.\textsuperscript{241}

The above potential failure modes can be caused by one of the following mechanisms:

Yield
Fatigue
Material Instability

Creep
Wear
Corrosion.\textsuperscript{242}

Failure modes may also result from a design failure such as:

Incorrect Material Specified
Inadequate Design Life Assumption
Over-stressing
Insufficient Lubrication Capability
Inadequate Maintenance Instructions
Poor Environment Protection
Incorrect Algorithm.\textsuperscript{243}

For process FMEAs, the manual provides two partial lists of potential failures:

[List 1 of Potential Process Failures]

Noise
Erratic Operation
Inoperative
Unstable
Draft
Poor Appearance

Rough
Excessive Effort Required
Unpleasant Odor
Operation Impaired
Intermittent Operation
Vehicle Control Impaired.\textsuperscript{244}

[List 2 of Potential Process Failures]

Can not fasten
Can not bore/tap
Can not mount
Can not face
Endangers operator.\textsuperscript{245}

Can not fit
Does not connect
Does not match
Damages equipment

These potential failures can be caused by:

Improper torque - over, under
Improper weld - current, time, pressure
Inaccurate gauging

\textsuperscript{241} Id.
\textsuperscript{242} Id. at 15.
\textsuperscript{243} Id.
\textsuperscript{244} Id. at 33.
\textsuperscript{245} Id.
Improper heat treat - time, temperature  
Inadequate gating/venting  
Inadequate or no lubrication  
Part missing or mislocated.  

During the second stage of FMEA, a Risk Priority Number (RPN) is calculated to evaluate the potential failures identified previously. The RPN “is a measure of design risk” and “is the product of the Severity (S), Occurrence (O), and Detection (D) ranking[:] RPN = (S) X (O) X (D).” Each RPN factor (i.e., Severity, Occurrence and Detection) consists of a number ranging from one to ten. Severity is defined as “an assessment of the seriousness of the effect ... of the potential failure mode to the next component, subsystem, system or customer if it occurs.” Occurrence is defined as “the likelihood that a specific cause/mechanism ... will occur.” Detection is defined as “an assessment of the ability ... to detect a potential cause/mechanism (design weakness), or the ability ... to detect the subsequent failure mode, before the component, subsystem, or system is released for production.” Detailed tables are provided to accurately assign numbers to each RPN factor.

During the third stage of FMEA, corrective actions are identified and acted upon. “When the failure modes have been rank ordered by RPN, corrective action should be first directed at the highest ranked concerns and critical items.” Each corrective action must be assigned to a specific organization and an individual responsible for implementation by a target completion date. As corrective actions are implemented, this third stage of FMEA should be repeated until no corrective actions are necessary. This repetitive cycle is also known as “continuous improvement.”

The potential FMEA process raises four major legal issues: (1) FMEA documentation may not be shielded from discovery by

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246 Id. at 37.  
247 Id. at 21.  
248 See id. at 13, 15, 21.  
249 Id. at 13.  
250 Id. at 15.  
251 Id. at 19.  
252 See, e.g., id. at 13, 17, 19.  
253 Id. at 21.  
254 See id.  
255 See QS-9000, supra note 23, at 53-4 (explaining the requirement of continuous improvement; see e.g., FMEA, supra note 171, at 5, 27.  
256 See QS-9000, supra note 23, at 53.
the "self-critical analysis" privilege; (2) FMEA documentation may not be shielded from discovery by the work product doctrine; (3) FMEA could help plaintiff establish that the product is defective; and (4) FMEA could help plaintiff establish a failure to warn.

First, FMEA documentation may not be shielded by the "self-critical analysis" privilege. The "self-critical analysis" privilege shields from discovery internal safety reviews in which companies evaluate causes of product failures and accidents. Although it is not clear whether the "self-critical analysis" privilege has been universally recognized, many courts have generally recognized the privilege when the following criteria have been satisfied:

1. the information must result from a critical and confidential self-analysis undertaken by the party seeking protection;
2. the public must have a strong interest in preserving the free flow of the type of information sought;
3. the information must be of the type whose flow would be curtailed, if discovery were allowed; [and]
4. the document involved] was prepared with the expectation that it would be kept confidential, and has in fact been kept confidential.

Accordingly, FMEAs could easily be covered by the "self-critical analysis" privilege, because the primary purpose of a FMEA is to evaluate the causes of product failures that could potentially result in accidents. However, the "self-critical analysis" privilege does not extend to "voluntary routine pre-accident safety reviews." The Ninth Circuit stated that the privilege could not be extended to cover pre-accident safety reviews because "[o]rganizations have many incentives to conduct such [safety] reviews that outweigh the [self-damning] harm that might result from disclosure." Since FMEAs are necessarily performed pre-accident during the pre-production design period, and because the FMEA failure mode analysis is analogous to a pre-accident safety review, FMEAs are not likely to be protected by the "self-critical analysis" privilege.

259 Dowling, 971 F.2d at 427.
260 Id. at 426.
Second, FMEA documentation may not be shielded by the work product doctrine. The work product doctrine protects materials prepared in anticipation for trial that reveal an attorney's strategy, intended lines of proof, evaluation of the case, and inferences from discovery materials. \(^{261}\) "The work product rule applies only to documents prepared primarily to assist anticipated or ongoing litigation: 'If a party prepares a document in the ordinary course of business, it will not be protected even if the party is aware that the document might also be useful in the event of litigation.'" \(^{262}\) Accordingly, since the primary purpose of FMEA is to improve quality, the work product doctrine may very well provide no protection against discovery of FMEA documentation.

Third, FMEA documentation could provide substantial help to plaintiffs in establishing that the product in question is defective. For example, to recover for a strict products liability claim in Texas based on a design defect for claims accruing prior to September 1, 1993, a "risk-utility" balancing test is applied in which a "defectively designed" product is defined as a product that is unreasonably dangerous as designed, taking into consideration the utility of the product and the risk involved in its use. \(^{263}\) FMEAs necessarily involve such a risk utility evaluation through the Risk Priority Number equation \(RPN = (S) \times (O) \times (D)\). \(^{264}\) Accordingly, FMEAs inherently provide all the basic ammunition to a plaintiff to establish a design defect. Similarly, FMEAs can also help plaintiffs establish manufacturing defects, provided a process FMEA is performed.

Fourth, FMEA documentation could help plaintiffs establish a marketing defect or failure to warn. A seller is liable if it fails to give adequate warnings of the product's dangers that were known or that should have been known. \(^{265}\) FMEAs can help plaintiffs show a product's dangers that were "known," because FMEAs are required to identify all potential failure modes.

Although the potential FMEA process fosters quality through continuous improvement, in the context of litigation the results

\(^{261}\) See Fed. R. Civ. P. 26(b)(3).


\(^{263}\) See Turner v. General Motors Corp., 584 S.W.2d 844, 847 n.1, 851 (Tex. 1979).

\(^{264}\) See supra note 247 and accompanying text.

\(^{265}\) See Caterpillar Inc. v. Shears, 911 S.W.2d 379, 381-382 (Tex. 1995).
of FMEAs may very well be discoverable and provide information invaluable to plaintiffs in establishing a products liability case. Therefore, a QS-9000 supplier is “damned if it does” comply with FMEA because it must develop discoverable, self-incriminating documentation, and “damned if it doesn’t” comply with FMEA, because it is required for QS-9000 certification.

H. ZERO DEFECT REQUIREMENT CREATES AN EXPRESS WARRANTY OF PERFECTION

The zero defect requirement of QS-9000 may also pose products liability problems for designers, manufacturers, and sellers. QS-9000 specifically states that “[a]cceptance criteria for attribute data sampling plans shall be zero defects.” This means that the only acceptable quality standard is a product free of any defects.

The zero defect concept originated at the Martin Company in 1961-62 when it was building Pershing missiles for the U.S. Army. During the height of the Cold War, Martin management made a commitment to the U.S. Army’s missile command to deliver the first field Pershing one month ahead of schedule in perfect condition, i.e., no hardware problems, no document errors, and all equipment set up and fully operational within ten days after delivery. To achieve this goal, Martin focused on building the missile right the first time. The zero defects program was very heavy on worker philosophy, motivation, and awareness, and much leaner when it came to specific proposals and problem-solving techniques. Previously, industry thought in terms of Acceptable Quality Levels (AQL), i.e., some non-zero level of defects was acceptable because a zero defect level is impracticable to achieve.

The zero defect requirement could result in liability based on the breach of an express warranty under U.C.C. § 2-313. “Breach of an express warranty arises when the defendant makes a representation of perfection.” U.C.C. § 2-313 defines an express warranty as “[a]ny affirmation of fact or promise made by

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266 QS-9000.4.10.1, supra note 23 (emphasis added).
267 See GARVIN, supra note 25, at 16.
268 See id. at 17.
269 See id.
270 See id.
271 See id. at 17-18.
Products made in accordance with QS-9000 are required to be "perfect," i.e., defect-free, as specifically required in QS-9000.4.10.1.274 Therefore, a seller's assertion that its product complies with QS-9000 could result in the breach of an express warranty, if the product is less than perfect and the imperfection causes injury.

I. Supplier Has No U.C.C. Opportunity to Cure

Under the U.C.C., a supplier has the right to cure during the contract time for performance.275 Specifically, if a buyer (in this case, an automobile manufacturer) notifies the supplier that he intends to reject the product, the supplier "may seasonably notify the buyer of his intention to cure and may then within the contract time make a conforming delivery."276 However, under the QS-9000, the choice whether to permit an opportunity to cure belongs to the buyer (i.e., the automobile manufacturer), not the supplier. QS-9000.4.13.2 states that "[n]onconforming [or suspect] product shall be reviewed in accordance with documented procedures. It may be a) reworked to meet the specified requirements, b) accepted with or without repair by concession, c) re-graded for alternative applications, or d) rejected or scrapped."277 "Conspicuously absent from this list of options is a provision granting the [supplier] the right to cure."278 Therefore, under QS-9000 as compared to the U.C.C., if a nonconforming product is delivered by the supplier, the automobile manufacturer may have the right to simply reject the goods "claiming that the [supplier] had an obligation to 'do it right the first time.'"279

J. Supplier Liability for Recall Created by QS-9000

According to Texas common law and the common law of many other jurisdictions, there is no post-sale duty to warn or recall a product.280 However, QS-9000 might contractually create a supplier's liability for recalls. Although QS-9000 does not

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274 See QS-9000.4.10.1, supra note 23.
276 Id.
277 QS-9000.4.13.2, supra note 23.
278 Bruno & Pynnonen, supra note 182, at 1082.
279 Id.
explicitly contain a recall provision, it does state that "[w]here incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements." Given the generally high standard of care imposed on the supplier by QS-9000, liability for recall expenses could easily be assessed on the supplier. Although liability for recall expenses might be disclaimed, a disclaimer might not be possible because of the QS-9000 express warranty of fitness.

VII. SUMMARY

The Quality Systems Requirements QS-9000 standard is a comprehensive quality system that has been tailored to the automotive industry. QS-9000 merges the quality programs of Chrysler, Ford, General Motors, and truck manufacturers into one document. This merging permits suppliers to meet the requirements of one standard, instead of separate requirements for each individual company. QS-9000 applies to all Tier 1 suppliers, i.e., suppliers that provide products and services directly to Chrysler, Ford, and General Motors. QS-9000 is now incorporated into all supplier contracts. For suppliers to Chrysler and General Motors, compliance to QS-9000 must be certified by a third-party registrar. A third-party registrar is an independent agency that audits the supplier and reviews its records to verify that the supplier satisfies the requirements of QS-9000. Ford does not currently require certification by third-party registrars.

The basis of QS-9000 is the ISO 9000 series of quality standards, which establish broad, general requirements for a quality management system. QS-9000 builds upon ISO 9000 by adding requirements specific to the automotive industry. QS-9000 is a management framework that defines a company's processes and provides for a structured approach to production so that a consistent level of quality is produced.

QS-9000 basically requires a supplier to: (1) define its process by documenting what it does; (2) follow its process by doing what is documented; (3) ensure the process is effective by continuously reviewing and adjusting; and (4) record the results of its work for review by the customer and auditors.

QS-9000 is composed of three sections: (1) ISO 9000-Based Requirements; (2) Sector-Specific Requirements which go beyond ISO

281 QS-9000.4.10.2.3, supra note 23 (emphasis added).
282 See supra Part VI.E.; see also Bruno & Pynnonen, supra note 182, at 1082.
9000 and address specific quality initiatives of the automotive industry, including Production Part Approval Process, Continuous Improvement, and Manufacturing Capabilities; and (3) Customer-Specific Requirements unique to Chrysler, Ford, and General Motors. Additional QS-9000 requirements are contained in five supplementary documents, including the Potential Failure Mode and Effects Analysis (FMEA) manual. Official interpretations of QS-9000 requirements are published by the International Automotive Sector Group (IASG).

QS-9000 raises ten issues of potential legal concern:
1. QS-9000 could potentially be used by public consumers to establish liability of a supplier or automobile manufacturer who did not comply with QS-9000 requirements.
2. Duties derived from QS-9000 might be limited only to the automobile manufacturer and Tier 1 suppliers, not Tier 2 and lower tier suppliers.
3. As a result of the formalized contract review requirements of QS-9000, suppliers cannot escape enforcement of any contract terms through lack of explicit assent.
4. Unless assumed by the automobile manufacturer, the supplier bears the large portion of the responsibility and liability for the design.
5. QS-9000 could transform implied warranties of fitness into express warranties which cannot be disclaimed.
6. QS-9000 documentation is limited to those processes performed by the supplier; the supplier need not maintain complete records for its lower-tier suppliers and subcontractors.
7. The Failure Mode and Effects (FMEA) program may produce discoverable documents, providing plaintiffs in products liability cases with an advantage.
8. The zero defect requirement could create an express warranty that the product is perfect.
9. In the event that the product does not meet contract requirements, the supplier has no right to cure the nonconformance—the buyer may simply reject the product.
10. The supplier might be liable for costs associated with recalls.

The legal issues noted above are speculative, because there has been no significant litigation involving QS-9000 and very little legal commentary on the subject. But QS-9000 is still a relatively new document, and suppliers are just beginning to become familiar with its requirements. The legal implications of QS-9000 will become better focused as use of QS-9000 and ISO 9000 become more ingrained in the aviation industry.