

IASG SANCTIONED QS-9000 INTERPRETATIONS  
December 1, 1997

To be used by Chrysler/Ford/General Motors Recognized Accreditation Bodies  
QS-9000 Qualified Registrars, Suppliers and Interested Parties with QS-9000,  
Second Edition.

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CONTACT: Peter B. Lake  
IASG FAX MAIL BOX: 412/940-1004  
Chairman, IAAR Auto Sector Committee  
Contact for the International Automotive Sector Group, IASG

I. INTRODUCTION

A. IASG MEMBERSHIP

The International Automotive Sector Group (IASG) is an international ad hoc working group consisting of representatives from:

1. Big Three Recognized Accreditation Bodies (Four)
2. QS-9000 Qualified Registrars (currently five from the Independent Association of Accredited Registrars, IAAR, and one from the IIOC.
3. Representatives of the Chrysler/Ford/General Motors Supplier Requirements Task Force (Three)
4. Tier 1 Automotive Suppliers (Two from North America)

The group meets periodically to discuss and resolve interpretation issues relative to the QS-9000 criteria and third party registration of auto

suppliers to QS-9000. The attached interpretations are recognized by the Chrysler, Ford, General Motors Supplier Quality Requirements Task Force, the participating ISO 9000 accreditation bodies and QS-9000 qualified registrars. The IASG intends to provide periodic releases of new and revised/updated QS-9000 interpretations for all interested parties.

The current participating members of the IASG are:

- \* Big Three Recognized Accreditation Bodies: Paul Fortlage, RAB; Peter Tempelman, RvA; Thomas Facklam, TGA; Steve Keeling, PAC.
- \* Chrysler/Ford/General Motors Supplier Quality Requirements Task Force: Warren Norrid, Chrysler; R. Dan Reid, General Motors; Steve Walsh, Ford.
- \* QS-9000 Qualified Registrars: From IAAR: Peter Lake (IASG Contact), Bob Levine, Malcolm Phipps, Michael Hochschwender, Royce Hoggard, From IIOC: Peter Herrmann.
- \* Automotive Suppliers: Brenda Dusek; Tom Turnbull.

This release was sanctioned, and its interpretations considered binding, by the Chrysler/ Ford/ General Motors Supplier Quality Requirements Task Force and the IASG, effective April 1, 1998, unless otherwise noted herein.

## B. HOW TO COMMUNICATE

To submit questions or issues to the IASG for consideration, Fax inquiries, in English, to the IASG Fax Voice Mail Box (412/940-1004). To obtain a copy of the latest IASG Sanctioned QS-9000 Interpretations, or an updated list of qualified QS-9000 accreditation bodies, qualified QS-9000 registrars, or QS-9000 registered suppliers, call the American Society for Quality at 1/800/248-1946 or 414/272-8575, or obtain a copy from the ASQ QS-9000 Web Site at <http://www.asq.org/9000>. In Europe, contact Carwin Continuous, Ltd. at Telephone No.: 01-708-861333 or Fax No.: 01-708-867941.

## II. QS-9000 INTERPRETATIONS

### A. GENERAL

#### Structure

A question and current IASG answer is labeled by a sequential reference number and a letter referring to the category in which it is found. Subsequent changes in an interpretation question and answer will show the same category/sequential number, but a new "Revision" date is so noted in the Table of Contents. Answers are valid as of the date they were agreed upon. All references are to QS-9000:1995, February, Second Edition, unless otherwise stated.

Responses to which the IASG have agreed, are grouped by the following categories:

A = Applicability

B = Appendix B: Code of Practice

C = Criteria: Subdivided by the 23 QS-9000 Elements within Sections I, II, III

D = Database  
O = Other  
L = Laboratory issues  
P = Process  
R = Registration/Accreditation  
T = Training

Any questions for the IASG should be directed to the IASG Fax Mail Box at: 412/940-1004.

Summary - Key Changes or Additions for December 1, 1997 Release:

All interpretations continue to be reviewed for relevance, and some are subjected to simplification, some deleted, some combined with others, and new ones added.

Note: because these interpretations are a binding extension of the QS-9000 Chrysler/Ford/General Motors Quality System Requirements, February 1995, Second Edition, they should be a part of every QS-9000 supplier's Contract Review documentation, and every QS-9000 registrar's audit information file.

Date Format

Dates are shown in month/day/year format.

## B. TABLE OF CONTENTS OF SANCTIONED QS-9000 INTERPRETATIONS

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- L. Laboratory Issues
- P. Process
- R. Registration/Accreditation
- T. Training

### 2. Information

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Agreed Upon Interpretations of December 1, 1997

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### Status Key:

A - Simplified does not mean that the interpretation has been “revised”, only simplified for the 10/18/96 and later releases. Only those revised in ACTIVE content will show a revision date.  
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### Type Key:

1. - Interpretation
2. - Information

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#### APPLICABILITY (A)

##### A02 Eligibility for Registration

Can anyone be certified by a QS-9000 qualified third party registrar to

QS-9000?

Only those suppliers meeting the “Applicability” definition are required to achieve compliance/registration. Any “site” may elect to pursue third party registration; however, to obtain QS-9000 registration, all elements of QS-9000 must be assessed and complied with. Only “Servicing” (and “Design Control” for ISO 9002) may be determined as not applicable by the registrar.

“Site” is defined as locations at which production processes occur. Definition of “site” includes warehouses and distributors of production or service parts/materials except those that only stage material and ship. The definition does not include indirect suppliers or vehicle assembly plants. Providers of bulk or raw materials should contact the procuring division buyer to determine if their material is considered to be production material. Contact your customer if in doubt.

Remote locations, e.g. Engineering, Purchasing, must be audited by registrar as they support a “site”, but they can not be a QS-9000 registered location.

The registrar must assure the Code of Practice, Appendix B, requirements are met.

A03 QS-9000 Certificates

Can a QS-9000 (ISO 9000) certificate be issued by anyone other than a “QS-9000 qualified” third party registrar?

No. The term QS-9000 is a protected copyright as property of the Big Three. Only those third party registrars accredited for QS-9000 by a Big Three recognized accreditation body are permitted to issue a registration certificate with the term QS-9000.

A08 Witness Audit Must Be a Tier 1 Supplier

Can the assessment of a Tier 1 supplier to a truck manufacturer listed in QS-9000 Section III be an acceptable witness audit for registrar qualification? If not, what is required for an acceptable witness audit candidate?

No. An acceptable witness audit for registrar qualification must include a supplier which meets all applicability requirements at the ISO 9001 level, and is a Tier 1 supplier of production or service parts to Chrysler, Ford, or GM.

Examples of suppliers which would not qualify for the witness audit are: Heat treaters, Platers, Painters, Strip or Slitting operations, Assembly-only operations. Those that qualify for witness audit are those that design and manufacture production parts (QS-9000/ISO 9001).

A11 Design Responsibility

We are a Tier 1 supplier to the automotive OEMs. How do we determine if we have “design responsibility”?

If the supplier has the authority to establish a new product specification, or change an existing product specification, for any product a supplier ships to an OEM customer, then they are design-responsible. Design responsible suppliers still must obtain customer approval prior to implementing any changes. Customer approval of a design-responsible supplier's product does NOT waive the supplier's design responsible status. Consult your procuring division buyer for further clarification if needed.

#### A13 Section III. Compliance

Our plants are being individually registered and certificated. If a specific plant supplies only to Ford and GM, is the plant also required to have Chrysler and other QS-9000 signatory requirements covered and registered?

A supplier can only be held accountable to the Section III requirements of its current customers. However, the supplier would be expected to have a documented policy and procedures stating that future order acceptance from additional OEMs would include their meeting of the additional Section III requirements, as appropriate. This must be monitored by the registrar in surveillances to determine if compliance with other customer requirements is appropriate, e.g. Element 4.3.

#### A18 Tier 2 (Subcontractors)

If I am a Tier 2 supplier (subcontractor), how do I treat my subcontractors?

Suppliers and subcontractors should deploy QS-9000 as appropriate. Any company may require QS-9000 registration of its suppliers, regardless of the company's position in the supply chain, e.g. Tier 3 and below.

#### A19 "Product" vs. "Material"

Can you define the difference between "product" and "material"?

In general, "product" is what you sell, "material" is, in part, what you use to produce the product you sell. Consult ISO 8402 for further guidance.

#### A31 Truck Aftermarket Supplier

We design and manufacturer a product for the aftermarket. Do the requirements of QS-9000 apply in this situation?

No; aftermarket material is not included in the QS-9000 applicability statement. QS-9000 does apply, however, to suppliers of service parts and/or materials manufactured to original OEM specifications for customers requiring QS-9000.

### APPENDIX B: CODE OF PRACTICE (B)

#### B01 Registrar Affiliate Consulting

A registrar's subsidiary provided on-site training and consulting on QS-9000 to Company Q. Will this prevent the registrar from doing QS-9000 registration later?

Registration is NOT allowed if the registrar or affiliate has provided quality system consulting to the same client in the last two years. On-site training is considered to be consulting.

#### B04 Audit Team Requirements

Must all members of the audit team on registrations and surveillances be QS-9000 trained?

Yes. All audit team members on all QS-9000 audits and surveillances must be QS-9000 qualified: Reference Appendix G, QS-9000:1995, Second Edition. At least one team member must have relevant “automotive industry experience.”

#### B10 Registrar Issuance of Certificates

Depending on the structure of the registrar, could a witnessed assessment of a registrar’s local operation allow the issuance of certificates by another affiliated office in a different country?

No. Any registrar office with a certification function (e.g. issuing of ISO 9000 certificates) must comply with Appendix G requirements. If a local operation wants to issue its own certificates, and thereby appear on the ASQ’s official list of accredited certification bodies, then this local operation must fulfill EN 45012 in total; i.e. independently from the mother organization, but could of course make use of services of the mother organization, and must meet all Appendix G Requirements.

If this local operation is not fully independent, it will not be included on the ASQ’s list. If the local operation is a part of the mother organization, then the focal operation’s certificate issuance responsibilities are with the mother-organization. (See R43)

#### B15 Consulting

Many times the IASG suggests that the supplier go to his registrar to obtain clarification information. Is this considered to be consulting and therefore in conflict with Appendix B, Number 6?

No. Registrars must meet the requirements of EN45012, their accreditation body(ies) and QS-9000. Registrars may not give specific advice, or have any ownership in what you do to meet the QS-9000. But, they may answer questions on clarifying or interpreting ISO 9000 and QS-9000.

#### B17 Audit Frequency - Design

Re: Appendix B, Number 7. A company has several sites, however, there is one corporate location that performs sales, design and purchasing for all of the other sites. Does this corporate site have to be assessed every six months?

No, the remote location, e.g. design center does not have to be visited every six months. Design centers and all “sites” should be audited at least once in each consecutive 12 month period for ISO 9001 with QS-9000 registrations. See P15 and R13 (Man-day Adjustment for “Corporate” Audit

Scheme)

#### B19 In-House Training

We are unsure of the position relating to provision of ISO 9000 training in association with registration in this field.

Is it permissible for us to be registered by an accredited registrar when we received in-house training on ISO 9000 (not QS-9000) or auditor training from the training division of that registrar?

NO.

#### CRITERIA (C)

##### Section 1. ISO 9000-Based Requirements

##### 4.1 Management Responsibility

###### C11 Business Plans are Controlled Documents

Is the business plan a controlled document or can it be treated as a quality record?

Business plans are not quality records by definition, however, they must be a controlled document.

##### 4.2 Quality System

###### C22 Quality Manual Responsibility

When documenting our Quality Policy Manual for QS-9000, is it required to include a responsible department/individual?

Yes. See ISO 10013 and QS-9000, clause 4.2.1, and QS-9000 Glossary under "Quality Manual." This manual should also include cross-references to general procedures and subordinate procedures and should include responsibilities and authorities for each element of the quality system.

###### C26 Glossary of Terms

There are some definitions in all of the QS-9000 manuals which seem at variance with definitions in ISO 8402. Will a glossary of terms with a single, standard definition be forthcoming?

Where there is inconsistent terminology between QS-9000 and ISO 8402 (or other similar documents, e.g., ISO A-3), QS-9000 takes precedence for QS-9000 registration.

###### C32 Prototype Control Plans

Customers have not requested prototype control plans. Are we expected to have them?



Suppliers are required to have a prototype control plan if they are supplying prototype materials, regardless of whether the customer requests it to be submitted for review.

#### C56 Quality Manual Definition

On page 98 in the glossary of the February, 1995 Edition of QS-9000 is a definition for quality manual. "Quality manuals shall include responsibilities and authorities for each element of the quality system." Must the manual be written this way?

See ISO 10013 for discussion of the quality manual requirements. The quality manual includes not only policy, but also includes or cross-references to general procedures and subordinate procedures. Hence, each cross-referenced procedure is part of the quality manual, and must include responsibilities and authorities for each element of the quality system. The Glossary is meant to aid interpretation in order to answer the question completely.

#### C107 QS-9000 Registration for Companies not Supplying "Big 3"

How do companies, not previously doing business with automotive, become registered to the QS-9000 requirement? For a third party audit, records must be available as objective evidence that a system is effective. With no previous automotive business, records would be unavailable for items such as PPAP.

Demonstrated capability, (e.g., Procedures, work instructions, FMEA, Control plans, etc.) must be in place to address all QS-9000 requirements. Evidence will be evaluated at a future surveillance audit. This assumes that they have no customer utilizing QS-9000 or PPAP.

#### C109 Ford's DCP Control Plan

We are a Ford supplier. Do we have to comply with Ford's DCP version of the control plan as listed in the APQP Manual?

Suppliers to Ford Powertrain Operations must comply with the DCP Control Plan. If in doubt, contact your customer's responsible quality activity.

#### 4.3 Contract Review

##### C106 Acknowledging Purchase Orders

Are suppliers required to return signed acknowledgment copies of purchase orders and amendments in order to comply with QS-9000?

NO.

##### C124 Unique Indicators

QS-9000 requires objective and valid evidence of customer satisfaction measuring.

"Trends in customer satisfaction and key indicators of customer

dissatisfaction shall be documented and supported by objective information.”

Can we develop our own unique indicators based on our delivery performance?

To satisfy the QS-9000 requirement for determining customer satisfaction, customers such as Chrysler, Ford, GM provide suppliers with performance reports either on-line, e.g. Chrysler’s “PASS” report and GM’s PRR system, or monthly, e.g. GM’s “quad” report for North American suppliers listing the relevant performance data.

Registrars should ask for copies of such reports to determine customer satisfaction during the registration audit and during surveillance.

#### 4.4 Design Control

##### C35 Waivers - CAD and ASN

How are requirements for computer-aided design (Element 4.4.4) and computerized system for ASN’s (Element 4.15.6) regarding waiver to be interpreted by registrars?

Sub-elements 4.4.4 and 4.15.6 can be “waived by the customer” per QS-9000. Objective evidence of a waiver must be available to show the auditor.

##### C102 Changes by Subscription

Element 4.4 requires design control, and Element 4.5 requires that we provide for timely ...implementation of all customer engineering standards/specifications and changes... In reality, we constantly receive updated engineering specifications from all of the Big 3 via subscription service. Is it understood that we are to implement and make PPAP changes mandated by these revised specifications, even though we have received no end-part drawing change or contract modification from the customer?

The quote is from 4.5.2 which refers to the Big 3 customer Engineering standards. These are distributed by subscription. The intent is to get these reviewed, distributed and implemented in several business days, rather than weeks. A change in these customer specifications will not automatically generate a revised PPAP process. PPAP would be affected only if these changed specifications were referenced on a design record or if they affect PPAP documents, e.g. Control Plan, FMEAs.

#### 4.5 Document and Data Control

##### C06 Obsolete Specifications

Regarding 4.5.2, how should the Tier 1 supplier handle a Big Three purchaser who continues to use outdated specs on old preexisting parts or specifications (but uses the new replacement specs on new parts)?

Whatever specs are being used by the customer should be used and retained by a supplier; i.e., keep all old specs in an active mode until they are no longer in use by the customer. Contract review by a registrar should take this into account if the Tier 1 supplier can show an active PO or

requirement to use the outdated specification... i.e., it is not really outdated yet!

#### C29 Special Characteristics Designation

Element 4.9 Designation of Special Characteristics (see Appendix C, also). Can suppliers deviate from this without a waiver?

The supplier can cross reference supplier designated characteristics, but not customer designated characteristics, unless the customer pre-approves it. At this time, equivalencies are not acceptable to any OEM except Chrysler. Work with the customer for interpretation and agreement on identification of characteristics identified in Appendix C.

#### C84 Document Identification

Regarding document control (Element 4.5) please clarify what is meant in the note on consolidation of documents locally? Do all shalls require a procedure?

“Consolidated locally” generally allows for locating all the customer drawings/specifications at one location in the manufacturing facility. The operator instructions/work instructions have to be available at each work site however. All “shalls” have to be covered in the quality system documentation, but they do not have to be addressed by individual procedures.

#### 4.6 Purchasing

##### C23 Approved Materials

Can you please clarify the reference to “(see Glossary)” in QS-9000, cl. 4.6.1, para. 3. What specifically is the Glossary defining?

Approved materials.

##### C41 Subcontractor Development

What is meant by “Subcontractor Development”?

Subcontractor development, as defined in QS-9000, refers to all activities designed to improve the fundamental quality system performance of the “subcontractor” (as defined in the QS-9000 glossary). The level of development is dependent upon the needs of the subcontractor relative to the requirements of QS-9000 and the importance of the product or process they supply. Deployment of QS-9000 through contracts, workshops, surveys, corrective/preventive actions and documentation requirements are all considered acceptable forms of subcontractor development.

##### C43 Subcontractor Development

If a subcontractor is so small as to not have adequate resources to develop a system according to QS-9000, I and II, should the supplier re-source?

No. Certain specified QS-9000 sub-elements may be waived by the supplier of his subcontractor. This provides some relief. The balance of QS-9000 contains fundamental quality system requirements which would be of value to any size of provider of production/ service parts/ materials. Note that there are many ways to implement a compliant system, so a simpler approach could be used for the smaller subcontractors.

#### C62 Restricted Substances

Do we have to perform on-site assessment of our subcontractors to assure their compliance with the “Restricted Substances” clause of 4.6.3 or is it sufficient to obtain written evidence of compliance from these subcontractors?

No, you do not have to perform on-site assessments, however, objective evidence of compliance to Clause 4.6.3, as with all QS-9000 requirements, is required.

#### C63 Restricted Substances

Which “manufacturing process” is referred to in 4.6.3, “Restricted Substances,” that of the subcontractor or supplier?

It refers to both -- the supplier's manufacturing process, but the reference to purchased products includes subcontracted materials. (Refer to C62)

#### C64 Distributors

We are a Tier 1 supplier, a distributor, but since we do not manufacture the products we supply, we apparently cannot perform any process control, (4.9). Since all QS-9000 requirements must be met for certification, it does not appear we can become certified to QS-9000 until the appropriate waivers are allowed for situations such as ours.

Incorrect. Process control relates to the product or service you provide the customer. If distribution, handling, storage, packaging, delivery, bar coding, acceptance, release, loading/unloading, etc. of someone else's products is your business, then process control relates to how you control your processes in those areas of your business, for example, “pick & pack” operations.

#### C114 Tracking Premium or Excess Freight

Under 4.6.2, does the requirement to track premium or excess freight apply in contracts where the subcontractor carries the freight costs (i.e., FIS) as well as where the supplier carries that cost (i.e., FOB), or only in the latter?

Yes, it must be tracked regardless of who pays for it. It is an opportunity for continuous improvement and reduction of waste in the supply chain.

#### C115 Use of Unapproved Suppliers

Is QS-9000 retroactive, i.e., does it apply to requirements already in

existence prior to certification? This particularly relates to 4.6.1 Approved Materials, where we have product in production which contain material purchased from subcontractors not on the customer lists -- once we are certified, will we have to change these pre-existing products to comply with the requirement to purchase from subcontractors on the customer's list? What do we have to do to comply given this?

Take appropriate actions to correct the noncompliance in order to proceed, e.g. use an approved subcontractor, get the unapproved subcontractor added or get a customer waiver. The supplier would also have to notify the customer that the product is "suspect" material per Element 4.13.1 until it can be dispositioned.

#### C122 Premium or Excess Freight

Under 4.6.2, does the requirement to track premium or excess freight apply in contracts where the subcontractor carries the freight costs (i.e. FIS) as well as where the supplier carries that cost (i.e. FOB), or only in the latter? Our argument in the FIS case would be that we don't care if he ships via Concorde, so long as we get it in time!

Yes, the supplier shall implement a system to monitor performance to the customer delivery requirements with corrective actions taken as appropriate. Records of premium freight should include both customer and supplier paid charges.

#### C123 Excessive Freight

When we were subjected to a pre-assessment of QS-9000 there was a difference in understanding between the qualified lead assessor of The Japanese registrar and us on the words of "excessive freight". According to his understanding, excessive freight means "Overloading on the truck or carrier". While our understanding is that excessive freight means "Too much transportation cost".

The latter is correct: Excessive freight is "premium" freight in this reference. (i.e., higher cost)

#### C127 Define "Production Materials"

Section 4.6 of the QS-9000 defines requirements of a supplier in regards to its subcontractors. The Glossary of QS-9000 defines subcontractors "as providers of production materials...".

Please define "production materials." Is this limited to materials incorporated into the product? If it covers other materials, what is the criteria for determining what those materials are?

"Production Materials" are materials which have been issued a production part number by the customer and are shipped directly to the customer.

#### C129 Approved Subcontractor List

QS-9000 Quality System Requirements, Element 4.6.1 requires that: "Where the

customer has an approved subcontractor list, the supplier shall purchase the relevant materials from subcontractors in that list.”

“If the Customer does not explicitly indicate in the purchase order the existence of an approved subcontractor list, can we assume that such a list does not exist?”

No. The customer normally communicates this via an engineering drawing or specification. To be added to any existing customer “approved subcontractor list,” a company should contact the appropriate customer engineering function to be considered. These lists exist only for certain commodities.

#### C133 Approved Suppliers List

Regarding the Approved Subcontractor’s list, I believe that some Registrars are mis-interpreting paragraph 4.6.1. Registrar’s are requesting “Approved Suppliers” lists too. Is there a requirement to maintain an Approved Suppliers list?

With regard to QS-9000 4.6.1, there is no requirement for the supplier to use an “approved supplier list,” however this is a common way to address the requirement, i.e. to communicate those suppliers who meet your quality requirements.

#### 4.7 Control of Customer Supplied Product

#### 4.8 Product Identification and Traceability

#### 4.9 Process Control

#### C08 Working Environment

Define environment (as used in 4.9(b), suitable working environment).

Environment will vary for each site, but generally includes: housekeeping, lighting, noise, HVAC, ESD controls, safety hazards relating to housekeeping. Environment is defined in the Glossary.

#### C09 Control Plan Customer Signature

Must all control plans be signed by the customer? The form information in the APQP book shows (if required); where is “if required” defined or found?

GM does not provide waivers to suppliers for control plan sign-off because GM signatures on the control plan are not required.

Chrysler representative signature is not required on the control plan.

Ford requires that all control plans must be approved by the responsible Ford quality activity prior to the production part submission date. Note: Signatory approval is only required on control plans for inverted delta ( ) products and those designated by Product Engineering (e.g. with an ES specifically requiring this approval). Design responsible suppliers must also prepare a design FMEA which is subject to the same review and approval

requirements. If in doubt, contact your customer responsible quality activity.

#### C16 PPAP - Waiver

Clause 4.9.6, PPAP, page 2, Waiver: Will the customer accept a letter from the supplier which states “unless noted otherwise it is understood you (the customer) accept this change and a waiver is granted.”

No. Waivers are only issued by the customer to the supplier as appropriate.

#### C34 Perishable Tools

A potential QS-9000 supplier has a question regarding perishable tools. They do not employ any statistical techniques relating to predictive maintenance of perishable tools. They do, however, perform last piece inspection as a means for monitoring tool wear. Is the intent of this practice acceptable to meet the requirements of QS-9000 4.9 (specifically, page 28 relating to preventative maintenance)?

This practice, as stated, is not acceptable and does not meet QS-9000 4.9.

#### C36 Appendix C. Special Characteristics

Are all of the characteristic classifications listed in the left-hand column of Appendix C meant to be classified as “Special Characteristics”?

The Appendix C chart defines various types of characteristics. The definitions are left open given the mutual responsibility for identifying and finalizing these characteristics. Work with your customer.

#### C39 Procedure/Job Instructions

Does 4.9.1 (QS-9000 requirement) requires “documented process monitoring and operator instructions for all employees.” This appears to negate 4.9 a) (ISO 9001 requirement) with regard to controlled conditions which require such documented instructions only “where the absence of such procedures could adversely affect quality?” Please clarify.

No. Clause 4.9. a) refers to Level Two Procedures (see the documentation graphic), while the intent of 4.9.1 is to refer to Level Three Job Instructions. 4.9.1 requires instructions to be in place for “all employees having responsibilities for operation of processes.” Clause 4.9.1 is more specific and requires broader coverage than 4.9 a).

#### C65 PPAP - Changes

“Who determines whether production part approval is required if there is a change in manufacturing “location” and/or production process environment (Element 4.9.6)?”

All anticipated changes require pre-notification from supplier to the customer to determine if PPAP submission is required. For guidance when PPAP is required, see PPAP Manual.

## C66 Documentation - Job Set-Ups

Concerning 4.9.5 Verification of Job Set-ups: Job set-ups shall be verified as producing parts that meet all requirements. Documentation shall be available for setup personnel. Does the term documentation refer to: a) documentation to record the verification of the set-up, or b) documentation describing how to perform the set-up?

Both are required. One is the documentation that is required, and the other is the record that proves the process was followed and records the results.

## C67 Continuous Improvement Plans

QS-9000, Element 4.9.3, last paragraph states: "Regardless of the capability requirement or the demonstrated process capability, continuous improvement is required, with the highest priority on special characteristics." Must all SPC characteristics, even those above a CpK of 1.33, have continuous improvement plans and results?

The intent of the 4.9.3 requirement above was that continuous improvement plans must consider all characteristics, with the highest priority placed upon special characteristics. A characteristic with a CpK above 1.33 still may not meet customer requirements, therefore the overall significance must be evaluated, documented and prioritized. The documented continuous improvement plans (at a "part" level or "characteristic" level) must be adequate for the auditor to feel confident that real progress is being made.

## C101 Proprietary Process

Our manufacturing Divisions use a proprietary process which is not documented in the process flow chart, FMEA, Control Plan, or in any written work instructions, for reasons of strict company confidentiality. This proprietary process does not affect the form, fit, or function of the product, and is only required to obtain practical levels of tool life.

Is it acceptable under the QS-9000 Quality System Requirements to exclude a proprietary process from the controlled process documentation? If not, what alternative methods will meet the standard, but still allow us to keep this portion of our process confidential from our customers (and even from our registrar), as required by our company policy?

Each process has to be described in the quality system documentation. The description can be a general one for confidential processes. It is not necessary to explain the details of confidential processes to assessors, but the supplier has to prove that the documentation is in place and working effectively.

## C108 Work Instruction Accessibility

QS-9000 requires job instructions to be accessible at the work station. Define "accessible."

It refers to "accessibility" at the work station. The job instructions have



to be available at the time they are needed without disruption to the job being performed by the operator.

#### C121 Environmental Regulations Certificates

At the paragraph entitled “Government Safety and Environmental Regulations” in element 4.9, it states”...shall have a process to ensure compliance with...safety and environmental regulations.” Then it says that “This should be evidenced by appropriate certificates...” We have interpreted this to mean that the intent of QS-9000 is for us to have a program in place whereby we make certain we comply with all applicable regulations. It is suggested that we have certificates to support our compliance but we don’t absolutely need to have those certificates because this is a “should” statement; other evidence is acceptable as long as we have met all requirements and can prove it. Is this an acceptable interpretation of this clause?

Yes, as long as you produce objective evidence that meets the QS-9000 intent.

#### C131 Set-up Instructions

Element 4.9.5 states “Documentation shall be available for set-up personnel.” The set-up instructions are often viewed as personal property of individual set-up employees; may not include a date or sign off. Have we satisfied the intent of QS-9000?

No. Documentation required to meet QS-9000 must be controlled per QS-9000 Element 4.5; this includes set-up documentation.

#### C139 Control Plans for Sampling

Does QS-9000 permit the call-out of MIL-STD-414, ANSI Z1.9, or other recognized standards or methods on control plans for sampling criteria/sampling plan?

Yes, but if used it must be valid for the application, e.g. provides effective control.

#### C141 Controls Listed on the Control Plan

Must all controls be listed on the control plan, or only special characteristics?

All controls.

#### 4.10 Inspection and Testing

##### C17 Final Inspection - Responsibility

When a subcontractor performs a final operation, such as painting, what is required of the supplier to meet the intent of 4.10.4? Is this requirement altered if the subcontractor is on an approved list?

The supplier shall assure all quality system requirements stated in the

quality plan (control plan) and/or documented procedures for final inspection and testing are met by the supplier and their subcontractor. The requirements of 4.10.4 are not altered if a subcontractor is on the suppliers approved list of subcontractors.

#### C125 General Motors Laboratory Certification Requirements

In QS-9000, page 71, under GP-10, it states "...for inspection and testing of their own product..." We send some gauging out for calibration but they are not inspecting or testing our product, they are calibrating our inspection, measuring and test equipment. Do these same laboratory certification requirements apply to these calibration labs?

Calibration of inspection, measuring or test equipment services must be conducted by a qualified laboratory, see "Accredited Laboratories" QS-9000 4.10.1 and Section III. If laboratories are not accredited to ISO/IEC Guide 25 with a scope which includes calibration of such equipment, then the lab must have evidence, e.g. GP-10 certificate or second party assessment, that they meet the intent of ISO/IEC Guide 25, e.g. traceability and professional competency.

#### C137 Five Methods of Ensuring the Quality of Incoming Product

A. Under the section "Incoming Product Quality" in Element 4.10 in the QS-9000 standard is listed five methods of ensuring the quality of incoming product. Does this require that one or more of these methods be used for every incoming part regardless of that part's in-process performance? For every lot of every incoming part? If we choose to use third party assessments of subcontractor locations as our method, we believe that QS-9000 certification of the subcontractor would fulfill this requirement.

Yes, the specified methodology must be used.

B. Is this correct? Does ISO 9000 certification qualify?

Yes.

C. What about other third party assessments?

Third party assessments or certification may be used, but whatever method is used (re. A., B. and C.) must be effective.

D. If the requirements under QS-9000 4.10.2 - Incoming Product Quality have been satisfied, does this also satisfy the requirement in 4.10.2.1 for the incoming product to be "inspected or otherwise verified" and the requirement in 4.10.2.2 for recorded evidence of conformance to be provided.

All 4.10.2.1 should be considered, and records for whatever technique is used must be maintained.

#### 4.11 Control of Inspection, Measuring, Test Equipment

##### C52 Employee-Owned Gages

Referencing Section 4.11, Control of Inspection, Measuring and Test Equipment, what is the significance of including employee owned gages within the control system, but not addressing employee owned measuring and test equipment?

The phrase “employee owned gages” includes employee owned measuring and test equipment.

#### C69 Calibration vs. Verification

Referencing 4.11.3 Inspection, Measuring and Test Equipment Records:

A. Please define the words calibration and verification as found in the first sentence of this element.

Calibration involves adjusting a measuring device to a known standard. Verification involves comparison of a (non-adjustable) device to a known standard.

B. Does calibration/verification include adjustments made to a gage, for example, on the shop floor due to environmental conditions?

No, this appears to be a gage adjustment pertaining to process control (4.9) rather than a calibration issue.

#### C88 Equipment Affecting Product Quality

Under Element 4.11.2 B, does “affect product quality” mean that measuring instruments used in the Tooling Department to maintain production tools must comply with the requirements?

Yes, for QS-9000 purposes.

#### C116 Calibration - Test Equipment

ISO 9000 Clause 4.11.2 (b) requires that the supplier shall identify all inspection measuring and test equipment that can affect product quality.

QS-9000 Clause 4.11.3 requires that specific records of the calibration/verification activity on all gauges, etc., including employee owned gauges be maintained.

Does the term all in 4.11.3 only include the equipment identified in 4.11.2? (Or is there a wider implication?)

Yes. 4.11.2(b) requires the supplier to identify and include all inspection equipment in a calibration system. 4.11.3 requires calibration records for all inspection, measuring and test equipment to contain specific items (e.g., gage conditions and actual readings) some of which are currently in an ISO 9001 guidance note (Note 18) referencing ISO 10012.

#### C120 Approval of the PPAP

411.4 states “This requirement applies to all measurement systems referenced

in the customer approved Control Plan.” Does the approval of the PPAP packet, with the Control Plan enclosed, constitute customer approval?

Yes, PPAP covers approval of the Big 3 for the control plan (even though this may not require a submission of the control plan).

#### C132 Calibration Sources

Element 4.11.3, second bullet states “gage conditions and actual readings as received for calibration/verification.” Must these actual readings be taken, as received, prior to initial cleaning of measuring surfaces? Current practice is to perform preliminary cleaning prior to all calibrations.

Upon contacting several calibration sources, we explained that our interpretation of “as received conditions” included errors in the instrument itself, such as damaged surfaces, errors in measurement in relation to known bias, etc. All contacted sources concurred with our interpretation. Dirt and debris, has not been included in this terminology for our facility, nor for the outside sources we contacted.

Yes. The “as received” readings should be taken from gages before cleaning. In practice, gages should be cleaned prior to calibration to ensure accurate readings. If gages being returned for calibration are dirty, or otherwise unsuitable, to ensure accurate measurements on the floor, then practices and procedures need to be revised.

#### C138 Statistical Analysis Certified and Traceable

We have recently had an individual participate in a Lead Assessor Training Program for QS-9000. The individual has returned and indicated that we are lacking in a particular area. His impression is that we are required to have all software which perform statistical analysis certified and traceable. We use a number of different packages here which provide the number crunching and analysis to our production department. He cites his references as 4.5.2 and 4.11. I am concerned that the impression may not be valid and I am looking for clarification.

Is it reasonable to assume that the nationally available software packages perform as expected or are we required to have them certified by the developer or perform rigorous testing to prove out their calculations?

When software is used to verify the acceptability of product, the software shall be checked to verify that appropriate formulas are used for calculations and verify the software accuracy, regarding 4.11.1. It is necessary to assure that all test equipment is using the same release level of software, for obvious reasons.

#### 4.12 Inspection and Test Status

##### C12 Product Status Identification

Clause 4.12 under Product Location states: “location of a product in the normal production flow does not constitute suitable indication of...status unless inherently obvious....”

Considering current production and inventory methods of KAN BAN, bar codes, cellular manufacture, etc., can this clause be strictly enforced to require additional tags, etc., on baskets, totes, product?

Latitude is permitted, beyond automated production transfer processes, if the test status is clearly identified, documented, and achieves the purpose (i.e., known status).

#### 4.13 Control of Nonconforming Product

##### C05 Verbal Documentation

Regarding 4.13.4 of QS-9000, does a verbal phone authorization from the customer, documented by the supplier, constitute “written” authorization?

No. Verbal temporary change authorizations must be followed by written authorization from the customer. All permanent changes must have prior written authorization.

##### C47 Product Changes - Lower Tiers

How far down the supply chain are process changes to be approved by the OEM?

OEM approval of process changes only needs to take place at the Tier 1 level; these are subject to the requirements and definitions found in the PPAP manual, which includes notifying the OEMs of subcontractor process changes.

Tier 1 suppliers must be made aware of changes by their subcontractors, and through the subcontractors, of changes throughout the subcontractor’s supply chain.

#### 4.14 Corrective and Preventive Action

#### 4.15 Handling, Storage, Packaging, Preservation and Delivery

##### C71 Production Scheduling vs. Forecasting

Sub-element 4.15.6 of QS-9000 requires that a suppliers production scheduling activity be order driven. Will production control systems based on customer provided forecasts or requirements to supply a certain number of parts per month, for example, satisfy this requirement? How about the supplier who uses a constant flow manufacturing process?

If the supplier’s production was scheduled based upon a commitment from the customer, this would constitute an “order” driven process. If it was based upon a customer or supplier forecast, this would not meet the intent of the requirement. A “pull” system of inventory management (parts/replenishment based upon consumption) which utilizes an optimal level of inventory on hand, e.g. days; not weeks or months, would satisfy the intent of an order-driven system.

#### 4.16 Control of Quality Records

## C25 Disposal - Quality Records

QS-9000 Element 4.16 specifies specific minimum retention requirement for certain records. Would it be considered a deficiency if records were maintained longer than the specified time?

Retention periods longer than those specified in QS-9000, Clause 4.16 can be specified by a supplier in their procedures, but records must eventually be disposed of in order to comply. Procedures should address retention and disposal.

## C38 Purchase Orders

Control of Quality Records, Element 4.16, under "Record Retention" refers to "..... purchase order and amendments shall be ....." Which purchase orders and amendments does it refer to?

Records retention reference to Purchase Orders and Amendments includes both those issued to and by the supplier.

## C72 Active Parts - Service

With regard to the 4.16 requirement that certain records "be maintained for the length of time that part (or a family of parts) is active....etc," what is the definition of "active for production?" How is service requirements defined?

"Active for production" is addressed in the QS-9000 Glossary definition of an active part. Service part requirements are provided by the customer service part operations divisions. Service requirements refers to the OEM Divisions that provide original equipment replacement parts/materials. This does not include aftermarket parts which are not manufactured to original OEM specifications.

## 4.17 Internal Quality Audits

### C27 Internal Audit

The QS-9000 portion of Element 4.17, Internal Quality Audits, uses the term "activity" as in "quality activities" and "activities to be audited." What activities are being referred to; areas or functions.

"Activity" can refer to departments, areas, processes, functions, etc. in a company.

### C136 Effective Internal Audit Schedule

Could you describe an effective internal audit schedule which would satisfy the intent of Element 4.17 of QS-9000?

Internal auditing should cover all shifts and be conducted according to an audit schedule updated annually. When internal/external nonconformances or customer complaints occur, the planned audit frequency should be increased.

## C142 QS-9000 Checklists

If a QS-9000 supplier is obliged to use the AEC-A100 (QSA) checklist for the supply of semiconductors, does this absolve them from the use of a QS-9000 checklist's extra requirements for conducting their internal audits?

There is no specified checklist that **MUST** be used for internal auditing purposes.

## 4.18 Training

### C33 Training Effectiveness

How can confirmation of training effectiveness be demonstrated as required by QS-9000 4.18?

Training effectiveness may be practically reviewed by various methods, such as pre- and post-testing and audits/appraisals of performance. See your registrar.

## 4.19 Servicing

### C28 After-Sales Servicing

The supplier's component is part of a subassembly which in turn is attached to the vehicle. It is not repairable by the dealer network, only replaceable. The supplier does provide engineering design support, warranty analysis and subassembly component interface investigation (review for non-conformances at the OEM). What supplier activities mentioned above, if any, are considered covered by QS-9000, Section 19, Servicing?

None. Any after-sales product servicing provided as part of the OEM contract or Purchase Order would fall under Element 4.19.

### C112 Service Concerns

Re. 4.19 Servicing: The QS-9000 added requirement refers to "service concerns." My question is: Does the word "service" refer to the service activities of the supplier or those of the Big 3?

The intent of the addition of "service concerns" to Element 4.19 is to ensure that the supplier's organization is aware of non-conformities that occur external to the supplier's own organization. This is also addressed in Element 4.14, in which suppliers are to analyze parts returned from customer's plants, engineering facilities and dealerships. This activity encompasses the reference to "final customers" in 4.1.6.

## 4.20 Statistical Techniques

### Section II. Chrysler, Ford and General Motors Requirements II.1 Production Part Approval Process

#### C02 PPAP Requests

Relative to PPAP, a QS-9000 applicant has continuously supplied products to the OEM's since 1987, having met all sample submission requirements, and having no interruptions or changes. They have not completed any PPAP's, nor have they been requested to do so. Is there anything else they must do to comply with QS-9000 requirements?

If there have been no changes in “part number, engineering change level, manufacturing location, material subcontractors or production process environment” since 1987, then no PPAP's would be expected unless specifically requested/notified by the OEM customer for that product. PPAP procedures must be in place and effective as appropriate for QS-9000 registration. (See C107)

#### C03 Documents at Supplier

Supplier has PPAP process documented adequately, and if he is requested to submit parts for approval, the documented process will meet the requirements. The supplier provides “off-the-shelf” items they design for customers. Their only OEM customer has issued PPAP approval documents showing part is approved without requiring the supplier to do the PPAP requirements. Should the registrar accept this and recommend for registration to QS-9000?

Supplier must meet all required steps according to PPAP or the previous customer requirement in effect, even if request is waived. PPAP files must be available for registrar or customer review and show compliance to part submission requirements in effect at time of submission.

#### C37 Submissions/Waivers

Relative to PPAP:

A. Can a lower level submission (Level 1) be used for any of the first three PPAP requirements of page two of the PPAP manual under Section II when submission is required?

The level of submission is defined by the customer upon notification by the supplier of a change.

B. Can a waiver be issued by the customer for any of the first three PPAP requirements of page two of the PPAP manual under Section II when submission is required?

Direct this question to your customer's part approval activity.

C. What would be a clear definition or example of a Level 1 submission?

This is defined in the Table on Page 5 of the PPAP Manual. Each of these items must be completed each time the process changes, but levels of evidence required for submission are determined by the customer.

#### C40 Subcontractor PPAP



QS-9000 notes that “primary suppliers are responsible for subcontracted material and services.” If I approve a PPAP from my supplier, (a subcontractor) do I then need to submit a PPAP to my customers (Ford, Chrysler, or GM) or am I entrusted to make final approval?

Suppliers control their subcontractor’s material and part approvals. Your PPAP file must include, or reference and have readily available, all appropriate subcontractor warrants and material certifications, which you would obtain from their submission to you. You are obliged to “notify” the OEM customer of any subcontractor changes made since the level of your last PPAP approval. The customer will determine if a new submission from a subcontractor is warranted.

#### C42 Process Changes

A Tier 1 supplier has used an “internal” engineering change level system and an external Big Three engineering change level system. This approach was accepted by a Big Three auditor according to our client.

Is the requirement for PPAP submission affected by whether it refers to the “internal” or the “external” change level system of the supplier?

Since the supplier covers the proprietary engineering changes with the “internal” change level system, he does not want to be subjected to PPAPs for these changes.

All changes must be covered by PPAP, as defined in the PPAP documentation; the establishment of two types or levels of change does not alter the supplier’s responsibility to meet PPAP. The supplier should discuss the concern about proprietary engineering changes with their customer’s responsible part approval activity.

#### C48 Grease/Oil Suppliers

We understand that producers of oil, grease, gasoline, anti-freeze, windshield cleaner and the like, were not required to obtain QS-9000 registration. These organizations have also never had to comply with PPAP etc.

A. Assuming a company supplies such product directly to the Big Three, do they need to register to QS-9000?

If these materials are considered to be “production” material by your OEM customer, then QS-9000 applies. Contact you customer’s purchasing activity to obtain final determination.

B. What are the requirements of a subcontractor to one of these Tier 1 suppliers?

QS-9000 registration of subcontractors is not required by QS-9000. As noted in 4.6, suppliers are expected to use QS-9000 to define the fundamental subcontractor quality system requirements. If in doubt about any additional requirements of your direct customer, ask them!

### C73 Emergency Runs

Do the PPAP requirements apply to temporary out source, plant assists, or emergency run situations? What if you only have the job a weekend, a week, a month, or a few months?

Yes, you must notify your customer. These situations may be handled under 4.13.4, Engineering Approved Product Authorization, or by a PPAP submission, based upon the customer direction.

### C75 Master Sample Waiver

A. Can the retention of master samples at a supplier's facility, of PPAP submission, be waived by written notice from the customer?

The customer can waive the requirement for keeping master samples. (Refer to C16)

B. Must a supplier, who is pursuing QS-9000 Certification, apply PPAP to non-Big 3 products?

Non Big 3 products do not have to be submitted for PPAP approval, unless required by another customer subscribing to QS-9000 (e.g., heavy truck manufacturers).

### C76 Design Centers

We are a research, development and design contractor working as a Tier 1 supplier. We are currently being assessed to QS-9000, and the registrar indicated that PPAP is mandatory. We do not (currently) manufacture any production parts. Seeking a waiver, we approached Ford, GM and Chrysler and obtained letters confirming that we do not manufacture production parts and that we are exempt from (performing) PPAP. Our Registrar asked that these waivers be sanctioned by IASG .... would you please?

This category of supplier, e.g. Design Centers, can not be QS-9000 registered. They do not meet the applicability requirements as defined in QS-9000, or the definition of "site" from R13. This assumes there are no automotive production processes located at this facility.

### C92 Superseded Parts

Please clarify the section on "superseded parts", on page 45 of February 1995 edition of QS-9000 Manual and possibly give an example of a document from superseded parts that would need to be retained in the new part file.

An example of a document that should be carried forward from the old file to the new part file would be a material certification from a raw material supplier for a new part that represents only a dimensional change from the old part number.

### C93 Waiver - Appearance

We do not have any appearance items designated on any of our drawings or

engineering specifications. Therefore, we do not have documentation of Appearance Approval Reports (Element 2). The Lead Auditor told us that we would have to obtain waivers from our customers stating that Appearance Approval Reports are not required.

Is it required to obtain these waivers if no appearance criteria are required on customer drawings or specifications?

No. The Appearance Approval Report (AAR) is only required to be completed if the part is designated by the customer as an “appearance item.” The supplier should discuss this with the customer if in doubt.

#### C94 Customer Notification

A subcontractor has changed the process that they are using to manufacture a part. They notified the supplier about the change and the supplier requested a Level III PPAP submission for the change. The supplier received the submission package, reviewed it and gave the subcontractor full approval for the change. Does the supplier have to notify the OEM customer about the change? Does the supplier have to receive approval from the OEM before having the authority to grant approval to the subcontractor?

Yes. Suppliers are to notify the procuring division’s part approval activity of the subcontractor process changes. Engineering Approved Product Authorization (QS-9000, cl. 4.13.4) says prior written customer authorization is required whenever the product or process is different from that currently approved. This applies equally to products or services purchased from subcontractors. The supplier shall concur with any requests by a subcontractor before submission to the customer. Based upon the type of subcontractor change, the customer may elect not to require a PPAP submission upon notification by the supplier. PPAP Element 1.2 requires suppliers to verify that changes are properly validated. This applies equally to subcontractor changes and the supplier’s changes. Contact your customer part approval activity if you have additional questions.

#### C97 PPAP Retroactivity

We have a product line of over 600 approved, active part numbers that do not all have the required PPAP or applicable GP-3 documentation. A) Must we backtrack through all incomplete PPAP’s and generate the required documentation and, if so, how do we document the required layout inspection at this late date? B) Must we initiate a new PPAP for all active parts that do not have the required documentation? C) For approved parts that pre-date PPAP but do not have the required documentation, do we need to initiate a new PPAP? If not, do we need to initiate a new GP-3?

If these were approved after PPAP was issued, it is not clear how these parts were approved without the PPAP documentation being complete. You should have the documentation that was required at the time of the part approval on file. For purposes of third party QS-9000 registration, you must initiate corrective action to ensure that you are in compliance with PPAP going forward. Contact your customer part approval activity for further direction on how to handle this.

## C98 Die Combination Changes

It is common practice in the closed-die steel forging industry to change dies (or die components) often due to die wear. Often, several dies are manufactured and maintained for a single job. The die components are not always kept as a set which creates a high number of combinations. To consider every change in a die or die component a process change requiring a PPAP places an infeasible burden on the forging industry. If die components are manufactured by a proven consistent process, does the requirement for PPAP with each die component change apply to the closed-die steel forging industry?

By definition, each different die combination is subject to PPAP requirements, since each affords an opportunity for variation in the process. Contact your procuring division's part approval activity to determine how this must be handled to provide customer assurances that the process is proven consistent.

## C99 PPAP Package - Location

A company ("Tier 1" to Ford, GM and Chrysler) keeps the originals of the control plan, process FMEA, process flow diagrams and some other documents in a binder on the production floor, near the actual assembly stations. They do not keep a copy of these documents together with the warrant and other supporting documentation in the PPAP file. Are they required to copy these documents for the sole purpose of fulfilling the PPAP record keeping requirements? Or is it acceptable to keep these documents in a separate file in a separate location, as long as they are accessible upon request?

Copies of all the PPAP required documents must be included or referenced in, and be readily available, the PPAP file as well as wherever else the supplier specifies.

## C103 Waivers

It is understood that if a certain submission level is waived then the supplier shall perform all of the 14 PPAP requirements.

None of these interpretations clearly address the following question: Can any of the actual PPAP fourteen (14) requirements be waived by the customer (i.e., not performed/documented by the supplier)?

PPAP levels of submission only refers to the type of evidence a customer requests in order to assure that the PPAP process has been complied with. Suppliers must notify the customer, and update the PPAP file whenever the process changes (see PPAP manual) The revised PPAP now has 15 items that may be required for completion. All 15 are not necessarily required for every part number from every supplier. For example, some parts do not have appearance requirements, and others do not have color requirements. In order to determine with certainty which items must be included consult the design record, e.g. part print, the relevant Engineering documents or specifications, and your customer part approval activity.

## C113 Steel Processors as Subcontractors

We purchase metal in coils from local subcontractors who slit and distribute the metal they have purchased from a large metal producer. Because our metal is traceable to the mill which produced it, can we submit PPAP with the mill, rather than the distributor as the subcontracted source; therefore allowing us to purchase from any distributor as long as the product comes from the mill approved on the PPAP for production purposes?

NOTE: The certification is from the distributor, but the producing mill also appears on the certification which is submitted with the PPAP.

The PPAP should list the steel processor as the subcontractor to the producing mill (see PPAP page 2, point 9), and also identify the mill with whom the contract exists, for traceability reasons. In the event you anticipate purchasing from a variety of steel processors, these can be identified as part of the PPAP submission to avoid future submittals.

#### C117 Written PPAP Approval Prior to Shipment

PPAP is submitted and a verbal approval or request is received regarding commencement of production material shipment. Is acceptance of the first production shipment in this event construed as being an acceptance of the PPAP? Some of our automotive customers are not “timely” regarding giving written approval of the PPAP submission.

No, written PPAP approval must be received prior to shipment of production parts. Reference Page 15 of PPAP. Acceptance of the first production shipment will not be considered as acceptance of PPAP.

#### C118 PPAP Reference Manual

##### Preliminary Process Capability Studies

For a recent PPAP submission (which has since been fully approved) the PP/Ppk studies were created using 20 sub-groups of 5 and therefore totaling 100 pieces. The reasoning for 20 sub-groups was my reference to the QS-9000 manual (page 98) quote “when X-bar and R charts, at least twenty sub-groups” etc.

The PPAP reference manual (Page 7) quotes, in contrast: “For these characteristics that can be studied using X-bar and R charts, a short term study should be based on 25 or more sub-groups of data containing at least a total of 100 individual readings”.

A minor non-conformance was raised due to non-adherence to the PPAP manual.

Must be 25 subgroups, not 20, QS-9000 third edition reconciles the discrepancy.

#### C119 Master Samples

##### Record and Master Sample Retention

On page 14 of the PPAP manual, the last paragraph refers to master samples

which must be retained for the same period as the PPAP records. Unfortunately, our customer requested these samples due to mis-use of their set; we obliged, and then got a minor non-conformance. Now what?

They must be retained or a waiver obtained from the customer. In this case, the customer should have provided you with documentation to account for the samples.

#### C126 PPAP Raw or Indirect Material

Re: Request for Interpretation, Production Part Approval Process (PPAP), General Motors Specific Instructions.

Reference: Production Part Approval Process (PPAP) February 1995; IASG Sanctioned QS-9000 Interpretations (March 22, 1996 meeting):

In the Production Part Approval Process (PPAP) manual, Appendix D, General Motors Specific Instructions, section II, Scope (PPAP, Sec. 1 A) states: This procedure is applicable to production... and.. raw materials. It also applies to all commodities supplied by external independent suppliers,...plus all commodities supplied to these suppliers (e.g., subcontractors, second and third tier suppliers).”

Our company supplies raw, or “bulk,” processed steel coil materials directly to General Motors. Our raw materials are purchased from our mill vendors.

Does the passage above indicate that we must not only submit a PPAP for the product we provide to GM (where required), but also request a PPAP from our mill vendor?

How about the following passage:

“Please note that for bulk, raw, or indirect material, it is the Procuring Division’s decision whether PPAP is required.”

It appears that we, Company X, as the “procuring division” of the raw materials used to make the product sold to GM, may decide whether or not a PPAP is required from our mill vendor. NOTE: Currently, General Motors has waived all PPAP requirements for materials produced by Company X.

If your GM customer requires you to comply with PPAP, then you must require PPAP of your suppliers or the GM subcontractor. If GM waives PPAP for you since you are a raw material supplier, then you can waive it of your supplier.

#### C128 Revision Levels

Re: Production part approvals, Does this include all revision levels? Example: If current revision level in part # 1234 is Engineer Change Level “G,” must we retain the PPAP warrants, control plans, forms, etc. on the superseded Engineer Change Levels “A thru F?”

Previous change levels of a part still active (see QS-9000 Glossary “Active Part”) for production or service would only have to be retained long enough

to satisfy the retention requirements from the time that the change level became obsolete.

#### C130 PPAP Manual

Regarding QS-9000 Section II.1, Production Part Approval Process, Item C103 - Waivers.

We are currently pursuing QS-9000 and have obtained all of the latest revisions of the reference manuals (APQP, SPC, MSA, PPAP, etc.). The latest revision of the PPAP Manual 7/95 lists only 14 requirements.

What is the 15th requirement?

There are 14 requirements with two steps in the tenth requirement (10a - Process FMEA and 10b - Design FMEA).

#### C135 Standard Catalog Product

Our company on occasion receives orders from any one of the Big Three for a standard catalog product. This product may have been in production for many years and has been successfully supplied to customers not in the automotive market. Will a complete PPAP file be required and all requirements of the default Level 3 be required? If a full PPAP file is not required, how is a waiver obtained to document the fact of a waiver?

Suppliers of catalogue items must comply with PPAP unless specifically waived by the customer. See C103. Tooling must be maintained for catalogue items as long as the items are offered or stated as being available.

#### C140 Waive Formal Submission of the PPAP

Can a customer subscribing to QS-9000 waive not just the formal submission of the PPAP warrant but also the production of ALL the information required for PPAP as defined in the PPAP manual?

A customer can waive PPAP entirely for suppliers of raw or bulk material. Other suppliers, as defined in the QS-9000 glossary, must comply with PPAP, and a customer can waive only items that do not apply, e.g. appearance approval for parts with no appearance requirements.

#### II.2 Continuous Improvement

##### C10 Cost/Price Elements

QS-9000 Section II, 2.1, first paragraph includes price as a continuous improvement factor. Registrars need guidelines of whether they can or should audit this and, if so, what criteria? This seems to equate price reduction with continuous improvement.

Auditing of specific part price information is not expected for third party quality system assessments. However, the use by a supplier of cost elements or price as one of the key indicators within a continuous improvement system is required and subject to registrar audit.

## C105 CI Scope

QS 9000, Section 2.1, Continuous Improvement contains the following: A comprehensive continuous improvement philosophy shall be full deployed throughout the suppliers organization.....Supplier should extend continuous improvement philosophy to all business processes and support services. Should we extend our Continuous Improvement efforts to functions outside QS-9000, such as accounting?

YES.

## II.3 Manufacturing Capabilities

### C77 Tool Definition

A. What is classified as a tool? Is a replacement component to a manufacturing machine that does not directly come into contact with the customer's product classified as a tool?

A tool is generally that part of a machine that comes in contact with the part and produces a change to the part (e.g., drill bit, reamer, broach).

B. Specifically, is a quill holder for a precision grinder, subject to this requirement?

A quill holder is not considered a tool. It is, however, considered part of the machine or equipment and is subject to the requirements of II.3.1.

### C78 Ownership and Identification

Section II.3.3 Tool Design and Fabrication states "Customer-owned tools and equipment shall be permanently marked so that the ownership of each item is visually apparent. The supplier's procedure states that all production tools are customer supplied and that upon receipt of said tool, the manufacturing engineer identifies the tool/equipment, assigns an identification number and model type on a metal tag, affixes it to the tool and enters the number into a computer log designating the individual customer ownership. Does this meet the requirements or must the supplier affix another tag that says Property of GM?

Yes, this apparently meets the requirements as long as the customer part number and/or customer name is cross-referenced providing clear traceability back to the customer. An affixed tag specifically containing the part number and/or customer name to identify ownership is preferred.

### C80 CI Methodologies

Referencing 2.3 Section II; why have registrars insisted that before our company can be registered, we must have in place all the points listed? In my opinion, our company should choose what points are appropriate, implement those and only be audited on those aspects. As far as our having to demonstrate knowledge of certain methodologies, could not our company decision maker determine what would be appropriate for our company?



Application of all the measures and methodologies listed in II.2.3 are not required. Knowledge of all is required. Use of all appropriate measures and methodologies is required. (Meeting the customer's requirements is typically an important part of getting his business; if his business is not important to you, the question of compliance to QS-9000 falls to your decision-maker.)

#### C81 Evaluating Effectiveness

What criteria are used to evaluate the effectiveness of methods employed to address manufacturing capabilities in Section II, 3.1?

The auditor will look for documented evidence that the company has evaluated and/or developed methods for the measuring and monitoring of the effectiveness of existing operations, the elements listed must be included.

#### Section III. Customer-Specific Requirements

##### C61 Subcontractor PPAP

Must a company obtaining QS-9000 certification, require Section II.1, PPAP, of their subcontractors?

For applicable subcontractors, all elements of QS-9000 should be applied, including PPAP. If you should require your subcontractors to be QS-9000 registered, or should the subcontractor seek registration due to other reasons, then they must have a PPAP system established and demonstrated as capable to perform PPAP if not already doing so.

All GM "suppliers" as defined in QS-9000, who are required to be certified to QS-9000, must require PPAP of their commodity subcontractors, as indicated in "General Motors Operating Policy for PPAP" on page 32, Appendix D, of the PPAP manual.

For bulk, raw, or indirect material, it is the customer's decision whether PPAP is required.

If not specifically required by the OEM customer, PPAP is a preferred subcontractor methodology, that can be replaced by an equivalent but more appropriate approach.

##### C82 Section III. Auditing

Will the registrar look at all of the customer specific requirements (Section III) over the three years involving the registration audit and surveillance audits?

Yes, the registrar will review compliance to essentially all applicable Section III requirements over the three years, including a significant sampling at the registration audit. A supplier can receive a "major hold" in the QS-9000 audit if there are significant non-conformances in Section III.

##### C90 Customer-Owned Tools

We would like to request a clarification to Section II.3.3 Tool Design and Fabrication. We have a wide variety of tooling, some of which is used by our suppliers to produce components for our products. Some tooling is owned by our customer (which can be Tier 1 or Tier 2), some is owned by us, and some has been funded from tooling programs the cost of which has been shared.

Canadian law is such that anyone other than the owner shown on the tool, regardless of bailees in their possession, will have great difficulty in retrieving the property in cases of bank repossession or insolvency, placing a real risk of customer shutdown due to lack of availability for resourcing.

Our current position is to show Company X as the owner on any tools outside of our building, with our internal records clearly showing the true and correct ownership. To comply with the standard will in our opinion put our customer at risk, and would not properly apply in the case of shared costs.

Is the current condition acceptable, or is another interpretation possible, such as permanently marking "Property of Company X held for the beneficial interest of CUSTOMER"?

No, each piece of tooling and equipment paid for by the customer or provided for the exclusive use of that customer (reference the customer Purchase Order) must be clearly identified as property of that customer, e.g. the customer-specific part number if applicable or company name.

C134 Waiver Letter

Section III says, "The requirements of the 17 systems shall be met by GM-NAO suppliers". We meet whatever systems GM requires us to meet depending on what program we are working on. We may not meet all of the 17 requirements at any one particular time. We believe that QS-9000 should be rewritten to state "as required" or "as specified." Our registrar has called this item to our attention and is requiring us to obtain a waiver letter based on the above "shall be met" statement. Your cooperation in this matter would be greatly appreciated.

It is generally not necessary to obtain a waiver from GM for GM Section III items. Applicability of each of the GM Section III items is specified within each document. If in doubt, contact your GM customer. Registrars have the right to have suppliers contact GM to obtain a waiver when it is deemed necessary.

DATABASE (D)

D05 ASQ Notification

How are supplier QS-9000 registrations documented, communicated, maintained and what information should a registrar provide?

The QS-9000 certificated supplier information shall now be provided to the ASQ, the sanctioned database provider, by each QS-9000 qualified registrar. The record should include:

1. Certified Company Name

2. Certified Company Address (mailing)
3. Certified Company Site Address
4. Certified Company Telephone Number
5. Certified Company Facsimile Number
6. Certified Company ISO Contact
7. ISO Standard Registered to
8. QS-9000 Edition Registered to
9. Issue Date of Initial QS-9000 Certificate
10. Registrar for Initial QS-9000 Certificate
11. Issue Date of Current QS-9000 Certificate
12. Certificate Number of Current QS-9000 Certificate
13. QS-9000 Scope
14. Commodity Code (US SIC or NACE)
15. Issuing Registrar Name
16. Issuing Registrar Office Address
17. Issuing Registrar Office Telephone
18. Accreditation Bodies Shown on Certificate
19. Supplier Code for each customer, e.g. Duns Number

This information shall be communicated in the ASQ-specified format. Each QS-9000 qualified registrar must maintain and can make public their list of QS-9000 registered companies. (See R04.)

#### OTHER (O)

##### 001 Tooling and Equipment Supplement

We heard of a "TE-9000" for automotive suppliers of tooling and equipment...what is it?

A Supplement to QS-9000 was released in August 1996 for auto suppliers of tooling and equipment. QS-9000:TE-Supplement is the name. It is a "voluntary" document released for guidance only. Third party registration to the TE Supplement is not permitted by the Big Three. Recognized accreditation bodies and QS-9000 registrars shall not register organizations (or issue certificates) with any indication or reference to the TE Supplement, or its previous reference "TE-9000." Instead, auto suppliers of tooling and/or equipment should consider ISO 9000 registration.

If you have questions regarding Tooling and Equipment Supplement in North America, contact the supplier "hotline" at 1-800-444-2810. Outside of North America, direct these questions to AIAG at 248-358-3003. Sanctioned TE training can be arranged through AIAG at 248-799-4228 or fax: 248-799-4220. Training in the Reliability and Maintainability Guidelines, which is included in the TE scheme is available from Chrysler at 313-252-6096, Ford at 313-248-2100, or GM at 810-947-0288.

##### 004 IASG Registrar Requests

I am a Registrar. An accreditation body mentioned concerns regarding the direct contact of a registrar with the Big 3 to clarify interpretative issues; the accreditation body considers it the role of the Registrar's own Automotive Advisory Board/Governing Board Member to be involved in these matters? What is the best and most timely method to use?

In case an interpretation issue arises with a registrar, the following route should be taken:

1. consult the accreditation body,
2. submit a question to IASG,
3. in a case where an immediate response is needed the Big Three Task force can be consulted. Any resulting question and answer should also be submitted in writing to IASG fax mailbox.

#### 007 Removal of the Automotive Logos

I notice that the appearance of the Quality System Requirements - QS-9000 manual has been changed by the removal of the automotive logos yet the "Second Edition" status did not change, it was only referred to as a Fourth Printing. Does this imply that in our own documentation system we can make non-text related changes that don't affect the system without having to change the revision level? This would include changes like numbering, spelling, structure, format and so on.

Change control for QS-9000 (and the other Task Force manuals) is necessary only when the Edition is revised, not the Printing.

#### 008 Selected Non-Production Materials (e.g. Coolants) in the TE Supplement Purpose

Please clarify what is meant by "selected non-production materials (e.g. coolants)" in the TE Supplement Purpose.

The TE Supplement defines the application of QS-9000 and communicates additional common system requirements unique to the manufacturers of Tooling and Equipment, i.e. machinery. The phrase "selected non-production materials (e.g. coolants)" will be deleted in the next edition of the TE Supplement. There is no defined target date for this release at this time.

#### LABORATORY ISSUES (L)

##### L01 GM GP-10 Requirements

A. Are the requirements of GM's GP-10 still in place even though formal GP-10 Accreditation is no longer required if QS-9000 certified?

GP-10 requirements still apply, but QS-9000 registration will satisfy this requirement for a supplier's in-house laboratory facilities utilized for inspections and testing of their own product for purposes of conformance to the specified requirements. Laboratories utilized for commercial lab services are excluded from this provision.

B. For example, is there still a need to complete a Test Facility Questionnaire or for a Test Facility Manual?

All Section III Customer Specific Requirements are subject to audit at any time. All Section III Customer Specific Requirements must be evaluated sometime during the contracted registration period.

## L02 ISO Guide 25 Conformance

Testing is an integral part of the manufacturing process and of Guide 25 requirements, yet it is being given little attention in the QS-9000. For commercial/independent laboratories, does QS-9000 or ISO/IEC Guide 25 apply in judgement of technical competency?

ISO/IEC Guide 25 is an internationally recognized standard, used to judge the technical competency of calibration and testing laboratories and applies to commercial/independent laboratories. Suppliers may use commercial/independent laboratories accredited by a nationally recognized accreditation body for test laboratory accreditation, e.g. A2LA, SCC to ISO/IEC Guide 25 for verification activities. However, commercial/Independent laboratories cannot be registered to QS-9000. QS-9000 registration is sufficient for supplier's in-house laboratories utilized by the supplier for inspection and testing of their own product for the purposes of meeting specified requirements. If a supplier is in doubt about the acceptability of an outside lab, confirm with your customer.

## L03 Subcontractor Laboratories

Must subcontractor laboratories meet Element 4.6.2 Subcontractor Development of QS-9000?

No. It is not applicable to outside test laboratories because they do not meet the definition of "QS-9000 subcontractors," hence these labs are not required nor permitted to be registered to QS-9000.

## L04 Auditor Qualifications

What qualifications should a QS-9000 auditor have in order to adequately judge a laboratory's compliance to QS-9000 requirements?

A QS-9000 auditor must meet all QS-9000 qualified auditor requirements. It is of benefit if the QS-9000 auditor is also familiar with the contents of ISO/IEC Guide 25, and even better (but not required), if the auditor has some experience in auditing to Guide 25. Auditing the quality system compliance of labs and testing facilities is but a small part of QS-9000.

An auditor with only Guide 25 experience has only part of the experience and capability required to audit to QS-9000.

## L05 ISO Guide 25

A. If Lab X is part of a division planning to be registered to QS-9000, does Lab X need to do anything if they are already accredited to Guide 25 (EN 45001) or registered to ISO-9000?

Being accredited or registered to Guide 25, or ISO 9000, alone does not satisfy all QS-9000 requirements for a lab, therefore, the lab should be included in the preparation activities.

B. Does A2LA certification satisfy all the requirements of QS-9000 for a

lab.

NO.

## PROCESS (P)

### P02 Opportunities for Improvement

Must auditors always report “Opportunities for Improvement” for a QS-9000 assessment?

Yes. These opportunities shall be included in the report to the supplier (see QS-9000 Appendix B, Number 8). If none are found, a statement to that effect must be reported.

### P03 Customer Performance Requirements

How should a QS-9000 auditor address customer performance requirements?

Effectiveness of a company's system must be measured by indicators which directly correlate and meet customer performance requirements, such as customer satisfaction (4.1.6), on-time delivery (4.15.6) or continuous improvement (2.1), and tracked by the use of these indicators. The presence of continued poor trends in these indicators, audit to audit, will jeopardize continued QS-9000 registration.

### P04 Section III. Auditing

We are going through a QS-9000 audit. When will Section III requirements be audited during the registration process?

Each applicable item in Section III must be audited during the initial audit and in the surveillance visits over the subsequent three-year period (See QS-9000 Appendix B, Number 7). Conformance to Section III requirements will be evaluated under Element 4.3 (Contract Review). The registrar must ascertain which of the Section III requirements are applicable to you based on your automotive customers; this should occur at the pre-audit visit, or before the registration audit.

### P09 Minimum Man-days - Surveillance

Does the matrix in Appendix H also apply to continuous surveillances performed in lieu of three year re-approvals?

Appendix H defines the minimum on-site audit-person days required for all initial and surveillance visits regardless of the registration cycle or surveillance approach. The need for a renewal or reassessment audit at the end of three years is governed by the ISO 9000 accreditation body requirements of their ISO 9000 registrars, not by the OEMs.

### P10 “Should” Requirements

Do the numerous questions relating to “should” items in QS-9000 indicate requirements?

Yes. A “should” statement is a requirement, but with some flexibility allowed in compliance methodology. An alternative method of satisfying the intent of the “should” requirement can be acceptable.

#### P12 Pre-Assessment Audit

Is a pre-assessment audit considered consulting?

No. See Item 2 under Notes in R13 for a summary definition of a pre-assessment. A pre-assessment by a registrar cannot include consulting. Note: Repeated pre-assessments by a registrar can be perceived as consulting.

#### P13 Business Plan

How far are auditors allowed to delve into the business plan?

They must verify that the supplier is conducting strategic business planning, with appropriate initiatives as defined in the QS-9000 Business Plan requirement. Often a review of evidence such as dated Tables of Contents, and a review of a few non-sensitive sections is sufficient confirmation that policies and procedures are being followed.

#### P15 Remote Locations, e.g. Design Centers

How should a design center for a manufacturing organization be audited according to QS-9000 if it is serving one or more manufacturing sites?

The design center would be included in the initial audit and then be included in the normal surveillance plan and at a regular frequency by the registrar. The design center cannot be registered by itself because it is not a “site.” (See A02) However, design functions must be visited at least once within each consecutive 12 month period. Design functions audited can be tracked by the registrar on his audit matrix.

#### P17 QSA for Second Party Audit

On page 4 of the Quality System Assessment (QSA) document, under the subheading, “Reporting of Assessment Findings” it states: “Notes regarding non-conformities should contain specific recommendations for corrective actions.” This is an apparent contradiction to the separation expected between assessors and consultants. Is this a typo?

No, this statement is for the QSA’s first and second party applications only. The third party registrars are only required to use the QSA questions in their QS-9000 checklists and use the definitions of major and minor non-conformities from QSA.

### REGISTRATION/ACCREDITATION (R)

#### R01 Multi-Site Registration — Remote Location, e.g. Design Center

If a multi-site corporation has a design engineering center (DEC) and three

manufacturing sites (M1, M2, M3), and is “design responsible” to Chrysler/Ford/General Motors, at what point can the QS-9000-qualified registrar issue an ISO certificate with QS-9000 notation? (They are seeking individual site certificates.)

Given that the organization is design responsible, and each site is seeking a separate certification, only an ISO 9001/QS-9000 is acceptable. Providing the design center has been assessed and certified as being 4.4 compliant, QS-9000/ISO 9001 certificates may be issued as each site becomes registered.

#### R02 Multi-Site Registration Certificates

If there are several sites, must each be audited and receive an individual certificate? Is “sampling” of sites permitted by the registrar?

Each site (definition see R13) must be audited; individual certificates for each are permissible but not necessary. No, “sampling” of sites are not permitted.

#### R03 Nonconformity Definitions

Although third party registrars must use the QSA definitions of “major” and “minor,” can each registrar continue to use its own interim step definitions as long as the registrar has “adopted acceptable QS-9000 criteria; i.e. that no major or minor non-conformities, as defined in QSA, may exist prior to granting QS-9000 certification”?

Each registrar can continue to use its accredited system of interim steps leading to certification, as long as the registrar has adopted the policy and practice that all major or minor audit non-conformities, as defined in QSA, are closed prior to granting QS-9000 certification.

#### R04 QS-9000 Certificate Requirements

What must the ISO 9000 certificate with QS-9000 notation have on it?

The certificate must meet all requirements of a typical ISO 9000 certificate and, in addition:

- a) QS-9000 scope statement(s) must include all products and services being supplied to one or more of the companies subscribing to this document;
- b) cite a separate QS-9000 scope (if applicable), QS-9000 Edition registered to, e.g. QS-9000: 1995, date of registration, date of expiration (if applicable), the current issue of the relevant ISO 9000 Standard, e.g. ISO 9001:1994;
- c) include the phrase somewhere on the first page: “having been audited in accordance with the requirements of QS-9000 Appendix B, Code of Practice;”
- d) list on the front page the company name, address, date of registration, date of expiration (if applicable), QS-9000 scope: If any appendix/schedules are a part of the certificate, the certificate must note that more pages are included, e.g. Page 1 of 3;



e) include for multi-site certificates every registered site, its location, and scope;

f) include any remote locations, e.g. design centers, purchasing, contract review, etc., which are part of the quality system and have been audited, their locations and scopes. If a remote location supports more than one site, the remote location shall appear on each site certificate; and

g) include the name of the registrar, with its issuing office identified (city/state/country) and the mark of at least one QS-9000 recognized accreditation body. (See D05 for more)

Certificates shall not reference other documents for which the registrar is not accredited or qualified, e.g. QS-9000 Tooling and Equipment Supplement, ISO Guide 25, etc.

#### R05 Witness Audit

Is there mutual recognition between accreditation bodies for acceptance of witnessed audits?

The recognition of witnessed audits between QS-9000 recognized Accreditation bodies is strongly supported by the IASG.

#### R08 Local Operation

In QS-9000 Appendix B Code, what is the definition of local operations?

The local operation of the registrar (which has to have been assessed by a QS-9000 recognized accreditation body) refers to the office contracted for QS-9000 registration. It does not necessarily refer to the registrar office in the closest proximity to the supplier. This pre-supposes that such offices have been authorized by the accreditation body to conduct assessment to QS-9000.

#### R10 Surveillance - Non-conformities

What are the requirements for closing non-conformities identified at surveillance?

Non-conformities are closed according to the rules of your QS-9000 qualified registrar. The status of any non-conformances must be documented so that an inquiry by a customer can be answered. Misrepresentation of customer complaint information (for customers subscribing to QS-9000) by a supplier to certification body/registrar shall result in the Registrar immediately invoking their delisting process for that supplier and immediately requiring the supplier to notify the customer involved.

#### R12 Automotive Experience

What are the minimums for defining “automotive experience” for at least one audit team member (Appendix G)?

For the purpose of QS-9000 the definition of an acceptable minimum criteria will remain with the accreditation body, but, must address the areas of work experience, audit experience, and education relative to the automotive industry.

### R13 QS-9000 Appendix H - Chart Revision

The minimum man-day requirements for on-site auditing are given in a recent issue of EN 45012 EAC Guidelines. Are there man-day guidelines for QS-9000?

Yes. The QS-9000:February 1995 release includes a "Survey Audit Days Table" in Appendix H. It has been modified several times since originally included in our IASG release. Please review the changes made since our last (March 22, 1996) IASG release - they have been underlined.

### Appendix H: Survey Audit Days Table

Table R13A below shows the MINIMUM number of on-site man days which should be spent by the registrar on initial QS-9000/ISO 9001 quality system audits (see Glossary) and ongoing surveillance audits (see Appendix B, Number 7). On-site surveillance audits should typically be scheduled every six months, but each site must be surveillance audited at least once every 12 months. Table R13A now indicates the minimum number of "on-site man-days within each 12-month period." The MINIMUM number of man days for QS-9000/ISO 9002 audits may be reduced by 20%. Registrars will document actual on-site audit man days, including any deviation below the MINIMUM. Accreditation bodies will review such documentation for appropriateness. Table R13A was developed to primarily apply to one site/one certificate situations. Use of this table by registrars is effective January 1, 1997 and remains in effect until modified by the Supplier Quality Requirements Task Force.

Table R13A Appendix H: Survey Audit Days (modified)

Certificated Entity: Number of Employees	Initial Audit Man-days)	Surveillance Audits if Conducted at 6-Month Intervals (Minimum Number of On-Site Man-days) Surveillance Audits: (Minimum Number of On-site Man-days within each 12 Month Period)	
		Number of On-Site Man-days)	Number of On-Site Man-days)
1-15	2	1.0	2
16-30	4	1.0	2
31-60	5	1.5	3
61-100	6	1.5	3
101-250	8	2.0	4
251-500	10	2.5	5
501-1000	12	3.0	6
1001-2000	15	3.5	7
2001-4000	18	4.5	9
4001-8000	21	5.5	11

Table R13A revised effective January 1, 1997. An audit man-day is defined as not less than 8 hours on-site performing the audit. Per RAB Advisory 9 (1/02/97), "An audit person-day is considered to be eight hours of a 24-hour day".

Table R13A (slightly) exceeds minimum man-day guidelines based on EAC Guidelines on EN 45012.

Notes on (modified) QS-9000:Feb 1995 Survey Audit Days Table (Table R13A):

1. Initial Audit (On-site Man-days) can not include “pre-audit document review” (whereas the EAC Guidelines do).
2. Initial Audit (On-site Man-days) can not include “pre-assessments” which are provided for supplier feedback only, with non-binding review, and corrective actions that are not part of the registration audit (don’t appear in the final report).
3. Initial Audit (On-site Man-days) a) can include single or multiple registration audit visits which occur less than three months after document review and the audit matrix are completed; b) do include binding non-conformances leading to; c) approved corrective actions which are included in the final registration audit report; and d) the audit team conducting subsequent visits or steps during the three month process must be comprised of at least one QS-9000 qualified member from the previous on-site audit team.
4. Audit man-days for registration upgrades from ISO 9001/2 to QS-9000 are not addressed in this table.
5. Each audit shall include auditing on all shifts.

In summary, only those man-days subsequent to completion of the document review, and development of the audit matrix, and that occur within a consecutive three month period may be counted as man-days in accordance with the Appendix H Table (R13A). Also, see Table 13B below.

The registrar should treat these man-days as true minimums. If the days quoted are below the minimums stated, the accreditation body shall assess the validity of such justification. (Refer to Accreditation Body Notification which follows). The actual on-site “initial audit” man-days must be reported in the QS-9000/ISO 9001/2 registration report.

Table R13B

[Image]

#### Chart Definitions

Column #1 of Appendix H (Table R13A), entitled Certificated Entity: Number of Employees, represents the total number of employees per site including all shifts, and all administrative, professional, etc. staff.

Column #2 of Appendix H (Table R13A), entitled Initial Audit (On-site man days), represents the minimum number of audit man-days for a site undergoing a single certificate site audit. Time required for documentation review is in addition to these days.

“Sites” are defined as locations at which production processes occur; “corporate” schemes apply only to multiple site registrations. Remote locations, e.g. Engineering, Purchasing, must be audited as they support a “site(s),” but man-days to conduct these audits are included in a “site” audit as defined in the Appendix H (Table R13A).

## Corporate/Multi-site Considerations

In multi-site situations, hereafter called a “Corporate” Audit Scheme, wherein multiple sites are assessed to be provided a single certificate, the following additional guidelines apply before a registrar can apply a “Corporate” certificate for QS-9000.

In order to adequately assess the quality system, it is necessary to visit every site but it is recognized that the number of man-days required to effectively assess each site may be less per site than the number given in the modified Appendix H chart (Table 13A).

The conditions required of the company for a “Corporate” certificate include:

- a) The quality system must be centrally structured and managed, and subjected to regular QS-9000 compliant internal audits at all sites.
- b) The quality system must comply with QS-9000/ISO 9001 or QS-9000/ISO 9002. If the system includes ISO 9001, all design activities must be evaluated.
- c) The balance of activities which could be centrally managed include:
  1. contract review, where local acceptance of orders is permitted;
  2. approval of suppliers;
  3. evaluation of training needs (activity may have local aspects);
  4. quality manual (Level 1 and Level 2) documentation and changes in same;
  5. management review;
  6. evaluation of corrective actions;
  7. internal audit planning and evaluation of the result;
  8. quality planning and continuous improvement activities (activity may have local aspects); and
  9. design activities.

Note: Variations are acknowledged due to size and/or organizational structure.

The registrar must establish, during the quotation process, how the multi-site company falling under the “Corporate” scenario meets these requirements.

### Man-day Adjustment for “Corporate” Audit Scheme

As a minimum, for a “corporate” certificate, the on-site audit man-days per site, are not expected to be less than the percentage in Table R13C below of the man-day values per site shown in the modified Appendix H chart “Survey Audit Days Table” (Table R13A). The same logic applies to the surveillance man-days in the Table R13A. “Sites” are defined as locations at which production processes occur; “corporate” schemes apply only to multiple site registrations. Remote locations, e.g. Engineering, Purchasing, must be audited as they support a “site(s),” but man-days to conduct these audits are included in a site audit as defined in the Table R13A.

TABLE R13C - Man-day Adjustment for "Corporate" Audit Scheme

Number of Sites Percent Reduction To

2 - 9	70
10 to 19	60
20 and above	50

Accreditation Body Notification

It is recognized that in "Corporate" multi-site audit approaches, the on-site audit man-days per site may be reduced to the percentages shown in Table R13C of the levels shown in the modified Appendix H Chart (Table R13A) for On-site audit days and/or surveillances.

For any "site" approach used by a QS-9000 qualified registrar, if the registrar quotes man-days per site below the minimum levels shown in Table R13A, the registrar must notify its QS-9000 accreditation bodies of the quoted man-days via the "QS-9000 Reporting Table." Also, he must provide the relevant supplier information, i.e. employees, number of sites, and product scope, in order to justify the quote.

For any "corporate" approach used by a QS-9000 qualified registrar, if the registrar quotes man-days per site below the percentages of the minimum levels per site shown in Table R13C, the registrar must submit/notify its QS-9000 accreditation bodies of the quoted man-days via the "QS-9000 Reporting Table." Also he must provide the relevant supplier information, i.e. employees, number of sites, and product scope, in order to justify the quoting of fewer man-days than permitted.

These notifications must occur within five days of the quotation date to the client. The accreditation body is expected to review each of these inputs and take corrective and preventive action where appropriate.

QS-9000 audit proposals with suppliers involving violations of the current interpretation of Appendix H must be revised with those suppliers. This requirement for justification and notification of accreditation bodies applies to all registration audits occurring after August 1, 1995.

Noncompliance places at risk the registrar, accreditation body and the resulting supplier QS-9000 certification.

R28 Recognition of Certificates - Registrars

We are a large Tier 1 company in Europe who has utilized five registrars in six countries to obtain ISO 9001. Now that we must upgrade to QS-9000, and all our registrars are not QS-9000 qualified, can we expect that registrars will recognize each other's ISO 9000 registrations?

No. The IASG and IAAR anticipate that all QS-9000 qualified registrars will recognize one another's accredited certifications, and cooperate in helping

you achieve an effective compliance to QS-9000. If a QS-9000 qualified registrar is contracted to assess for an upgrade from ISO 9000 to QS-9000, registrars try to accept as much of the ISO 9000 registrar's assessment report as possible, but the upgrade assessment would typically sample all elements of QS-9000, thereby, involving some repeat of previous ISO 9000 elements sampled.

### R29 QS-9000 Audit Team Requirements

What are the requirements for auditors and audit teams to be qualified to conduct QS-9000 audits for a QS-9000 qualified registrar?

1. All auditors on the team must have completed the sanctioned registrar QS-9000 training course available from AIAG for auditors and have passed the exam.
2. At least one auditor on the audit team must be qualified for the relevant SIC/NACE code of the supplier.
3. At least one member of the audit team must meet the accreditation body requirements for automotive experience of Appendix G: see R12.
4. At least one member of the audit team has to have participated in every step of the registration audit.

### R30 Site Scope Clarification

Can a single division achieve QS-9000 certification if it operates in the same building as other divisions which are not pursuing QS-9000 certification? The different divisions operate independently for the most part with overlap in accounting, purchasing, maintenance, and quality control.

Where a supplier division operates in the same building as other divisions, the division which wishes to be QS-9000 registered may do so (separately from the other divisions) if they address all 23 QS-9000 elements (with requirements as noted in QS-9000 Introduction: Applicability) and none of the other divisions at the same sites produce automotive products. All automotive products at one site manufactured for a customer subscribing to QS-9000 must be included in the QS-9000 registration scope before that site can be registered to QS-9000.

Note: If these divisions have separate supplier codes established with the customer, they can be treated independently.

### R31 Multi-Site Registration

We are a transplant company (Company U) with production facilities and some design capabilities located in the U.S.

- \* Our parent company (Company J) is located in Japan.
- \* Company U supplies parts to the Big Three, and is the main contact for all situations dealing with these parts.
- \* The production is in the U.S., and the validation testing is jointly done by both Companies U & J.
- \* Company U is responsible for submitting any new and/or changed specifications, but Company J issues all new and/or changed

specifications.

- \* Company U signs the documents before sending them to the Big Three.
- \* Company U is currently registering for ISO 9001/QS-9000 (includes 4.4) while Company J is registering for ISO 9002.

A. What is the appropriate option for Company U registration? Does our Company U registrar need to audit Company J?

Company J appears to be a remote design center, which supports Company U, the manufacturing site, and the supplier. Unless Company J is a site, at which production processes occur, it can not be QS-9000 registered. However, Company J must be audited and cited on Company U's QS-9000/ISO 9001 certificate.

B. If Company U opts for QS-9002, does Company J need to be registered for QS-9001 or ISO 9001?

There is no QS-9001 or QS-9002. QS-9000 is cited on an ISO 9001 or 9002 certificate, if appropriate. Company U cannot opt for QS-9000/ ISO 9002 if it is design-responsible and required to obtain QS-9000. Then Company J would have to be audited to QS-9000/ ISO 9001, (See A. above), and cited on Company U's QS-9000/ ISO 9001 certificate.

C. In Design Responsibility, how is authority to establish defined? Does authority mean approve & sign off on the documents?

Reference A11. Contact your customer purchasing or quality activity for verification if necessary.

D. Since it seems like a shared Design Responsibility which company should be audited for 4.4 or do both companies need to be audited?

Both companies would need to be audited.

E. Is there more than one option for registration for the above case?

Both must be QS-9000/ISO 9001:1994, probably under a certificate for company U.

### R33 ISO 9000 Upgrades

Our plants are currently ISO 9002 certified and our design responsible corporate office is not ISO 9001 certified. Should we get ISO 9001 first, then upgrade later (two-step process), or can we go for QS-9000/ISO 9001 directly?

You can obtain QS-9000/ISO 9001 either way, so long as it is done in compliance with R34 / R35.

### R34 Two Step QS-9000 Registration Process

What are the guidelines for registrars and suppliers when using a two-step process for achieving QS-9000 registration?

In general, assure that the registrar is QS-9000 qualified, approved for the applicable business sector (SIC, NACE) and that all QS-9000 guidelines and rules are followed for both/all steps, i.e., use of only QS-9000 qualified auditors for all steps, etc.

Registration to QS-9000 could be achieved in a variety of ways:

- a) A two-step process for one site, within the three-month window (see R45),
- b) a two-step (or more) process involving a multi-site/corporate certificate, involving many months from auditing of the initial site to completion of the final site or design location,
- c) a two-step process wherein ISO 9000 certification was obtained first, followed by QS-9000 upgrade later.

Where QS-9000 is an established customer requirement, all steps must meet QS-9000 Appendices B, G and H requirements and these IASG Sanctioned Interpretations. The audit team for all steps must be “QS-9000 qualified,” etc., and the individual on-site man-days of auditing must meet the QS-9000 requirements (R13).

If the first step involves ISO 9000 certification, it is expected to meet EAC minimum man-day requirements for ISO 9000. If the full team for the first, or any, step did not meet all QS-9000 requirements, then the man-day requirements for the QS-9000 upgrade step(s) must meet the full Appendix H man-day values. (Refer to R13)

If the ISO 9000 (first step) occurred before April 1, 1996 and the upgrade to QS-9000 (second step) occurs after April 1, 1996, then the certification body and the accreditation body must agree on the appropriate on-site man-days for the upgrade given that all QS-9000-specific requirements are covered, and QS-9000 qualified auditors are utilized for the upgrade. For audits where both steps occur after April 1, 1996, the initial H-chart man-day requirements apply to the combined audit days. If the upgrade coincides with a surveillance audit, then the surveillance day requirements must be in addition to the Initial H-Chart man-day requirements.

### R35 Two Step Registration - Limitations

Our company has been approached by Registrar B and been offered a plan for registration which includes on-site man-days which meet the totals of Appendix H, but they will be provided/served in two distinct stages. The audit team will visit this site initially for three days followed by an additional four, within 90 days, to complete the audit. This appears to us that the Registrar B is including a pre-assessment visit in the on-site days as part of the total. Is this acceptable? Under what conditions would the initial session of three days not be considered as a pre-assessment and acceptable for inclusion in the totals for Appendix H?

This is an acceptable route to QS-9000 registration (see R13) providing the following criteria are met:

1. Quality Manual Review and audit schedule (matrix) completed prior to



initial visit.

2. Non-conformances raised at both visits are considered binding and therefore must be cleared before the registration is approved, and both steps and resulting corrective actions are documented in the final audit report.
3. The same QS-9000 qualified auditor(s) are used for each visit.

If any of the above conditions are not met, then this scheme cannot be applied. If it is a pre-assessment, then it is not acceptable. It is unfortunate that a registrar may be conducting a process that places his own QS-9000 qualification at risk, and also risks the acceptability of the audit results and certificate by the Big Three. You should document the occurrence and report it to the accreditation bodies involved, and if you obtain documented evidence of violation of the integrity of the process, you should also submit those details.

### R36 Remote Locations

We have a manufacturing plant that supplies products to GM. However, the Design and Sales/Marketing activities are distributed on 4 locations in Asia-Pacific. What elements of the QS-9000, in addition to 4.4 Design Control, could be audit able in the 4 Design & Sales/Marketing locations?

The Design sites must be included in the registration if the company is design responsible for products supplied to the Big Three.

Sites providing support to manufacturing sites registered to QS-9000 must operate within a system which meets QS-9000 requirements for all functions it performs or activities which pertain to QS-9000. That is, documents must be controlled according to paragraph 4.5, purchasing must be done according to paragraph 4.6, test equipment controlled according to paragraph 4.11, etc.

### R37 Multiple Registrars - Same Company

We are a large supplier with several technical centers in the US and numerous manufacturing sites across the world. All technical centers will be assessed to QS-9000 by the same registrar, however, several of the overseas sites are already registered to ISO 9002 by different registrars. These sites will receive an additional assessment to verify compliance to QS-9000, but they receive engineering support from the technical centers in the US. Will the engineering centers need to be assessed by each registrar? If not, what documentation will need to be provided to the registrars of the overseas plants to verify that engineering centers have been assessed to QS-9000 by an accredited registrar?

It is possible that QS-9000-qualified registrars, using QS-9000-qualified auditors, could recognize each other's audits of companies. An agreement between registrars is usually obtained beforehand, whereby Registrar A could audit a manufacturing site to QS-9000, and Registrar B conduct an audit of a remote location, e.g. design center, if deemed necessary. Registrar B would submit its audit report to Registrar A who could then review the audit report, and when A is satisfied, issue a QS-9000/ISO 9001 certificate covering both the manufacturing site and the design center.

There is no standardized procedure among QS-9000-qualified registrars. It is likely that some limited auditing of the design location by Registrar A, in this case, could be required before a certificate could be issued. Further, there would need to be a formal agreement between cooperating registrars that audit reports of each surveillance conducted by Registrar B would be sent to Registrar A, which has responsibility for the ultimate certificate. In this case, Registrar B acts as a subcontractor to Registrar A for the maintenance of the certificate.

Each qualified QS-9000 registrar is obliged to be directly responsible for all operations involved in the registrations it provides; this will involve auditing. None may issue a certificate solely on the basis of work accomplished by any other, unless the "other" is a fully qualified QS-9000 registrar that also meets the first QS-9000 registrar's requirements.

#### R39 Multiple Products - Same Location

My company has two auto product lines, A and B; with differing quality systems, all at location M. Quality system A is certified to ISO 9002, B is not. Can we get QS-9000 for A, and leave B alone until next year?

No. All manufacturing operations at a single site which are involved in producing products for the auto industry must be QS-9000 compliant before any can be registered. They could conceivably operate under two separate quality systems, but then would need to be registered separately, but at the same time. Reference QS-9000:Feb. 1995, Appendix B. (Code of Practice)

#### R40 Remote Location Sampling

We know "sampling" of sites is forbidden. Can a registrar sample non-sites such as sales offices (contract review) or storage warehouses (delivery), to avoid all being visited?

Yes, except sampling cannot involve any "site" (see A02) with a value-added process to the dimensions or attributes of the service or product provided. If the supplier is a distribution company, all sites must be audited for registration.

#### R41 Use of Other Auditor Resources

Is it possible for QS-9000 accredited certification bodies to cooperate with another QS-9000 accredited certification body in sharing QS-9000 qualified auditors with special technical knowledge?

Yes, but the responsibility for demonstrating auditor qualifications/competence is still the responsibility of the certification body granting the certificate.

#### R43 Authority for Certificate Issuance

A. Is it possible for a local registrar that is accredited by a Chrysler/Ford/GM recognized accreditation body, to issue QS-9000 certificates to a foreign company?

Yes, if the accreditation body rules, Task Force policies and Appendix G. requirements are followed.

B. In this case is it possible for the QS-9000 registrar to perform an audit in a foreign country using one or more QS-9000 qualified auditors provided by a non QS-9000 qualified accredited registrar of that country?

The QS-9000 requirements for audit team continuity and make-up must be met by the QS-9000 qualified registrar. Use of subcontracted auditors from another registrar often limits controls. Their use should represent a minority of team man-days.

#### R44 Design Responsibility Requires QS-9000/ISO 9001

We are a small Tier 2 stamping company without design responsibility at the present time, pursuing QS-9000/ISO 9002 certification. However, we may contract to design a part in the near future. Is it possible to obtain QS-9000/ISO 9002 certification while possessing “design responsibility” on a single part (i.e., not audited for that particular process per element 4.4)?

No, If you are “design responsible” for any parts supplied to the Big Three, then you must be registered for QS-9000/ISO 9001.

#### R45 Two-Step Registration Process

Please clarify whether the registration audit approach described below is in compliance with the requirements of Appendix H.

The registrar does not perform a pre-audit. Instead the registration audit is scheduled in two parts, which may be 6 to 8 weeks apart. Each part of the registration audit will include half the elements of the QS-9000 Requirements. After the first part, the registrar gives the client the chance to implement corrective action of the non-conformances found during the first part of the audit. The second part of the registration audit covers the remaining elements, and verifies implemented corrective actions of the first part.

Yes, providing you have met all QS-9000 requirements, including: you have used QS-9000-qualified auditors for both steps, both steps occur after the completion of the document review phase, both steps occur within three months of one another, and all non-conformances and other findings from both steps are fully described in the final audit report. However, time spent in the second step to review closure of previously issued non-conformances must be in addition to the H-Chart minimum man-day. Therefore, in the approach described, the total on-site man-days must normally exceed the H-Chart minimums. See R13.

#### R46 Definition of a Man-day

What is the definition of a manday, in terms of number of hours. Most Registrars say 8 - 10 hours. Other registrars have been utilizing the RAB certification requirement (6 hours minimum per manday, per the assessment logs) as their manday definition, so that if they work an 8 hour audit day,

that is counted as 1.25 mandays, 9 hour day is 1.5 mandays, etc. I feel that this is another method that is being used to “cheat” on mandays. Does the IASG define minimum hours per manday? (to eliminate this cheating).

An audit man-day is defined as not less than 8 hours on-site performing the audit. Per RAB Advisory 9 (1/02/97), “An audit person-day is considered to be eight hours of a 24-hour day”.

#### R47 Sales and Distribution

Corporation X is a supplier to the Big Three. We are the Sales and Distribution Division of a Multi-National Manufacturer. Our factory locations are in Southeast Asia. In the USA we have four warehouse locations. We accept the contracts in the USA and order product from the factory locations in Southeast Asia. We bring the product into our warehouses and distribute it to the customer (including the Big Three). The factory locations are now in the process of obtaining QS-9000. Do we have to certify the Sales and Distribution Company in the USA as well?

Your USA offices appears to be “remote locations,” e.g. Sales, Engineering, Purchasing, Off-Site Warehouses which must be included in the factory certification process, and audited as they support a site, but cannot be independently QS-9000 registered.

#### R48 Auditing on all Shifts

Interpretation #9503-R13 states on page 44" 5. It is expected that the audit mandays will include auditing on all shifts”. We would have some clarification about this:

A. We understand that all shifts and production lines shall be covered during the audit. Is this correct?

Sampling of quality system activities is to occur on all shifts and all production lines.

B. For a company operating on a 6 shifts basis; i.e. 3 shifts during the week and 3 shifts only working during the weekend (Saturday and Sunday). Is it acceptable that the audit covers only the duration of the audit (during the week) or do weekend activities have to be covered?

If the weekend crews are dedicated and non-rotating into the weekly shift schedule, then auditing of the weekend shifts is required.

#### R49 Design Responsible

Does this interpretation apply to Tier 2 suppliers to the auto companies who are not directly “design responsible” to Chrysler/Ford/GM; but are “design responsible” to the Tier 1 suppliers?

Our Company is in the business of manufacturing compounded engineering thermoplastics. These materials are sold to Tier 1 suppliers to the auto companies. Otherwise, our organization structure is similar to the case with separate manufacturing plants and an R&D center.

The Tier 1 supplier is design-responsible in the above case.  
Design-responsible suppliers must be registered to ISO 9001 and QS-9000, and must be able to fully document compliance to QS-9000 Element 4.4 regardless of subcontracted design assistance/support.

#### R50 ISO Guide 62

Can ISO Guide 62 be used in lieu of EAC/EN 45012? (See Appendix B).

ISO/IEC Guide 62:1996(E), General requirements for bodies operating assessment and certification/registration of quality systems, and the IAF Guidance on the Application of ISO/IEC Guide 62:1996, Issue 1, 2 June 1997 may be used in place of EN45012, General Criteria for Certification Bodies Operating Quality System Certification and the accompanying EAC Guidelines on the application to EN 45012 (EAC/G3) Rev. 01, 09-1995 in QS-9000 Appendix B.5.

#### R51 Audits of All Shifts

During a recent QS-9000 audit, the company claimed that they were scheduling audits of all shifts by auditing shifts when they rotated to day shift. As a registrar, we plan to carry out surveillance audits during the three year cycle to cover all shift periods and appropriate activities. We expect the companies with QS-9000 systems to arrange internal audits likewise. There is no current interpretation clarifying either the responsibility of the registrar for auditing on all shifts during surveillance (Appendix B) or the supplier scheduling internal audits to cover all shift periods (Section I, Clause 4.17).

See R13, Note 5, which includes surveillance audits, b) The planned internal audits must include all shifts to verify the effectiveness of the quality system, see 4.1, 4.17.

#### R52 Reciprocal Recognition for 4.6.2 and 4.17.

We are suppliers to car manufacturers. For our supplier development and our internal audits we use one of the European commonly agreed catalogues. Is this accepted for QS-9000 conformance to 4.6.2 and 4.17?

Yes, as long as the latest European manuals used in the registration included the QS-9000 appendices to the European catalogue. However, those suppliers required to be QS-9000 registered shall have a valid ISO 9000 certificate also indicating QS-9000 compliance. Third party registration to EAQF, AVSQ, or VDA6 will not satisfy the QS-9000 registration requirement. One audit can be used to satisfy both QS-9000 and one or more of the current European schemes if the registrar is QS-9000 qualified and meets all the QS-9000 registration scheme requirements, e.g. Appendices B, G, H and these Sanctioned Interpretations.

#### R53 Notification of Suspension

What are the notification requirements when a supplier is put on QS-9000 suspension by the certification body/registrar?

When a Certification Body/Registrar places an existing QS-9000 registered company on suspension because of nonconformances or a violation of the rules of registration: the Certification Body/Registrar shall notify, within 10 working days, each Chrysler/Ford/General Motors Supplier Quality Requirements Task Force representative of this action. These notifications are intended to remain confidential to the Certification Body/Registrar, Client, and the Chrysler, Ford, and General Motors representatives.

This notification process is a requirement for all QS-9000 - Qualified Certification Bodies/Registrars, and QS-9000 - Certified Suppliers. The effective date for this new requirement is February 1, 1998.

#### R54 Registrar Oversight

What oversight requirements do Accreditation Bodies have with respect to QS-9000 Qualified Registrars?

Effective for the year 1998, Accreditation Bodies shall:

- \* conduct ongoing office assessments and witness audits, according to Table R54A below, using auditors with relevant automotive experience;
- \* develop an audit schedule for these office assessments and witness audits of its qualified Certification Body/Registrar offices taking into account all countries where QS-9000 registrations are issued by each Certification Body/Registrar;
- \* schedule witness audits so as to observe as many different auditors as possible across all Certification Bodies/Registrars;
- \* send, upon request, audit schedules to Chrysler, Ford, or General Motors;
- \* allow, upon request, Chrysler, Ford or General Motors Supplier Quality Requirements Task Force representatives or their designees, to accompany Accreditation Bodies on witness audits of registrars, as automotive "Technical Expert Observers", if client permission is obtained; and if all potential issues regarding "confidentiality" and "conflict of interest" have been resolved.

The accreditation bodies are strongly encouraged to implement mutual recognition of each other's QS-9000 office assessments and witness audits thereby using mutual recognition to satisfy the Table R54A requirements. It is expected this can occur for any visits greater than any minimum number each accreditation body may now require be conducted by themselves. The annual assessments defined below are not intended to create undue redundancy between accreditation bodies for any single QS-9000 Qualified registrar.

TABLE R54A: Annual Assessments by Accreditation Body of Certification Body/Registrar

#### # QS-9000 CERTIFICATES IN FORCE

(at the beginning of each calendar year)

Minimum Number of Annual:      1 - 30   31 - 100   101 - 250   251+

Office Assessments*	1	1	1	1
Witness Audits**	1	2	3	4

\* Office Assessments of the QS-9000 Qualified-Certification Body/Registrar are conducted at the site where their QS-9000 records reside. Office Assessments shall review Certification Body/Registrar compliance with all requirements of QS-9000, QS-9000 Appendices and the IASG QS-9000 Sanctioned Interpretations (e.g. Timely notification of registrations and changes to ASQ -- see D05).

\* \*Witness Audits are conducted by an accreditation body, at a client's site, observing an audit team from a Certification Body/Registrar, during a QS-9000 audit to verify Certification Body/Registrar compliance with all requirements of QS-9000, QS-9000 Appendices and the IASG QS-9000 Sanctioned Interpretations.

## TRAINING (T)

### T03 Registrar Training

Who is qualified to provide Big 3 recognized training on QS-9000?

There is only one worldwide provider of QS-9000 registrar training recognized by the Big Three, General Physics Corp.(GPC). There are no registrars qualified to deliver registrar training.

Supplier training availability is under review with the current providers, Bureau Veritas (BV) and GPC. Providers of this training are subject to the restrictions of Appendix B and QS-9000 definition for consulting. "Internal Auditor Training" sanctioned by the Chrysler, Ford, GM Supplier Quality Requirements Task Force is available in both North America and Europe. The purpose of the internal auditor training is to provide OEM and supplier auditors with an appropriate understanding of the QS-9000 and audit process requirements, e.g. ISO 10011. The internal auditor course will involve three days of training which includes an examination -- participants which successfully complete the course, including the exam, will be provided with a certificate of recognition as a QS-9000 "Internal Auditor." Course registration will be handled by AIAG (248-358-3003), and in Europe by Bureau Veritas (33-1-6079-9205).

## QS-9000 INFORMATION ITEMS

### APPLICABILITY (A2)

#### A04 QS-9000 Registration Requirements

Would you please clarify each of the Big Three's positions on QS-9000 timing, third party registration, compliance requirements, etc.?

Chrysler:

All Production and Service Part Suppliers to Chrysler must be Third-Party Registered to QS-9000 by July 31, 1997.

Ford:

For Ford North America suppliers, compliance with QS-9000 is expected by June, 1995. This means:

- \* A self-assessment has been conducted.
- \* Nonconformance issues have been identified.
- \* A work plan is in place to address these issues.

Ford does not require that you obtain an audit by a third party registrar. Ford will contact you on an individual basis if Ford wishes to receive a copy, or conduct an on-site review of your self-assessment.

Ford Australia unique suppliers shall be third-party registered to QS-9000 by December 31, 1997. Ford Argentina and Ford Brazil non-Q1 suppliers shall be third-party registered to QS-9000 (specific requirements are available from the local Supplier Technical Assistance activity).

General Motors:

New suppliers to General Motors North American operations by January 1, 1996. All suppliers to General Motors Europe to ISO 9000 by January 1, 1996. All suppliers to General Motors worldwide to QS-9000 by December 31, 1997.

Suppliers located outside North America will receive QS-9000 instructions regarding timing requirements as the documents are issued.

All suppliers to GM worldwide to QS-9000 by December 31, 1997, except: a) local suppliers to GM-Asia Pacific Operations (except GM-Holdens) by December 31, 1999; b) suppliers to Delco Electronics by July 31, 1998.

A10 TE Registration not Permitted

Registrars are receiving requests for QS-9000 registrations from many companies, such as tooling and equipment suppliers, that do not fall under the current scope of the standard. Many of these companies would like to pursue QS-9000 in preparation for TE-9000. Are Registrars required to refuse to provide QS-9000 registration services for those tooling companies requesting it?

Yes. The TE Supplement to QS-9000 (released August 1, 1996), a voluntary guideline, will not be permitted to be referenced on a third party registration certificate, at this time. The only option at present is registration to ISO 9000. (See O01)

A16 Semiconductor QS-9000 Supplement

Does the semiconductor supplement from Delco Electronics, Ford and Chrysler have to be used for a QS-9000 audit of a semiconductor supplier to the Big Three?

Yes, the supplement says that QS-9000 and the supplement becomes the requirements for semiconductor suppliers. NOTE: This does not extend to



other electronic products beyond semiconductors.

#### A20 European GM Requirements

Are the applicable requirements to the GM NAO suppliers also to be applied to the GM Europe suppliers?

The requirements are the same with the exceptions noted in Section III on the GM-specific pages.

#### A29 Delco Electronics

Are Delco and Delphi considered GM? Are suppliers to Delco and Delphi considered suppliers or subcontractors?

Both Delco Electronics and Delphi are considered GM locations. Suppliers to Delphi are required to achieve third party QS-9000 registration by December 31, 1997. Suppliers to Delco Electronics are required to achieve third party QS-9000 registration by July 31, 1998.”

### APPENDIX B: CODE OF PRACTICE (B2)

#### B11 Registrar Training - Eligibility to Attend

A. Is the C/F/GM QS-9000 registrar training course and certification available to any Certified Auditor not working for a registrar?

No. To support the worldwide launch of QS-9000, only those auditors who will conduct QS-9000 audits for QS-9000 qualified certification bodies/registrars, and who meet all other registrar requirements as a registrar’s auditors, are permitted to attend the C/F/GM QS-9000 registrar training.

B. If the QS-9000 Registrar Certification course is only open to Registrars, how do customer auditors obtain such certification?

Because of many requests from internal auditors of suppliers and OEMs, the C/F/GM Supplier Quality Requirements Task Force has authorized the development of a “QS-9000 Internal Auditor” course. This course provides internal auditors with a QS-9000 training and a recognition credential which parallels that required of registrars’ auditors. Contact AIAG (248-358-3003) for enrollment information. (Refer to T03)

#### B16 Handling Confidential Material

Re: Appendix B, Instructions to Suppliers, 4th paragraph: it states: “The registrar’s reports shall be made available to customers upon request.” If the certified company is not a first tier supplier, and its customer is a direct competitor, will the supplier be required to provide the referenced report? The concern on the part of lower tier suppliers is that this report could contain confidential information.

Yes, any customer can request and receive, a copy of the ISO/QS-9000 certification report from their supplier, or the supplier may authorize the

registrar to provide the report. It should not contain any proprietary information outside of the results of the QS-9000 system's audit. You can request that any (truly) proprietary information be removed.

## B18 Registrar Reporting Format

To what extent should a registrar follow RvA Model B? Is it the intent of Appendix B, Art. 8, which states that all QS-9000 reports should be per Model B, that also format and lay-out should be like model B?

The registrars are strongly encouraged to use the RvA Model B as the format basis in their QS-9000 audit report. Their QS-9000 audit report, if in a different format, shall contain as a minimum the prescribed content of Model B, per QS-9000 Appendix B.

## CRITERIA (C2)

### Section 1. ISO 9000-Based Requirements

#### 4.1 Management Responsibility

##### C59 Cross Functional Teams

What does "Cross-Functional Team" approach mean? Is it mandatory that the suppliers use a cross-functional team for developing facilities, processes and equipment plans or is it acceptable to use a "Multi-Disciplinary Team"?

For the purpose of QS-9000, cross-functional teams and multi-disciplinary teams are the same thing.

## DATABASE (D2)

### D03 QS-9000 Database

Will a database exist of QS-9000 certified companies? Can anyone use it for searches, etc.?

A database of QS-9000 certified companies has been developed. ASQ will be providing quarterly, written copies of the "QS-9000 Worldwide Registered Company Directory." Additionally the data base is accessible through the ASQ QS-9000 Web Page, <http://www.asq.org/9000> Search capability for this database exists through the Web Page and by ASQ. Call ASQ at 1-800-248-1946 (North America) or 1-414-272-8575 and ask for the Quality Information Center for more information.

### D11 IASG Subscriptions

Is there any way to get a subscription to the IASG releases? How can we keep up to date on this useful information?

IASG QS-9000 Sanctioned Interpretations are available on the InterNet on the ASQ Home Page (<http://www.asq.org/9000>). Hard Copy is available from ASQ or from Carwin Continuous Ltd. In Europe (441-708-861333) for a small fee.

## OTHER (O2)

O06 Comply with Revision Status of 7 Pack

Would you confirm the latest revision status of the following documents:

- Quality System Requirements QS-9000
- Measurement Systems Analysis
- Statistical Process Control
- Potential Failure Mode and Effects Analysis
- Production Part Approval Process
- Advanced Product Quality Planning and Control Plan
- Quality System Assessment

The latest revisions of all QS-9000 documents can be obtained at AIAG (Phone No. 248-358-3003 / Fax No. 248-358-3253), or Carwin Continuous in Europe (Phone No. 44-1708-861333 / Fax No. 44-1708-867941). Local translations of these manuals may not be at the latest change level, therefore they should be used for "reference" only.

The latest revisions are:

- QS-9000; 2nd. Ed, 2/95
- MSA: 2nd. Ed, 2/95
- PFMEA: 2nd. Ed. 2/95
- PPAP: 2nd. Ed, 2nd. Print. 7/95
- QSA: 1st. Ed. 8/94
- TE Supplement: 1st Edition, 7/96
- QSA - TE: 1st Edition, 7/96

All documents listed are currently available from the AIAG.

## PROCESS (P2)

P01 Supplier Audit Confirmation Route

Will the Big Three accept any ISO 9000/QS-9000 certificates based primarily on first party internal audits, such as the Supplier Audit Confirmation (SAC) Approach?

No. The Chrysler, Ford and GM Supplier Quality Requirements Task Force have issued a position paper relative to the proposed Supplier Audit Confirmation (SAC) approach. The Big Three do not accept any first party declarations of conformance to QS-9000; nor do they accept any third party assessment which does not fully meet the QS-9000 requirements...the latter includes the assessment of all quality system elements by a QS-9000 qualified assessor working for a QS-9000 qualified registrar.

The only acceptable declaration of compliance is an ISO 9000 certificate with QS-9000 notation issued by a QS-9000 registrar qualified by a Big Three recognized accreditation body.

P05 Use of QSA Checklist

Is there an approved checklist of questions available for QS-9000 auditing?

Yes. QSA (Ref. Appendix A, QS-9000:1995) is an approved checklist, however, it is not comprehensive nor is it intended to completely prepare a supplier for QS-9000. Suppliers and registrars should supplement the QSA with additional auditing material to assure conformance with all elements of QS-9000.

#### P07 Auditing In-House Lab Facilities

How can the IASG help to improve auditor consistency relative to inspection and testing, e.g. in house lab facilities?

Auditor teams for QS-9000-qualified registrars must be qualified to audit in-house lab facilities in order to audit compliance to QS-9000, including Clause 4.10 and 4.11. Auditor on-site verification must include:

- \* adequacy of the laboratory procedures;
- \* qualifications of the lab personnel conducting tests;
- \* conducting of the appropriate tests for the commodity(s); and
- \* performing these tests correctly, to the appropriate process standard, e.g. ASTM.

Accreditation bodies must provide competent auditors for the registrar witness audits and verify that adequate time is devoted to the audit of the in-house laboratories by registrars.

#### P08 Compliance Regulations Auditing

Is the QS-9000 auditor expected also to cover the requirements for safety, health and environmental issues according to Federal, State and Local ordinances and regulations when carrying out a QS-9000 audit?

QS-9000 requires that the supplier has knowledge of those requirements that are applicable and that the supplier have evidence of compliance to applicable requirements, but the third party QS-9000 auditor is not expected to conduct any type of compliance audit to these requirements.

#### P14 Audit Scope

What will the auditor assess during a QS-9000 audit if the purchase order does not require any QS-9000 compliance?

The auditor must audit to the requirements of QS-9000 and PPAP regardless of what is or is not specified in the client's purchase order.

#### P16 Waiver Documentation

Should a waiver by the customer always be documented in writing?

Yes, only a documented response from the customer is acceptable.

#### REGISTRATION/ACCREDITATION (R2)

## R06 No Registrar Endorsement

Is there any registrar especially supported or endorsed by any of the Big Three?

No. All QS-9000 qualified registrars that are listed by the IASG and the ASQ QS-9000 Database are considered equally QS-9000 qualified.

## R14 Registering Other Companies

Should a registrar encourage companies not meeting the QS-9000, page 2, statement on applicability be registered?

No! Suppliers should not be encouraged by registrars, but rather should determine, and respond to, the requirements of their customers.

## R17 IASG Role

Does the IASG also consider International issues for QS-9000, or will there be other similar interpretation groups in Europe, Japan, or elsewhere?

The IASG operates as the only group providing International Sanctioned QS-9000 Interpretations. As an international ad hoc working group it consists at present of representatives from around the world; Chrysler/Ford/General Motors Supplier Requirements Task Force (Three), Big Three Recognized Accreditation Bodies (Four), QS-9000 Qualified Registrars (Seven) and Tier 1 Automotive Suppliers (Two). The group's size and make-up can change.

## TRAINING (T2)

### T02 QS-9000 Training

Is a QSA (Quality System Assessment) Awareness Training Course sufficient to meet the training requirements for plant personnel to become first party internal auditors, as required by Element 4.17 in QS-9000?

No, the only sanctioned QSA Awareness Training Course is for general awareness; it alone does not fulfil Element 4.17 requirements. Chrysler, Ford and GM now offer an "Internal Auditing for QS-9000" course that provides internal auditor credentials for participants who successfully pass the exam at completion of the class. This is available through AIAG (GPC) in North America and through Bureau Veritas in Europe.

### T04 Copyright Permission for Training

How can an independent training organization formally obtain copyright permission to conduct training courses in QS-9000?

The Big Three will not formally sanction public providers of courses concerning QS-9000, but also will not stop same from providing training. Training materials can be handed out at the trainers discretion, but training organizations can not reproduce copyrighted material without permission of the content owners (which has not been given to any

non-sanctioned trainers). QS-9000 manuals could be purchased and utilized in the classes.....costs of the manuals can be recovered in tuition charges paid by the class participants.

#### APPENDIX "A"

##### International Auto Sector Group (IASG) Protocol

1) All IASG QS-9000 interpretations must be processed at the issue level as follows:

Step 1:"New" Issue presented to the IASG for discussion - May include only the question.

Step 2:"Draft" language distributed to the IASG members for consensus - This would include questions and draft answers by members of the IASG or from a submission.

Step 3:"Agreed" status is achieved after consensus of all members - the "Agreed" date applied is the meeting date.

Step 4:Incorporation into the "IASG Sanctioned QS-9000 Interpretations" document.

Step 5:The sanctioned interpretations document is distributed to stakeholders, IASG members, all QS-9000 recognized accreditation bodies, all accredited registrars' associations with membership represented and the public.

2) Representatives from Chrysler, Ford and GM must, individually, agree with interpretations and IASG decisions prior to completing Step #3 above.

3) All discussions, tentative decisions, and minutes resulting at and from the IASG meetings are considered confidential to the working group, and are treated as such until the "Agreed" status is reached and Step #5 above is initiated.

4) The IASG retains final approval of IASG membership, configuration and size of the group. No substitutes, alternates or back-up company representatives are permitted to attend.

5) Regular attendance at IASG meetings is critical and is expected. Repeated absences may result in being replaced as a working member of the IASG. The IASG will typically schedule at least three meetings in advance of a current meeting.

#### APPENDIX "B"

##### REGISTRAR TRAINING SCHEDULE FOR 1998 WORLDWIDE AND DOMESTIC

Schedule can change at any time

January 27 - 29, 1998 AIAG, Crescent BuildingSouthfield, MI  
January 28 - 30, 1998 SINCERT Milan, Italy  
February 02 - 04, 1998 COFRAC Paris, France  
February 17 - 19, 1998 AIAG, Crescent BuildingSouthfield, MI  
March 10 - 12, 1998 AIAG, Crescent BuildingSouthfield, MI

For information on registrar training after March, 1998, contact AIAG at  
(248) 358-3570.