

MANAGEMENT SYSTEMS BULLETIN NO. 5 DECEMBER 2003

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1.0 PROGRAM STATISTICS TO DATE (FISCAL YEAR 2003-2004)

| Number of clients | QMS | EMS |
|----------------------------|---------------------|-----|
| Total Accredited RB's | 18 | 9 |
| Applications in process | 8 | 1 |
| New Initial Accreditations | - | - |
| Voluntary Withdrawals | 1 | 1 |
| Total CMDCAS Qualified | 9 (8 applicants) | - |
| New CMDCAS Qualifications | 1 | - |
| CMDCAS Sector Withdrawal | 1 | - |
| Total TE 9000 Qualified | 3 | - |
| Total QS 9000 Qualified | 8 (1 applicant) | - |
| Total TL 9000 Qualified | 3 (1 applicant) | - |
| Total AS 9000 Qualified | - | - |
| Total SFM Qualified | - | 2 |

| | | (1 Applicant) |
|----------------|---|---------------|
| SFM Applicants | - | 1 |

2.0 <u>NEW/REVISED PROGRAM CRITERIA</u>

2.1 IAF Documents

Several IAF guidance documents and policies have recently been approved. In addition, the IAF has instituted a new document nomenclature system for numbering.

| Document title | New Document | Document | Application |
|------------------------------------|-----------------|-------------------|-------------|
| | Nomenclature | | Date |
| IAF Guidance on Cross Frontier | (IAF GD 3:2003) | http://www.iaf.nu | 2004-05-01 |
| Accreditation | | | |
| Issue 1 v. 3 | | | |
| IAF Procedure for Exchange of | (IAF ML 1:2003) | http://www.iaf.nu | 2003-11-01 |
| Documentation among MLA | | | |
| Accreditation Bodies for Purposes | | | |
| of Assessment | | | |
| Issue 1 | | | |
| IAF Guidance on the Application of | (IAF GD 1:2003) | http://www.iaf.nu | 2004-11-01 |
| ISO/IEC Guide 61: 1996 | | | |
| Issue 3, version 3 | | | |
| IAF Guidance on the application of | (IAF GD 2:2003) | http://www.iaf.nu | 2004-11-01 |
| ISO IEC Guide 62 | | | |
| Issue 3 | | | |
| IAF Guidance on the application of | (IAF GD 6:2003) | http://www.iaf.nu | 2004-11-01 |
| ISO IEC Guide 66 | | | |
| Issue 3 | | | |

Application

The application date for each document is indicated above. The SCC will begin using and referencing the new documents during audit activity commencing January 2004. From January 2004 to the application date will be the transition period. During the transition period, Opportunities for improvement will be cited against the deltas of the revised IAF Guidance documents. Changes to the new documents have been identified below.

Changes (IAF GD 62 and 66):

| GUIDE 62 :1996 ISSUE 3 | | |
|------------------------|--|------------------------|
| Clause: | Comment: | Page: |
| 2.1.2 | Note editorial change now | 8 |
| 2.1.7 | "ISO 9001" | 9 |
| 3.5.7 | | 24 |
| Annex 4- 0 – 0.1 | | 45 |
| 2.1.44 | The IAF definition of "should" to be applied when understanding the word "should" in 19011. | Intro page and page 15 |

| 2.2.1 - 2.2.8 | New section | 17 |
|---|---|--------------------------------------|
| 2.2.9 | Criteria for auditors – cross | 18 |
| 2.2.9 | reference old 2.2.3 | 10 |
| 2.2.11 | Selection procedure – cross | 19 |
| 2.2.11 | reference old 2.25 | 19 |
| 2.2.12 | - cross reference old 2.2.10 | |
| 2.2.12 | Assignment for a specific | 19 |
| 2.2.13 - 10 | assessment | 19 |
| 3.5.4 | Decision on | 23 |
| 5.5.4 | certification/registration | 23 |
| 3.5.10 | New section | 25 |
| 3.5.14 | New clause – cross reference | 27 |
| 5.5.14 | old 3.5.2 | 21 |
| 3.7.1 | Use of Certificates and Logo's | 28 |
| 5.7.1 | – major edit | 20 |
| Annex 1 | 5 | 31 |
| Annex 1 Annex 2 | New published edition Auditor time – note addition | 31 32 |
| Annex 2 | | 32 |
| | of words total # of employees and all shifts | |
| | | 22 |
| Annex 2 Annex 2 | 1. Last sentence added | 33 34 |
| Annex 2 | 5. Cross reference numbers | 34 |
| | changed | |
| GUIDE 66 :1996 ISSUE 3 Clause: | Comments | Deser |
| | Comment: | Page: |
| 0.1.1 | Editorial | 5 |
| 1012 | | - - |
| 0.1.3 | Editorial | 5 |
| 4.2.1 | Editorial and a note added | 5 18 |
| 4.2.1 4.2.5 | Editorial and a note added Editorial | 5 18 19 |
| 4.2.1 | Editorial and a note added Editorial Deleted 14012 and replaced | 5 18 |
| 4.2.1 4.2.5 4.2.11 | Editorial and a note added Editorial Deleted 14012 and replaced by 19011 | 5 18 19 21 |
| 4.2.1 4.2.5 4.2.11 5.3.20 b – bullets 1,3, 5 | Editorial and a note added Editorial Deleted 14012 and replaced by 19011 Editorial (19011) | 5 18 19 21 31 |
| 4.2.1 4.2.5 4.2.11 | Editorial and a note added Editorial Deleted 14012 and replaced by 19011 Editorial (19011) Editorial (19011) reference | 5 18 19 21 |
| 4.2.1 4.2.5 4.2.11 5.3.20 b – bullets 1,3, 5 5.5.2 | Editorial and a note added Editorial Deleted 14012 and replaced by 19011 Editorial (19011) Editorial (19011) reference clause 6.6 | 5 18 19 21 31 34 |
| 4.2.1 4.2.5 4.2.11 5.3.20 b – bullets 1,3, 5 | Editorial and a note added Editorial Deleted 14012 and replaced by 19011 Editorial (19011) Editorial (19011) reference clause 6.6 Effective date has been | 5 18 19 21 31 |
| 4.2.1 4.2.5 4.2.11 5.3.20 b - bullets 1,3, 5 5.5.2 5.5.5 | Editorial and a note added Editorial Deleted 14012 and replaced by 19011 Editorial (19011) Editorial (19011) reference clause 6.6 Effective date has been amended | 5 18 19 21 31 34 34 |
| 4.2.1 4.2.5 4.2.11 5.3.20 b – bullets 1,3, 5 5.5.2 | Editorial and a note added Editorial Deleted 14012 and replaced by 19011 Editorial (19011) Editorial (19011) reference clause 6.6 Effective date has been amended New clause added re | 5 18 19 21 31 34 |
| 4.2.1 4.2.5 4.2.11 5.3.20 b – bullets 1,3, 5 5.5.2 5.5.5 5.6.15 | Editorial and a note added Editorial Deleted 14012 and replaced by 19011 Editorial (19011) Editorial (19011) reference clause 6.6 Effective date has been amended New clause added re reviewing reports | 5 18 19 21 31 34 34 38 |
| 4.2.1 4.2.5 4.2.11 5.3.20 b - bullets 1,3, 5 5.5.2 5.5.5 | Editorial and a note added Editorial Deleted 14012 and replaced by 19011 Editorial (19011) Editorial (19011) reference clause 6.6 Effective date has been amended New clause added re | 5 18 19 21 31 34 34 |

2.2 ISO 19011

At the last IAF Technical Committee meeting, a working group was established to determine which clauses of ISO 19011 would apply to the various references in Guidance documents. Notation has been made in the revised IAF Guidance documents on the application of ISO/IEC Guides 62 and 66 at the reference points where ISO 19011 is applied. The reference will be supported with a separate document to be developed by the working group to specify those specific clauses.

In addition, with the publication of the revised IAF Guidance documents, the deadline for implementation of ISO 19011 by the Registration Bodies has now been confirmed as November 2004. The ISO 10011 and 14010, 14011 and 14012 series have now expired. Therefore, during audit activities, non-conformities will be cited to ISO 19011 clauses, if the clause is consistent with ISO 10011 or 14010, 14011, and 14012. If the clause in the guideline is new, an opportunity for improvement will be identified.

2.3 IAF Guidance on Cross Frontier Accreditation

The IAF Guidance on Cross Frontier Accreditation was published in November 2003, and procedures for implementation by AB's are required within 6 months. The document provides guidance to AB's accrediting CRB's in countries other then their own and will require implementation arrangements amongst AB's e.g. American National Standards Institute-Registrar Accreditation Board (ANSI-RAB) and Japan signed an Agreement of Cooperation during recent IAF Plenary. The SCC policy for Cross Frontier Accreditation will be included in the next version of CAN-P-1517B.

2.4 IAF Procedure for Exchange of Documentation Among MLA Accreditation Bodies for the Purposes of Assessment

Under the IAF MLÅ, TG auditors have begun reviewing and considering information from other accreditation bodies to complement, or in lieu of audit activities. The IAF has recently published a procedure for exchange of such documentation and its review. The SCC will be expanding this procedure in the future. Registration bodies should note section 3 Review of Exchanged Information, Section 4 Outcome of Review, and Section 5 Accreditation Decision as they will serve the basis for the SCC procedure.

2.5 CAN-P-1517B and CAN-P-1518A

In November 2003, the IAF published revisions to the IAF Guidance on the application of ISO/IEC Guide 61, and IAF Guidance on the application of ISO/IEC Guide 62, and two new policy documents related to Cross Frontier Accreditation and Exchange of Information amongst IAF MLA signatories. The CAN-P-1517B and CAN-P-1518A will be updated to incorporate the new policies and requirements. It is expected that these documents will be put forward for approval in the first quarter of 2004.

3.0 ITEMS FOR IMPLEMENTATION / INTERPRETATIONS

3.1 IAF Policy - Conformity Assessment Services:

A Technical Committee Resolution was passed at the last IAF Technical Committee meeting regarding accreditation and certification/registration activities. It was agreed that accreditors should accredit and certifiers should certify and there should be no confusion between the two. As such Registration bodies should not be offering registration to accreditation requirements like ISO 17025. In addition, Accreditation bodies should not be offering auditor certification services.

3.2 Registration Marks on wrapping for milled/cut timber products

The EMSAP program issued an interpretation regarding the "*RB's use of Marks on wrapping for milled/cut timber*" on the 16 October 2003. Note: the general interpretation of use of RBs marks applies to other industry sectors seeking registration to EMS standards. Please feel free to contact Stefan Janhager at email: <u>sjanhager@scc.ca</u> if you have any questions.

3.3 ISO 9001:2000 Transition

The ISO 9001:2000 transition status, including SCC survey results, was discussed by the IAF Technical Committee at the IAF Plenary in September 2003. A resolution was passed confirming the 2003-12-15 deadline "for the migration of accredited certific ates from the 1994 editions of ISO 9001/2/3 to the new ISO 9001:2000 edition". Registration Bodies were notified of the IAF resolution and a press release reflecting the IAF position was issued by the SCC in October 2003.

Based on the SCC/RAB survey results and other available information, approximately 24% of ISO 9001/2/3:1994 registrations will become unaccredited and outside of the ISO system after the transition deadline. Registration bodies have indicated that unaccredited registration certificates and letters of conformity will be issued to these clients, and that most will have transitioned to the new standard by June 2004.

Given the fact unaccredited registration certificates / letters of conformity to ISO 9001/2/3:1994 will exist after the transition deadline, the SCC has requested Registration bodies address the following items to prevent misrepresentation of ISO registration and to avoid confusion in the marketplace:

- Registration bodies shall notify all clients registered to ISO 9001/2/3:1994 of the expiration of the standard and accredited registration documents.
- Registration bodies shall request return of registration certificates issued to ISO 9001/2/3:1994 when the term of registration or expiry date is not found on the registration certificate;
- Registration bodies shall ensure their policies related to use of certificates and logos, representation of registration in the marketplace, and publicizing registration are communicated to registered organizations;
- Registration bodies may consider registration activities to support ISO 9001/2/3:1994 registration for those clients transitioning to ISO 9001:2000 after the transition deadline. In all cases, the Registration body shall validate the applicability of ISO 9001/2/3:1994 audit activity results during the audit planning process for ISO 9001:2000 registration, and Annex 2 of the IAF Guidance on the application of ISO /IEC Guide 62 shall be used when determining auditor time.

Finally, please be advised that the published listing of ISO TC176's interpretations for ISO 9001:2000 can be found at <u>http://www.tc176.org/Interpre.asp</u>. These were vetted through TC176's Interpretations Committee in a pilot program throughout 2003. Future interpretation requests can also be submitted via this URL.

4.0 <u>MEETINGS</u>

The following provides an overview of meetings of interest to Registration bodies and auditors related to the Management Systems program.

4.1 IAF AND PAC MEETINGS

The IAF Technical Committee and IAF Plenary meetings were held jointly with the ILAC Plenary in September 2003. The PAC Plenary was held in India in November 2003. At these meetings, several key issues were discussed and decisions made as follows:

IAF/PAC Peer Evaluation/Re-Evaluation of SCC: The QMS program continues to be recognized following the April 2002 peer evaluation. SCC signed the PAC Environmental

Management System (EMS) MLA in November 2003. A revisit for the EMS and Product evaluation is tentatively scheduled for July 2004. The IAF EMS MLA will be signed at the 2004 plenary in South Africa.

Customer Satisfaction Survey: IAF conducted a survey to measure Certification / Registration Bodies (CRBs) overall satisfaction with AB's, identify areas for potential improvement by AB's, and examine the perceived value of the IAF MLA. An IAF Working Group has been set up to identify proposed corrective actions. The SCC will review the information and compare the results to those of the International Association of Accredited Registrars (IAAR) survey, SCC Customer Satisfaction Survey, and SCC internal audit results. The information will also be reviewed in relation to IAF strategic directions and the SCC Canadian Standards Strategy (CSS) renewal exercise.

Code of Conduct: This document was approved by IAF members and will be ready for signing by CEO's of IAF AB members after formatting and application of the new IAF logo. SCC staff authored this document.

ISO/IEC 17024 Certification of Persons: The draft IAF Guidance on the Application of ISO/IEC 17024:2003 will be circulated to members for approval by a 60 day letter ballot due on the 23 December 2003. This document, once approved, will form the basis for the IAF MLA for personnel certification.

IAF Seal and MLA Mark: The IAF Seal and the MLA Mark were approved. The "General Principles for Use, Registration and Protection of the International Mark," a joint document with International Laboratory Accreditation Cooperation (ILAC), will be letter balloted to members for approval. When approved, the MLA Mark will be registered internationally by the IAF Secretariat and oversight of use will be provided by IAF AB Members. AB members will be allowed to use the MLA Mark alongside their own Marks, and to license the IAF MLA Mark to be used on CRB certificates alongside respective AB accreditation marks. The SCC will be updating the trademark license agreement to include use of the IAF Mark.

ISO/ILAC/IAF Joint Efforts: A draft Memorandum of Understanding (MoU) between IAF/ILAC/ISO is being developed (anticipated signature by the end of the 2rd quarter of 2004). This is an initiative of the Joint IAF/ISO Working Group on Image and Integrity. The final document will be signed by the CEO's of IAF, ILAC and ISO. ISO has requested IAF and ILAC input on the ISO Horizons 2010 document.

Upcoming Meetings: The next GA will be hosted by South African National Accreditation System (SANAS) in Cape Town, South Africa 2003-10-4 to 10. The next IAF Executive Committee and Technical Committee Meetings, as well as a 2 day training workshop for Peer Evaluators, will be held in Vancouver, B.C. 2004-02-23 to 2004-03-02.

4.2 IAAC

The 2003 Plenary of the Interamerican Accreditation Cooperation was held 2003-10-06 to 10 in Guatemala. Further information related to the IAAC mandate and activities can be found at the following URL: <u>http://iaac-accreditation.org/</u>. The IAAC functions as a regional group for Product certification, Management Systems, and Laboratory Accreditation bodies. This body has structured themselves in the same manner as the IAF and ILAC to facilitate input into these organizations. In the future, the IAAC will become the Americas regional group to the IAF and ILAC.

The Director, CA attended and participated at the meeting on behalf of the SCC accreditation programs. The SCC has provided input into several committees of the IAAC including the MLA Committee and Technical Committees. Currently, terms of references and workplans have been approved for the IAAC committees.

The draft resolutions from this meeting are not available electronically, but are available in paper copy by contacting the SCC.

4.3 CASCO

The Canadian Advisory Committee on ISO Conformity Assessment Matters (CAC/CASCO), a subcommittee of the Advisory Committee on Conformity Assessment (ACCA), provides Canadian input on ISO/CASCO matters.

The roles of CAC/CASCO include reviewing and commenting on ISO/CASCO activities (namely the preparation of International Standards and Guides related to conformity assessment), and preparing the Canadian delegation to the annual ISO/CASCO plenary meeting with Canadian positions on decision and discussion items. Canadian positions on matters slated for discussion at the annual ISO/CASCO plenary are developed at a full meeting of the CAC/CASCO.

FY 2003-2004 Activity Summary

Since 2002-12-04, CAC/CASCO received one hundred and one (101) ISO/CASCO documents for information, review and comment. CAC/CASCO provided comments and/or votes on twenty-five (25) technical documents, administrative proposals and reports to ISO/CASCO.

ISO/CASCO has completed the development of three documents this past year¹. These documents include:

- *ISO/IEC Guide* 68 Arrangements for the recognition and acceptance of conformity assessment results This ISO/IEC Guide provides an introduction to the development, issuance and operation of arrangements for the recognition and acceptance of results produced by bodies undertaking similar conformity assessment and related activities.
- *ISO/IEC 17024 General requirements for bodies operating certification of persons –* This International Standard contains the requirements for personnel certification bodies and forms the basis of the SCC's Personnel Certification Body Accreditation Program (PCBAP).
- *ISO/IEC 17030 Third party marks of conformity and their use –* This International Standard outlines the proper use of third party marks of conformity.

CAC/CASCO held its annual meeting on 2003-10-24. Members reviewed the ISO document package for the 2003-11-06/07 ISO/CASCO Plenary and reviewed / prepared agenda item positions for the Canadian delegation. The Canadian delegation for the 2003-11-06/07 ISO/CASCO plenary included Mr. William Cunningham (CAC/CASCO Chair), Mr. David Shortall (Convenor of ISO/CASCO WG 22 – *Code of Good Practice for Conformity Assessment*)

¹ Canadian experts participated in each of the respective ISO/CASCO Working Groups that developed these documents.

and M. Gilles Béland (Canadian Expert ISO/CASCO WG 5 – *Conformity Assessment – General Vocabulary*).

CASCO WG Activities

- WG 5 Revision of conformity assessment part of the current ISO/IEC Guide 2:1996 as an International Standard – ISO/IEC 17000 - Conformity assessment – General vocabulary: Canada voted in favour of DIS with comments on 2003-10-15 – FDIS expected early 2004
- WG 18 Development of an International Standard for assessment and accreditation on the basis of ISO/IEC Guides 58, 61 and ISO/IEC TR 17010 future **ISO/IEC 17011 General requirements for bodies accrediting conformity assessment bodies**: Canada voted in favour of Draft International Standard (DIS) on 2002-09-18 FDIS expected early 2004
- WG 21 See CASCO Working Group 21 below.
- WG 22 Revision of **ISO/IEC Guide 60:1994 Code of good practice for conformity assessment**: Working Draft (WD) #5 reviewed at 2003-11-03 WG 22 meeting – Draft Guide to be released for comment in early 2004
- WG 23 Identify common elements in ISO/IEC Standards for conformity assessment bodies and their activities – Common elements in ISO/IEC Standards for conformity assessment activities: Canada supported three New Work Item Proposals (NPs) on the development of Publicly Available Specifications (PASs) for (1) impartiality and related bodies (2) confidentiality and (3) complaints and appeals on 2003-06-30 – groups will be struck to pursue these items in 2004

Additional information on any of these items is available upon request from Mr. Bill Cunningham or Mr. Allan Wilson (Secretary - CAC/CASCO - <u>awilson@scc.ca</u>)

CASCO Working Group 21 (ISO/IEC 17021)

The CASCO Working Group (WG) 21 last met in June 2003 to discuss and further the development of ISO/IEC CD 2 17021 – *General requirements for bodies operating assessment and certification of management systems* that will supersede ISO/IEC Guide 62 and ISO/IEC Guide 66. The scope of standard goes beyond ISO 9001 and ISO 14001, it applies to all recognized management system standards.

The WG 21 drafting group met in Washington, D.C. in July 2003 to address some of the key issues discussed at the last meeting. As well, the WG 21 met again in Geneva on October 2 and 3, 2003 to finalize and agree to the publication of CD 2 of ISO/IEC Guide 17021.

On November 16, 2003 the SCC requested feedback from RB's on the acceptability of ISO/IEC CD 2 17021. In particular RB's were asked to provide:

- A) Guidance on whether to support ISO/IEC CD 2 17021 proceeding to a DIS level?
- B) Comments regarding ISO/IEC CD 2 17021 in the comment template provided (note: comments will only be accepted using the approved template).

The above required information is required by no later than the **2004-01-07**. Comments should be sent to Stefan Janhager, SCC email: <u>sjanhager@scc.ca</u>

4.4 SCC-ANSI/RAB MRA/MLA HARMONIZATION COMMITTEE

This committee, which has a mandate to increase the harmonization of the two organizations' accreditation programs, and thereby reduce redundancies for clients, held a conference call on October 21, 2003. Among the issues discussed were the following:

IAF's Cross Frontier Accreditation Policy and Exchange of Information between Accreditation Bodies: Given the approval of these new IAF policies, ANSI-RAB and SCC have recognized the need for a procedure to efficiently implement the policies. The two accreditation bodies will be working with a number of peers to identify the best means to put these new policies into effect.

Joint Audit Procedures: ANSI-RAB and SCC are moving towards the development of procedures for joint audit activities to address audit coordination and planning, classification of findings, conduct of joint audits, sharing of information, and audit reporting.

IAF Scope Category – Harmonization of process: SCC and ANSI-RAB are finalizing a joint procedure for scope extensions. Final activities include agreement on risk categories for each IAF scope.

MRA: RAB and JAB recently signed a Multilateral Cooperative Accreditation arrangement (MCAA) to increase co-operation between their respective organizations and to demonstrate implementation of the IAF Cross Frontier Policy. RAB, with the support of the IAAR representative, proposed the expansion of SCC/RAB MRA to include ABs from other countries and that the MCAA would be a good vehicle to do so. SCC is considering the process and will send comments on the agreement to RAB.

5.0 <u>SECTOR UPDATES</u>

5.1 **QS9000** AND TE 9000

The QS 9000 and TE 9000 program continue to wind down, and registrations to QS 9000 are decreasing in anticipation of the 2006 cessation of the program. The QS 9000 database will be maintained by Quality Systems Update magazine. In addition, three interpretations have been issued as attached. The interpretations will be reviewed by TG auditors, and audit points incorporated into QS oversight activities (on-site and witnessing) for those registration bodies qualified under the QS 9000 program.

| Date | Subject | Attachment |
|------------|--|---|
| 2003-11-13 | Clarification: Renewal of auditor QS 9000 certification | Policy renewal QS certs |
| 2003-11-01 | IASG interpretations of QS 9000 (Section 4.10.6, 4.10.7, item 40 of appendix I, Definition of Accredited Lab) | QS 9000 Interpretations |
| 2003-09-01 | Daimler/Chrysler Customer Specific Requirements | Daimler/Chrys customer specific requ |

5.2 CMDCAS

HC CMDCAS RB Forum

The third CMDCAS HC RB Forum was held 2003-12-11/12 at the Health Canada offices located in Tunney's Pasture in Ottawa. The Agenda for the 3^{rd} HC CMDCAS RB Forum can be found on the CMDCAS sitescape area located through the SCC website (www.scc.ca). The draft minutes from the 2^{nd} CMDCAS RB Forum held in May 2003 are also available on this site.

Registration Body representatives should be registered to the HC CMDCAS RB Forum sitescape area and are required by Health Canada to attend meetings. Participation in the HC CMDCAS RB Forum is mandatory and supports Registration Body maintenance of competency to operate in the CMDCAS program.

Access to the website is now found on the SCC main homepage. Members of the Forum should enter login and password information under Canadian Work Area.

ISO 13485:2003 Transition Status

The following provides an update on the status of the ISO 13485:2003 transition for year one of the transition period ending July 15th 2004.

| Item | |
|---|----|
| Total Applicant and Qualified CMDCAS RB's | 17 |
| Number of Transition Plans Received for Review To-Date | 8 |
| Option 1 (Document review as part of on-site assessment activity) | 0 |
| Option 2 (Off-Site Document Review) | 3 |
| Submission Incomplete | 5 |
| Registration Bodies who have not responded | 9 |

Submission of Transition Plans under Option 1

Some Registration bodies have requested review of transition plans while an audit is in process, or only a few days before an audit is scheduled to take place. Document reviews will need sufficient scheduling and time allocated for review of implementation at the on-site assessment. When requesting review of transition plans under Option 1, plans should be submitted to the SCC at least 5 weeks before the scheduled audit activity and with supporting documentation for the on-site audit activity. Transition plans will not be accepted on-site by the TG auditors.

Submission of Transition Plans under Option 2

Several Registration Bodies have sent transition plans for review under option 2 which have future action implementation dates for key items, or they have not provided evidence of the implementation of key activities. If a Registration Body submits incomplete plans, or evidence of implementation of key items is not provided for review, the plans will not be accepted by the SCC. Review of the transition plans will not commence until all items are included and evidence of implementation is provided. Note the SCC will not accept partial submissions.

To assist Registration Bodies when determining what evidence of implementation should be submitted, the following information should be noted.

In the transition requirements, registration bodies are requested to address the following items in their transition plans: Documentation, Assessment Personnel Competency and Client relations. These are considered key items of the transition plan. To be eligible for review of implementation off-site under Option 2, Registration bodies should have actually implemented the activities they have identified to address these three subject areas, and provide evidence of their implementation.

During the review auditors will be verifying that:

- Procedures and tools are in place for ISO 13485:2003 registration activities and to address personnel competency, and that the procedures contain the relevant updates to reflect the new standard (e.g. Updated procedures);
- Those involved in the registration process have received training on the new standard and RB Procedures (e.g. Training agenda and supporting presentations);
- Registered clients are aware of the new standard and the Registration body policy and procedure for transitioning to the new standard (e.g. copy of communications materials).

Regardless of the option selected by Registration Bodies for review of the transition plans, a witness audit will only be scheduled once the transition plans, and evidence of implementation, has been reviewed and accepted by the SCC and Health Canada representative.

5.3 AEROSPACE

The American's Aerospace Quality Group (AAQG) and Registrar Management Committee met in Montreal Canada 2003-09-08/09/10. At the meetings, several relevant items were addressed and decisions made as follows:

Recognition of NQI lead auditor certification by RAB during the Aerospace auditor certification process

An issue was brought forward by the SCC following the RAB rejection of an applicant aerospace auditor. It was found that the auditor had been rejected as RAB did not recognize NQI lead auditor certification as they are not signatories to the IATCA MLA. Aerospace auditors can be approved through two programs- sponsored by the applicant or qualified Registration Body and approved through the RMC process (through the approved AB), or through the RAB aerospace auditor certification program. While RAB indicated they will not recognize NQI in the RAB Aerospace auditor certification program, the RMC agreed that NQI lead auditor certification would be recognized through the RMC approval process. As a note, the SCC will need to review the second option for auditor approval, through the AB. This may conflict with the recent IAF resolution related to accreditation bodies providing auditor certification.

Oasis Database

At the June RMC meeting in Wichita, a decision was made that information and scoring of registered suppliers conforming under the AS 9100 program shall be entered into the Oasis database by the registration body at the time of initial registration or re-registration. This practice should begin by January 1, 2004. An initial fee of \$500 will be applicable to the Registration bodies for each supplier entered into the database, and annual maintenance fees of a lesser amount to be determined, may also be levied.

AIR 5359B

The latest version of criteria applicable to Accreditation bodies and Registration bodies was approved in July 2003. The deadline for implementation of AIR 5359B is January 1, 2004 and updated copies are available at <u>www.sae.org</u>. In December 2003, a letter from the AAQG RMC Chairperson was distributed to Registration Bodies by the SCC. This letter provides further information related to implementation of the new AIR 5359B requirements.

Aerospace Auditor Approval

The Auditor approval committee reported a high level of rejection of Aerospace auditors due to unclear fulfillment of auditor qualification criteria and lack of relevant aerospace experience. AB's were actioned to request CRB's review aerospace auditor qualifications and applications before submitting for approval to ensure criteria have been addressed, and relevant experience clearly documented and brought forward.

OEM Oversight

Within the AS Sector program, OEM representatives may accompany Accreditation Body auditors during on-site or witness audit activity. At this time, OEM's are attempting to participate in 100% of AB oversight activities under the AS Sector and are considered as observers on audit teams. Registration Bodies may find Aerospace observers on SCC audit teams when oversight is conducted jointly with RAB.

The next meeting of the RMC will be held 2004-01-19/20/21 at the Fiesta Inn in Tempe Arizona. At that meeting, annual oversight will be planned with the OEM representatives.

5.4 TL 9000

No items to report

5.5 SUSTAINABLE FOREST MANAGEMENT Canadian SFM Market: Canada's Certification Progress

- ISO 14001 119.3 Million hectares
- CAN/CSA Z809 17.9 Million hectares

Certification in Canada's forests is on the rise. According to the September 7, 2003 Coalition certification status report 129 million hectares of forest land across the country, representing an annual allowable cut of approximately 110 million m³ have been certified.

Many companies are finding that when ISO 14001 is applied to forest management it provides a sound foundation for moving on to the forestry-specific certification standard CAN/CSA Z809.

Canadian forest companies' performance in seeking 3^d party accredited certification is clear evidence of broad industry commitment to sustainable forest management, meeting customer needs and assuring Canadians that our forests are well managed and competitive in the national and international market place.

Memorandum of Understanding with the Ontario Ministry of Natural Resources Forests Division:

SCC's and OMNR's signed its MOU on November 2002. The intent of this agreement is to utilize SCC's accredited EMS RB's that are industry sector qualified to the SFM program in

applying CAN/CSA SFM Z809 3rd party accredited certification audits on defined forest areas; in support of the Ontario Ministry of Natural Resources Forests (OMNR) regulatory responsibilities for the Sustainable Forest Management of all Crown land forests within the province of Ontario. SCC and OMNR are finalizing the MOU implementation documentation and it is expected to be finalized during March 2004. SCC will be updating EMS RB's as this progresses.

CAN/CSA SFM Z809 Standard:

The CAN/CSA Z809: 2002 standard was approved by SCC in May 2003. SCC's accredited EMS registration bodies, that are SFM industry sector qualified, have been provided transition guidance for the new standard to be addressed. This was issued on the 28 September 2003. SCC's accredited EMS registration bodies qualified to the SFM industry sector program are requested to submit the requested information as soon as possible. SCC will be contacting each qualified or applicant RB in addressing this matter. Documents supporting the SFM sector qualification program, like the application form are currently being updated.

International SFM work:

IAF conducted a survey regarding forestry certification schemes among its members. At this time, forestry specific MLA activities will not take place. However, it was recognized that IAF members are working strongly in the SFM field and will most likely become another EMS industry sector scheme for IAF in the future.

SCC is still engaged in the Pan European Forestry Council (PEFC- MLA) work. The PEFC application is expected to be submitted by CSA in January 2004. This is an SFM MLA framework, which will apply to all SCC accredited EMS registration bodies which are industry sector qualified to the SFM program – implementing the CAN/CSA Z809 standard. The point is that CAN/CSA Z809 certified forest companies – products will be accepted among PEFC member countries. SCC will be keeping RB's updated on the progress of this matter.

5.6 EMS INDUSTRY SECTOR PROGRAM FOR HOG OPERATIONS

The Pork Council of Canada has requested SCC, on the 18 November 2003, to set up an industry sector program (e.g. like the SFM industry sector program to CAN/CSA Z809: 2002) applying the national standard CAN/CSA Z771. This standard is planned to become a national standard of Canada in February 2004. The Pork Council of Canada is expecting this industry sector program to be ready by February 2004. This program may be applicable to some 15,000 hog operations in Canada. SCC will update on the development of this program.

5.7 CLIMATE CHANGE

UNFCCC: SCC is still observing the UNFCC work regarding accreditation and registration body activities. The objective of this organization is to accredit EMS registration bodies to ISO/IEC Guide 66 conducting assessment of Clean Development Projects (CDM) and/or organizations improving Climate Change performance as per specified standards. To date, SCC has two accreditation auditors working for UNFCCC.

ISO TC 207 WG 5: SCC staff is participating in working group 5 (TC 207). This group is developing the International Standards for GHG verification – Clean Development Mechanism etc. This may provide the basis for a new industry sector program for SCC and its EMSAP program. It may apply to other conformity assessment programs such as product certification.

Canadian Government:

SCC staff is still attending meetings with the Canadian Government to promote the utilization of the national standardization system. The Canadian Government ratified the Kyoto protocol in December 2002. SCC is participating in meetings with Industry Canada and Environment Canada to seek conformity assessment opportunities for its accreditation programs e.g. EMS registration bodies. SCC will keep you updated on this matter.

5.8 PERSONNEL CERTIFICATION BODIES ACCREDITATION PROGRAM (PCBAP)

The EMS/QMS auditor certification body accreditation program will be superseded by PCBAP. To date, interest in the new revised program is increasing, from both bodies with delegated authority (licensing agencies) to voluntary certification bodies (Canadian Coast Guard, NRCan, CCHREI, Canadian Registered Health and Safety Professionals etc. SCC staff has been meeting with many different organizations providing certification services over the past year.

SCC has finalized its program documentation including the fee structure. The program is expected to be formally launched shortly.

6.0 <u>STAFFING IN CONFORMITY ASSESSMENT</u>

There have been several changes over the last few months in the Management Systems Division. Stephen Cross has moved from Manager - PALCAN and Certification and now joins us as Manager – Management Systems. Martin Goldenberg has recently been hired as Program Officer and Loreto Lamb has left Management Systems to move into a new position in the Communications Marketing Division of the SCC.

7.0 <u>ADMINISTRATIVE ITEMS</u>

Please note that offices of the SCC will be closed for the holiday season from 2003-12-25 to 2004-01-05. SCC staff and auditors would like to wish you all a safe and happy holiday!

We appreciate all suggestions, feedback and questions. Kindly forward any comments, questions and/or suggestions to:

Sylvia Bienvenu Tel: (613) 238-3222 (ext. 439) Fax: (613)569-7808 sbienvenu@scc.ca



Date: November 13, 2003

To: QS-9000 Certification Bodies

From: AIAG Quality/Certification Department

Re: Clarification – QS-9000 Auditor Certificate Renewal Policy

Dear Certification Body:

In a memo dated March 7, 2003, the Supplier Quality Requirements Task Force reiterated the policy for QS-9000 certificate renewal requests. According to that memo, QS-9000 Certificate Renewal Requests would be accepted for a grace period of 30 days after the certificate expiration date.

Please note that if a Certification Body fails to renew an auditor's certificate by the certificate expiration date, the auditor is no longer qualified to conduct QS-9000 audits until such time that a) the certificate is renewed within the 30-day grace period or b) the auditor attends and passes the QS-9000 Certification program (4 ¹/₂ day session).

Example: Auditor certificate expires October 1, 2003. A certificate renewal request was submitted on October 10, 2003 (within the 30-day grace period). The certificate renewal request was reviewed and approved on October 13, 2003. The auditor is not qualified to conduct audits from October 2, 2003 through October 12, 2003.

It is the Certification Body's responsibility to inform their auditors of the QS-9000 certificate renewal policy. AIAG does not send notifications to the auditors. Please ensure that all of your auditors receive the QS-9000 Certificate Renewal Policy, as it will be strictly enforced.

If you have any questions please feel free to contact the AIAG Quality/Certification Department at (248) 358-3570, fax (248) 223-5713, or email <u>quality@aiag.org</u>.

Sincerely, AIAG Quality/Certification Department

IASG SANCTIONED QS-9000:1998 THIRD EDITION **INTERPRETATIONS**

(Previously Released: March 31, 2003)

Effective date: November 1, 2003

(Underlined are the changes/additions to the Interpretations in the previous 03-31-03 release.

The changes in this release include:

- Entire Section 4.10.6 "Supplier Internal Laboratory Requirements" Entire Section 4.10.7 "Supplier External Laboratory Requirements" Item 40. in Appendix I: "Notification of Probation" The Glossary definition of an "Accredited Laboratory"

To be used by DaimlerChrysler/Ford Motor Company/General Motors Recognized Accreditation Bodies

QS-9000 Qualified Registrars, Suppliers and Interested Parties with QS-9000:1998 Third Edition.

IASG QS-9000:1998 Sanctioned Interpretations will only be updated based on substantial need, and not more frequently than once every six months. QS-9000:1998 Third Edition requirements are not revised by these interpretations, the latter's purpose being to provide clarification and assistance relative to implementation issues of the QS-9000:1998 Third Edition requirements.

- I. INTRODUCTION
- II. **QS-9000 INTERPRETATIONS**
- Α. General
- B. **IASG Protocol**
- C. Table of Contents – Interpretations
- D. Interpretations and Information Items

Copyright November 1, 2003. All rights retained by DaimlerChrysler, Ford Motor Company and General Motors, with permission given to members of the IASG, DaimlerChrysler/Ford Motor_Company/General Motors recognized accreditation bodies, accredited ISO 9000 registrars, automotive OEM customers and suppliers, and industry media, to reproduce this document for the purposes of improving the understanding and communication of QS-9000 Interpretations. This copyright must be displayed.

CONTACT: Peter B. Lake

Chairman, IAAR Auto Sector Contact for the International Automotive Sector Group, IASG IASG <u>E-MAIL ADDRESS</u>: Questions <u>should</u> be submitted through http://www.QS-9000.org.

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, one representing IQNET and one representing the IIOC.)

3. DaimlerChrysler/Ford Motor Company/General Motors Supplier Requirements Quality Task Force (Three).

The group meets periodically to discuss and resolve interpretation issues relative to the QS-9000:1998 criteria and third party registration of auto suppliers to QS-9000:1998. The attached interpretations are recognized by the DaimlerChrysler, Ford Motor Company, General Motors Supplier Quality Requirements Task Force, the participating ISO 9000:1994 Accreditation Bodies and QS-9000:1998 qualified registrars.

The current participating members of the IASG are:

- Big Three Recognized Accreditation Bodies: Randy Dougherty, RAB; Thomas Facklam, TGA; Steve Keeling, JAS-ANZ (PAC), and Mr. K. Groen, (RvA).
- DaimlerChrysler/Ford Motor Company/General Motors Supplier Quality Requirements Task Force: Hank Gryn of DaimlerChrysler; Russ Hopkins of Ford Motor Company; Joe Bransky of General Motors.
- QS-9000 Qualified Registrars: From the IAAR: Peter Lake (IASG Contact), Garnett Davis, Michael Hochschwender, Bill Vosburg; From IIOC: Peter Herrmann; From IAAR and IQnet: Malcolm Phipps.

This release is sanctioned, and its interpretations considered binding, by the DaimlerChrysler/ Ford Motor Company/ General Motors Supplier Quality Requirements Task Force. The sanctioned interpretations are effective as of the date shown in parentheses at the end of the heading related to each sequential reference number.

B. How To Communicate

To submit questions or issues to the IASG for consideration, e-mail inquiries, in English, to the IASG E-mail Address via internet at www.QS-9000.org. To obtain a copy of the latest IASG Sanctioned QS-9000 Interpretations, they may be accessed on the Internet World Wide Web at http://qs9000.asq.org/sancl.html.

The interpretations and other information such as an updated list of qualified QS-9000 accreditation bodies, qualified QS-9000 registrars, or QS-9000 registered suppliers, may be accessed on the QSU Publishing Internet Web Page (http://www.whosregistered.com/qs-9000). This database also lists the recognized accreditation and QS-9000 qualified certification body/registrar offices.

Worldwide QS-9000 Certified Company DatabaseQSU Publishing Company - Tel. No.: 703-359-8460 (North America only: 866-225-3122)

In Europe, one contacts Carwin Continuous, Ltd. at Tel No. 44-1-708-861333 or Fax No. 44-1-708-867941.

II. QS-9000 INTERPRETATIONS

A. General

A current IASG clarification is labeled by a sequential reference number and a letter referring to the category in which it is found. Subsequent changes in an interpretation will show the same category/sequential number, but a new "Revision" date is so noted in the Table of Contents. The sanctioned interpretations are effective as of the date shown in parentheses at the end of the heading related to each sequential reference number. Dates are shown in month/day/year format. All references are to QS-9000:1998 Third Edition, unless otherwise stated.

IASG Sanctioned QS-9000 Interpretations:

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

- Applicability (A)
- Implementation (I)
- Section I: Criteria: Subdivided by the 20 QS-9000 Elements within Section I (C)
- Section II: Company-Specific Requirements (C)
- Appendices A J (AP)
- Glossary (G)
- Process (P)
- Registration/Accreditation (R)
- Training (T)
- Information (INF)

Any questions for the IASG should be directed to the IASG E-mail Address on the World Wide Web at http://www.QS-9000.org.

Because these interpretations are a binding extension of the DaimlerChrysler/Ford Motor Company/General Motors Quality System Requirements, QS-9000:1998 Third Edition, they should be a part of every QS-9000 supplier's Contract Review documentation, and every QS-9000 qualified registrar's audit information file.

B. 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 DaimlerChrysler, Ford Motor Company and General Motors 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) Attendance at IASG meetings is critical and is expected. Repeated absences may result in being replaced. The IASG will not typically schedule far in advance.

C. TABLE OF CONTENTS OF SANCTIONED QS-9000 INTERPRETATIONS

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D. INTERPRETATIONS AND INFORMATION ITEMS

General Information

1. AIAG WEBSITE: http://www.aiag.org/quality

Other general information and links to OEM websites relative to QS-9000 may be available at the above AIAG website.

2. Sanctioned Interpretations Submissions: http://www.QS-9000.org As stated in this document in the introductory language, the IASG receives and looks at all submissions of substance, but does not and cannot respond to them individually. In most cases we find the interpretation can be reached correctly by discussions with your registrar or by them with their accreditation body. Continued submissions are accepted – please use the website (http://www.QS-9000.org) so that communication to others on the IASG is facilitated.

SECTION I: ISO 9000 – BASED REQUIREMENTS (C)

Element 4.1 Management Responsibility

C1 Certification Body/Registrar Notification (4.1.6.1) (01/22/99)

General Motors Level II Containment is treated the same as "Level II Controlled Shipping".

C8 General Motors "Level II Containment" (4.1.6.1) (02/29/00)

"New Business Hold-Quality" replaces "Level II Containment" as the status which requires GM suppliers to notify their certification body/registrar.

NOTE: "New Business Hold – Quality" status is an additional status level for GM suppliers following Level II Containment.

Element 4.6 Purchasing

C9 Supplier Development (4.6.2.1) (07/01/01)

"Goal of subcontractor compliance" requires subcontractors to achieve compliance within a defined period of time not to exceed 18 months from the effective date of this sanctioned interpretation. Minimum subcontractor compliance shall be certification by an accredited certification body to a current version of the ISO 9000 Quality Management Series of Standards, excluding ISO 9003; plus any requirements specified by the customer. Assessment by an OEM or an OEM-approved second party will be recognized as meeting subcontractor compliance requirements to 4.6.2.1.

Note: The second note under 4.6.2.1 referencing "prioritization" does not negate this requirement.

Element 4.9 Maintaining Process Control

C7 Maintaining Process Control (4.9.2) (11/01/99)

The intent of this requirement is based on the maintenance of the process and not the level of the indices' value. To maintain (or exceed) requires two components:

- (1) Monitoring of the process over time to verify capability and stability; and
- (2) If the process is capable and stable, then to verify that the process meets the requirements as described in PPAP I.2.2.9.3.

Element 4.10 Inspection and Testing (11/01/03)

C11 Supplier Internal Laboratory Requirements, (4.10.6) (ref. ISO/TS 16949:2002 cl. 7.6.3.1)

A supplier's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test or calibration services. This laboratory scope shall be included in the quality management system documentation. The laboratory shall specify and implement, as a minimum, technical requirements for:

- adequacy of the laboratory procedures,
- competency of the laboratory personnel,
- testing of the product,
- capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.), and
- <u>review of the related records.</u>

Note: Accreditation to ISO/IEC 17025 may be used to demonstrate supplier inhouse laboratory conformity to this requirement but is not mandatory.

C12 Supplier External Laboratory Requirements, (4.10.7) (ref. ISO/TS 16949:2002 cl. 7.6.3.2)

External/commercial/independent laboratory facilities used for inspection, test or calibration services by the supplier shall have a defined laboratory scope that includes the capability to perform the required inspection, test or calibration, and either:

- there shall be evidence that the external laboratory is acceptable to the customer, or
- the laboratory shall be accredited to ISO/IEC 17025 or national equivalent. (See glossary).

Note 1: Such evidence may be demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent. **Note 2:** Where a qualified laboratory is not available to perform calibration services for a given piece of equipment, such calibration services may be performed by the equipment manufacturer. In such cases, the supplier should ensure that the requirements listed in Sanctioned Interpretation, C11 (above), have been met.

Element 4.11 Control of Inspection, Measuring and Test Equipment

C2 Calibration Laboratory Requirements, (4.11.2.b.1) (01/22/99)

Due to a current lack of suppliers of accredited calibration services for calibration laboratories, compliance to QS-9000:1998 Third Edition laboratory requirements, 4.11.2.b.1, may be satisfied if the supplier has a documented plan to assure that, effective January 1, 2001, the supplier is fully in compliance with QS-9000:1998 Third Edition cl. 4.11.2.b.1 requirements.

More information is available in a QS-9000 Laboratory Requirements Self Study Guide available from AIAG at (USA) 248-358-3003 and on the AIAG website at http://www.aiag.org/quality.

C3 Test Equipment at Work Station (QS-9000, cl. 4.11.2) (01/22/99)

Individuals verifying gages at their in process work station do not have to comply with the requirements for test laboratory if they are not calibrating equipment at their work station.

If individuals are calibrating equipment, they shall be included in the laboratory organization.

C4 Design and Development Parts (QS-9000 cl. 4.10.7 and 4.11.2.b.1) (01/22/99)

The requirements of cl. 4.10.7 and 4.11.2.b.1 apply only to production or service parts or production materials released by the customer for purchase or manufacture, including all testing for PPAP requirements. This excludes testing for parts or materials under design or development.

SECTION II: CUSTOMER-SPECIFIC REQUIREMENTS (C)

C5 Customer-Specific Requirements (QS-9000, Section II) (01/22/99)

Customer-specific requirements take precedent over the QS-9000 requirements.

C6 Appendix C: Special Characteristics (11/01/99)

Across from "Definition:" under CHRYSLER, above the symbol "DIAMOND - <D>" the wording is entirely replaced by:

"(this) Identifies a Key Quality Characteristic of a part, system, process or test specification that is sensitive to variation with the potential of degrading customer satisfaction. For all Diamond characteristics, a process control plan is required."

C10 Ford Motor Company Specific Requirements (07/01/02)

- Third Party Registration Requirements: Unless waived in writing by Ford Motor Company for the supplier site, third party registration to QS-9000 or ISO/TS16949 is required to meet the "capable quality management system" element of Q1 2002. This is a global requirement effective February 1, 2002 for production suppliers to North America and Europe.
- 2. Manufacturing Site Assessment

i. The QOS Assessment Guideline currently specified by QS-9000 Ford-Specific

Requirements do not identify suitable metrics. Some Quality Operating System (QOS) metrics are given by the Manufacturing Site Assessment of

Q1

2002, available through https://web.bli.ford.com/.

 Tier 1 suppliers to Ford Motor Company are authorized to use the Manufacturing Site Assessment for sub-supplier evaluations per C9 of these Sanctioned Interpretations and per the Ford letter of authorization on <u>https://web.bli.ford.com/</u>. Note: if access to <u>https://web.bli.ford.com/</u> is not available, Ford tier 1 suppliers can provide the necessary documents from the web site.

APPENDICES (AP)

AP1 Change in QS-9000 Sanctioned Database Provider (03-31-03)

Effective March 20, 2003, QSU Publishing is replacing ASQ as the QS-9000 Sanctioned Database provider. QS-9000 Recognized Accreditation Bodies and QS-9000 Qualified Registrars should send the required information to QSU Publishing.

The specific Foreword and Appendix references affected by this change are:

Foreword To The Third Edition

Certification bodies/registrars are required to promptly report QS-9000 registrations to QSU Publishing Company, the administrator of the sanctioned QS-9000 Worldwide Registered Company Database. A quarterly directory is available for a fee, and the information can be accessed on the QSU Publishing Internet Web Page

(http://www.whosregistered.com/qs-9000). This database also lists the recognized accreditation and QS-9000 qualified certification body/registrar offices.

Worldwide QS-9000 Certified Company Database QSU Publishing Company

Telephone No.: 703-359-8460 (North America only: 866-225-3122)

Appendix G: QS-9000 Accreditation Body Implementation Requirements (03-31-03)

A. QUALIFIED CERTIFICATION BODIES/REGISTRARS shall:

16) Notify QSU Publishing, the provider of the sanctioned **QS-9000** Registered Company Database, within ten (10) working days of all sites registered to **QS-9000** and of changes in registration status of current registered sites. All information shall be communicated in the QSU Publishing-specified format. All information requested shall be provided.

B. RECOGNIZED ACCREDITATION BODIES shall (except as noted below):

14) Notify QSU Publishing, the provider of the sanctioned **QS-9000** database, within ten (10) working days of all certification bodies/registrars qualified to issue certificates citing compliance with **QS-9000**. Changes in the qualified status of current certification body/registrars shall also be promptly communicated to QSU Publishing. All information shall be communicated in the QSU Publishing-specified format. All information requested shall be provided in the submission.

Appendix I: Additional QS-9000 Registration Requirements

22. QSU Publishing Sanctioned Worldwide Registered Company Database Notification (03-31-03)

The **QS-9000** certificated supplier information shall now be provided to QSU Publishing Company, the sanctioned database provider, by each **QS-9000** qualified certification body/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 9000 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 (U.S. SIC or NACE)
- 15) Issuing Certification Body/Registrar Name
- 16) Issuing Certification Body/Registrar Office Address
- 17) Issuing Certification Body/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 QSU Publishing-specified format. Each **QS-9000** qualified certification body/registrar must maintain and can make public their list of **QS-9000** registered companies.

34. No Certification Body/Registrar Endorsement (03-31-03)

All **QS-9000** certification bodies/registrars that are listed in the QSU Publishing **QS-9000** Database (http://www.whosregistered.com/qs-9000) are considered **QS-9000** qualified by Chrysler, Ford and General Motors.

40. Notification of Probation (11-01-03)

When a certification body/registrar places an existing **QS-9000** registered company on probation because of nonconformances or a violation of the rules of registration; the certification body/registrar shall notify, within 10 working days:

- <u>each Chrysler/Ford/General Motors Supplier Quality Requirements Task Force</u> <u>representative, and</u>
- the QS-9000 database administrator,

of this action. These notifications are intended to remain confidential to the certification body/registrar, client, and the Chrysler, Ford, General Motors representatives.

This notification process is a requirement for all **QS-9000** qualified certification bodies/registrars, and **QS-9000** certified suppliers.

41. Registrar Oversight (03-31-03)

Table A, Office Assessments*

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 Sanctioned QS-9000 Interpretations** (e.g. Timely notification of registrations and changes to QSU Publishing).

Glossary (11-01-03)

Accredited Laboratory

Accredited Laboratory is one that has been reviewed and approved by a nationallyrecognized accreditation body, or as an alternative a customer recognized accreditation body, conforming to ISO/IEC Guide 58 for calibration or test laboratory accreditation to ISO/IEC Guide 17025, or national equivalent.

Note: The definition also applies to the QS-9000 reference manuals currently in effect.

REGISTRATION/ACCREDITATION (R)

R1 Big Three Requirements for Third Party Registration to ISO/TS 16949 (02/29/00)

Information regarding ISO/TS 16949 and the IATF globalautomotive registration process may be found on the IATF International Automotive Office Bureau (IAOB) website at http://www.IAOB.org.

R2 Findings (01/01/00)

Registrar and Accreditation Body auditors are restricted to only three types of findings during an audit: "major non-conformances", "minor non-conformances" and "opportunities for improvement". No other form or type of finding may be issued.

R3 Probation and Delisting of Suppliers (03/31/00)

A supplier's registration will be placed on immediate probation * by their registrar if any of the following occur:

- The Registrar issues a major non-conformance **; or
- The supplier is notified by Ford Motor Company of "Q-1 Revocation", by DaimlerChrysler of "Needs Improvement" ("Quality Rating only – not Total Rating"), or by General Motors of "New_Business Hold – Quality"; or
- Minor non-conformance corrective action is verified by the Registrar as not being effectively implemented within 60 days of the date identified; minor non-conformance closure may require on-site verification by the Registrar.

* Probation replaces the previously used term 'suspension' and is defined as notice given a supplier by their registrar that failure to take corrective action to eliminate the major or minor nonconformities, or Ford Motor Company "Q-1 Revocation", DaimlerChrysler "Needs Improvement", or General Motors "New Business Hold-Quality" will result in a supplier's certificate being revoked by their registrar (refer to clause R3.E, R3.F, R3.G).

** The QSA states "...a number of minor nonconformities against one requirement which when combined can represent a total breakdown of the system and thus be considered a major nonconformity." Additionally, minor nonconformances, which occur on successive surveillance assessments, should be viewed as a pattern. If a pattern of minor nonconformities occurs over successive assessments, it may represent a total breakdown of the system and a major nonconformance shall be issued.

A. If Probation results from the issuance of a major nonconformance, the registrar will notify the supplier in writing of the probation within five days of the issuance of the major nonconformance (whether or not an appeal is initiated).

IASG SANCTIONED QS-9000 INTERPRETATIONS, Copyright 11/01/03. All rights retained by DaimlerChrysler, Ford Motor Company, General Motors.

- B. If probation is warranted for any other reason, written notification will be provided to the supplier immediately.
- C. In the event probation is the result of the Registrar issuing a major nonconformance or the supplier is notified by Ford Motor Company of "Q1 Revocation," by DaimlerChrysler of "Needs Improvement" ("Quality Rating only – not Total Rating"), or by General Motors of "New Business Hold – Quality," the supplier shall complete a corrective action plan. The supplier shall submit the corrective action plan to the Registrar and to the affected customer(s) within 10 business days of the date of the letter of notification of probation. The supplier corrective action plan shall be consistent with the affected customer(s) requirements including correction steps, responsibilities, timing information, and key metrics to identify effectiveness of the action plan.

- D. If the certification is "corporate" then all sites under the corporate certification shall be placed on probation. If a "corporate" certification is placed on probation, it cannot be changed, such as being broken-up into many "sitespecific" registrations. While on probation from QS-9000, "new" locations may be added to the corporate registration, or a location within a corporate certification may be removed if such location is completely "closed."
- E. If a supplier files an appeal with their registrar, the supplier and registrar will have 30 days from notification to complete the appeal process. The affected customer(s) shall be notified by the supplier of the appeal. At the completion of this 30-day period, if the probation is continued, the registrar will notify the <u>QSU Publishing</u> database of the result, and the supplier will notify those customers that have required them to obtain QS-9000 registration.
- F. Before any probation can be lifted, the registrar will conduct an on-site assessment of appropriate length to verify effective implementation of all corrective actions.
- G. If probation is not lifted within four months of it's issuance, the registrar shall revoke a supplier's certificate. Exceptions to this revocation shall be justified by the registrar in writing based upon the registrar's on-site review of the supplier corrective action plan's effectiveness and agreement obtained from:
 - the affected customer(s), and
 - the accreditation body(s) whose mark appears on the certificate.

The registrar shall provide the supplier in question a copy of this justification.

- H. Registrars will notify the <u>QSU Publishing</u> database of all probation, and of all registration de-listings for failure of the supplier to comply with QS-9000 requirements.
- If a supplier transfers registration services from one registrar to another while a probation is pending resolution, the accepting registrar cannot register same supplier until the accepting registrar has conducted a complete registration assessment for which the on-site registration duration cannot be less than shown in the man-day table of Appendix H – regardless of the reason for the transfer.
- J. Registrars may wait for a period, not to exceed five working days, after an audit event, before issuing a major non-conformance to a supplier.
- K. (07/01/01) If a supplier is placed on probation as defined in R3, and thereafter such probation is lifted by the registrar, the interval between subsequent surveillance audits shall not exceed 6 months for a minimum period of 18 months from the date the probation was lifted. For "Corporate" certificates, as a minimum, the site(s) established as the source(s) of the probation shall each be subject to this same surveillance requirement. This requirement shall survive a change of registrar or supplier site ownership.

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R4 Changing Registrars (01/01/00)

When a registered QS-9000 supplier switches from one registrar to another, the supplier shall notify their current (previous) registrar, and their OEM customers. The supplier notification shall include a brief explanation to the OEM customer. If a supplier has been on probation, or delisted, from QS-9000 registration, that supplier shall notify any potential "new" registrar of this fact. The "new" or "accepting" or "transfer" registrar shall then notify in writing all OEM customers, as well as the current or past registrar, as to whether the "new" registrar has (or has not) "accepted/agreed" to take the supplier as a client.

R5 Probation and Delisting of Certification Bodies and/or Accreditation Bodies (01/01/00)

It is expected that all QS-9000 qualified certification bodies/registrars and accreditation bodies follow, support, and enforce the supplier and third party system requirements of QS-9000. Violations can lead to probation and delisting. (See QS-9000, Third Edition, Appendix G.C.5)

R6 Clarification Regarding Automotive Representatives Oversight of a QS-9000 Audit Event (11/01/99)

The definition that takes precedence (especially regarding notice and client permission) is that found in Appendix B, i.e. the first definition quoted hereunder.

Appendix B, page 86, under INSTRUCTIONS TO SUPPLIERS CONCERNING THIRD PARTY REGISTRATION, paragraph 4, "Suppliers shall permit the certification body/registrar's audit team to be accompanied by representatives from a witnessing accreditation body, and DaimlerChrysler, Ford Motor Company or General Motors SQRTF representatives or their designees, without objection or a requirement for prior notice."

Appendix I.41 "REGISTRAR OVERSIGHT – QS-9000 recognized accreditation bodies shall: (bullet 5) "Allow, upon request, DaimlerChrysler, Ford Motor Company, or General Motors SQRTF representatives or their designees, to accompany accreditation bodies on witness audits of certification bodies/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."

R7 Joint Ventures, Mergers, Acquisitions (07/01/01)

A supplier shall notify its registrar of the following site changes: closure, transfer of ownership including merger, acquisition or joint venture. Notification shall be provided by the supplier to the registrar of record within 30 days from the time such site change was announced. Failure of the supplier to comply with the notification requirements shall result in a major non-conformity issued from the registrar of record, a major nonconformance which can only be closed by the registrar conducting a special on-site surveillance audit, up to and including a full audit.

Within 60 days of supplier notification to the registrar of record, such registrar shall complete the following: determine the timeliness, scope and extent of surveillance audit requirements; and if necessary, conduct a special surveillance assessment, up to and including a full audit.

R8 Expiration of ISO 9001:1994 and ISO 9002:1994 on December 15, 2003 - certificate language for QS-9000 certificates to be recognized after December 15, 2003 (07/01/02)

Any new or renewed QS-9000 certificate issued after July 1, 2002 shall not reference ISO 9001:1994 or ISO 9002:1994 other than in one of the following statements which must be included on the certificate: "Registered to QS-9000:1998 (Based on and including ISO 9001:1994)" or "Registered to QS-9000:1998 (Based on and including ISO 9002:1994)". All QS-9000 certificates with dates extending beyond December 15, 2003 shall comply with this wording by December 15, 2003. [All other aspects of Appendices G.A.13, I.18, and I.23 shall remain in effect.]

The Registrar may provide a letter to suppliers indicating that the above statement confirms the supplier is certified to ISO 9001:1994 or ISO 9002:1994 until December 15, 2003.

QS-9000:1998 certificates shall not reference ISO 9001:2000. Note: ISO 9001:2000 requires a separate certification.

QS-9000:1998 certificates shall not show an ending date later than December 14, 2006. Note: the current version of QS-9000 (TE supplement) and the current version of the semi-conductor supplement to QS-9000 shall also remain in effect until December 14, 2006.

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