Registration Bodies Bulletin

JUNE 2002

Welcome to our second issue of the *Registration Bodies Bulletin*

We hope that the previous issue was both interesting and informative. In order to provide you with information that is useful, we welcome your comments regarding information that you would like to see included in this bulletin. We have structured this edition of the RB Bulletin in three sections: ***Items for Noting, Items for Action*** and ***Items for Implementation***. Any suggestions for improvement should be forwarded to Monica Pantusa (mpantusa@scc.ca)

Part 1 Items for Noting

INSIDE SCC

1.1 APPOINTMENTS

On August 02, 2001, the SCC announced that Mr. Hugh A. Krentz had been formally appointed chair. Mr. Krentz, chairman and CEO of the Canadian Steel Construction Council and the Executive Director of the Steel Structures Education Foundation, became the Standards Council's eighth chair and succeeded Ms. Linda Lusby whose term ended in April 2001.

The chair of the Standards Council of Canada is appointed by the Minister of Industry and oversees a 15 person volunteer Council, which governs the organization. The chair works closely with the Council and the executive director to make strategic decisions that will benefit the National Standards System.

Upon the recommendation of the Minister of Industry, Mr. Peter D. Clark will remain as Executive Director of the Standards Council of Canada, for another three year term effective April 26th, 2002.

SCC is also pleased to announce the appointment of Mr. Pat Paladino, P. Eng, to the position of Director of Conformity Assessment, effective May 6, 2002.

Mr. Paladino has several years of experience in certification, testing and standards development gained through positions he has held as V.P., Engineering at Intertek Testing Services, and as V.P. Certification and V.P. Standards Development at the Canadian Standards Association.

Mr. Paladino succeeds Don Wilson, who recently announced his retirement from the Standards Council of Canada (SCC). Mr. Wilson will remain with the SCC, in the capacity of Director, Business Development, until his retirement later this year.
Correspondence formerly directed to Mr. Wilson should now be sent to Mr. Paladino's attention. Mr. Paladino may also be contacted by telephone at (613) 238-3222 ext. 467, or by email at ppaladino@scc.ca.

Ms. Monica Pantusa joined the Conformity Assessment Team in the position of Program Officer, Management Systems, effective March 20, 2002. Monica has been with the SCC since March 2001, and had been working in our Human Resources Division prior to her appointment to Program Officer.

PROGRAM ADMINISTRATIVE ITEMS

1.2 SCC CONFORMITY ASSESSMENT CUSTOMER FEEDBACK

As indicated in our previous RB Bulletin, the QMS and EMS programs will begin use of a confidential customer feedback questionnaire. We will be distributing these following each audit, effective July 2002.

The objective of this survey is to assist us in evaluating both the quality of audit services conducted on behalf of the Standards Council of Canada (SCC) and the professionalism of the Task Group on Quality/Environmental Management Registration Systems Organizations (TG Q/EMSRO) representative conducting the audit activity. Our intent is to use the feedback which you provide to enhance the overall quality of our Program(s). Your assistance is greatly appreciated.

1.3 PAC/IAF PEER EVALUATION

The SCC underwent a peer evaluation during the second and third weeks of April, 2002. IAF and PAC auditors were on hand to conduct a re-evaluation of our QMS program, as well as initial evaluations of our EMS and Product Certification Programs.

Program staff were happy to receive the results, and are currently responding to the audit findings. Successful completion of this process will enable SCC's continual IAF MLA signatory status, as well as taking us one step closer to becoming a signatory to the IAF/PAC MLA for EMS and Product.

1.4 SCC AUDIT ACTIVITIES

REMINDER:
In order to ensure that your accreditation related audit activities are processed in a timely fashion, responses should be submitted to the SCC in one complete package. An inability to comply with this request may result in unnecessary delays. In the event that you are unable to comply with this request, kindly contact Ms. Sylvia Bienvenu (613-238-3222, ext 429; sbienvenu@scc.ca,) in order to discuss alternate arrangements.

1.5 INCREASED CCAC PARTICIPATION REQUESTED

We would like to take this opportunity to thank those members of the CCAC for taking the time to respond to our requests for comments and for providing us with valuable feedback with regards to program related documents and requirements distributed for review and input. The SCC provides our clients with opportunity to comment and provide input on program related criteria (ISO, IAF, CASCO) and meeting documentation for review and comment prior to all IAF Plenary and IAF

Technical Committee meetings. We would like to remind all members of CCAC of the importance of their active participation in this process and urge you to take advantage of the opportunity to represent your opinions.

1.6 IAF/ILAC CONFERENCE 2002 ON ACCREDITATION IN GLOBAL TRADE

For the first time ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum) will hold a joint Conference on Accreditation in Global Trade in Berlin, from September 23-25, 2002. It will focus on conformity assessment which is gaining ever greater importance internationally thus having a great impact on global trade.

The objective of this ILAC/IAF Conference is to discuss all issues of mutual interest among the conformity assessment community and to provide a forum with topics addressing representatives from:

Certification bodies
Testing and calibration laboratories
Inspection bodies
Authorities and politicians
Industry
International standardization and accreditation

For additional information regarding the Conference and/or IAF Annual Meeting, please log on to http://www.ilac-iaf-2002.de, http://www.ilac-iaf-2002.de/pre2.html.

1.7 ISO/TC 176 INTERPRETATION PROCESS

At its 18th meeting, July 2000, ISO/TC176 recommended the adoption of a formal interpretation process for the ISO 9000 quality management system standards. The ISO TMB, at its September 2000 meeting, noting some concerns with the robustness and timeliness of the recommended process, approved it as a pilot project for a one year period.

At its recent Birmingham plenary, ISO/TC 176 conducted a review of the results obtained. Opportunities for improvement of the process were identified and revisions were introduced, with a view to improve the robustness of the process without reducing its timeliness. As a consequence, it was felt that the additional time is needed to test and validate the revised interpretation process.

In order therefore to validate the improvements made to the interpretation process, ISO/TC 176 recommended unanimously that the modified process should be granted a one year extension as a pilot project.
The above referenced document is posted on the TC 176 website and is available for viewing at www.tc176.org.

1.8 25TH ISO GENERAL ASSEMBLY

The 25th ISO General Assembly will be held at the Conference City Centre Norra Latin, Stockholm, Sweden, 23-28 September, 2002.

Registration and Programme Information is available at the following web site www.sis.se/iso2002.

1.9 IAF/ISO: CLOSER COOPERATION ON PROTECTING INTEGRITY OF ACCREDITATION

Representatives of the International Accreditation Forum, Inc. (IAF), International Laboratory Accreditation Cooperation (ILAC) and the Conformity Assessment Committee (CASCO) of ISO formed the IAF-ILAC-ISO/CASCO Joint Working Group on Image and Integrity of Conformity Assessment in December 2000, to discuss what contribution IAF, ILAC and CASCO could collaboratively make to protect the customers and users of conformity assessment services from unethical or inappropriate practices.

The Executive Committee of the International Accreditation Forum, Inc. (IAF) met in Vancouver at the end of May 2002. The Executive Committee re-affirmed its commitment that IAF will work tirelessly to ensure that conformity assessment activities meet the expectations of industry and consumers and operate with the highest integrity and competence.

The Executive Committee welcomed the release of a Communiqué by the Joint Working Group on Image and Integrity of Conformity Assessment, a copy of which has been attached.

1.10 IAF SURVEY ON ACCEPTANCE OF ACCREDITED CERTIFICATES 2001

Attached for your information and use, is a press release announcing the results of a survey carried out by the IAF in late 2001 regarding the acceptability by customers of accredited certificates. Copies of the survey results may be obtained from the IAF Secretariat, as per the contact information contained in the press release.

1.11 CASCO ACTIVITIES

Seventeenth (17th) Annual Meeting of the ISO Committee on Conformity Assessment

The Seventeenth (17th) Annual Meeting of ISO/CASCO was held in Geneva on 29-30 November 2001. The meeting was attended by one hundred and ten (110) delegates representing thirty-six (36) ISO members, five (5) international liaisons, eight (8) international organizations, IEC and CEN/CENELEC. Participants from the Canadian Advisory Committee for ISO/CASCO (CAC/CASCO) included Mr. William Cunningham (CAC/CASCO Chair, Canadian General

Standards Board), Mr. Allan Wilson (CAC/CASCO Secretary) and Mr. David Shortall (SCC, Convenor of ISO/CASCO Working Group 22 – *Revision of ISO/IEC Guide 60 - Code of Good Practice for Conformity Assessment*).

During the Plenary, the Canadian delegation commented on a number of issues under consideration including efforts to obtain information on the balance / composition of national mirror committees, the activities of WG 22 and the need for a wider distribution of the ISO/CASCO Strategic Plan for communication purposes.

Key elements of the 17th ISO/CASCO Plenary included:

1. Implementation of ISO/CASCO's 1st Strategic Plan - Strategies 2002-2004: Serving the Needs of Global Trade. The document addresses ISO/CASCO's commitment to enhance the *market relevance* of its work, its *leadership* in the proper use of its documents and in supporting developing country participation in its work and the development of their conformity assessment infrastructure, its *communication* to the global conformity assessment community and its *optimization* – coordination of its projects to ensure adequate alignment among its documents.

2. Common Elements & Functional Approach – ISO/CASCO confirmed that the ISO/CASCO Chairman's Advisory Group (CAG) would establish deadlines for the implementation of "common elements" in individual ISO/CASCO projects. ISO/CASCO also formally endorsed the "functional approach" to the development of Standards and Guides. Briefly, the "functional approach" advocates the description and organization of ISO/CASCO Standards and Guides on the basis of core functions and not on the structure of particular conformity assessment bodies. Taken together, these measures aim to establish a more coherent and market-friendly framework of ISO/CASCO documentation.

3. Balanced Stakeholder Representation – ISO/CASCO welcomed six new 'A-Liaison' members (IFAN, IATCA, UILI, IQNet, BIPM and OIML) and noted the ongoing need to capture the needs and inputs of industry and regulatory concerns in ISO/CASCO work. ISO/CASCO also accepted the Canadian proposal for a more in-depth survey of the participation of stakeholders in national mirror committees and working groups (CASCO Resolution 26/2001).

Cooperation with DEVCO – ISO/CASCO welcomed the establishment of a joint DEVCO-CASCO Group on Conformity Assessment Strategies that employs an interactive website to involve more developing countries in the process of establishing ISO/CASCO documents. ISO/CASCO also noted Canada's support for two developing country delegates (Tunisia and Costa Rica) in the activities of WG 22 ***ISO/CASCO) - Geneva, 2001-11-29/30***

1.12 TIC/CAR DATABASE

The Asia-Pacific Economic Cooperation (APEC) has set up a TIC/CAR (Testing, Inspection, Calibration, Certification, Accreditation and Mutual Recognition) database of Conformity Assessment Bodies (CAB's). This will be an on-line database to serve as a source of information about CAB's in the APEC region providing testing, inspection, calibration, certification and accreditation services. Registering with the database is voluntary but may increase the visibility of your organization by promoting your services to a wide audience within the Asia-Pacific region. For more information, visit the website at http://www.apectic-car.org/. or http://www.apeca3ca.org/.

Part 2 Items for Action

2.1 SCC/RAB

Registrar Accreditation Board – Standards Council of Canada
Mutual Recognition Agreement / Multilateral Arrangement Deepening Committee

In May 2002, the Registrar Accreditation Board (RAB) and Standards Council of Canada (SCC) met to review and discuss the status of the ANSI/RAB-SCC Mutual Recognition Agreement. During the meeting, several issues were considered and discussed related to the MRA and IAF MLA including:

1. Accreditation body program operations;
2. Consistency in the application of accreditation requirements; and,
3. Harmonization of accreditation body procedures.

A need for increased collaboration between the SCC and RAB was identified for the following subject areas:

- Mutual recognition of approved scopes;
- Recognition of registration body maturity when establishing audit activities;
- Consistency in the auditing of accreditation requirements;
- Value of Accreditation;
- Harmonization of criteria to determine and conduct witness audit activities;
- Sharing of information between RAB and SCC;
- Harmonization of procedures for accreditation, scope recognition and sector qualification;
- Consistent competency criteria for accreditation body auditors;
- Consistency in the application of accreditation requirements.

In addition to the above listed subject areas, the accreditation bodies also noted the need for an increased understanding by all parties (eg. Registration bodies, registered organizations) of the purpose and intent of MRA's and MLA's.

To ensure that relevant parties were considered related to MRA and MLA implementation, the SCC and RAB determined a need for the participation of registration bodies, accreditation body auditors, and registered clients in any discussion. As such, agreement was reached to strike a MRA/MLA Deepening Committee.

Membership:
Membership of the MRA/MLA Deepening Committee is proposed as follows:

1. 2 Representatives from RAB
2. 2 Representatives from SCC
3. 1 Representative from the IAAR
   - IAAR representative to be jointly accredited and based in US
4. 1 Representative from the Canadian Conformity Assessment Conference
   - CCAC representative to be jointly accredited and based in Canada
5. 1 RAB Auditor representative
6. 1 TG-QMSRO representative
7. 1 Registered Company (RAB accreditation)
8. 1 Registered Company (SCC accreditation)

The secretariat of the MRA/MLA Deepening Committee will be held jointly by the SCC and RAB.

It is expected that relevant associations would nominate Registration Body representatives.
The Committee shall meet at least once annually, with the meetings alternating between SCC and RAB. The host organization shall serve as the secretariat with the other AB serving as the chair.

The SCC will be requesting, at the June 27th CCAC meeting, for nomination of a member to this committee. The CCAC representative will participate in this committee and act as a liaison for CCAC members.

Part 3: Items for Implementation

IAF/ISO

3.1 IAF PLENARY MEETING, KYOTO JAPAN – 2001-11-6/8

Further to our previous *RB Bulletin,* attached please find the list of the Resolutions adopted by the members of IAF at their Annual Meeting held in Kyoto, Japan on 6 and 8 November 2001. This document also includes notes on action taken on the Resolutions up to the time of preparation of the file. Registration Bodies should review and note the resolutions for information and implementation, specifically, resolutions 2001-29 to 2001-33.

The IAF Annual Meeting in 2002 will be held in conjunction with the IAF/ILAC Conference in Berlin, Germany from **15 to 21 September 2002.** As with previous meetings, the SCC will be distributing supporting documentation for your input and comment prior to the meeting. Please take the time to examine these documents and provide input.

3.2 IAF GUIDANCE TO GUIDES 62 AND 66 (ISSUE 2)

The transition period for implementation of the IAF Guidance on the application of ISO/IEC Guides 62 and 66 Issue 2 ends July 1 2002. Registration bodies are required to have fully implemented Issue 2 of the IAF Guidance by this date. As per our notification to Registration Bodies of January 2002, all *Opportunities for Improvement (OFI's)* previously cited to this Guidance Document will be considered *Corrective Actions Requests (CAR),* after July 1, 2002.

Please ensure that you have implemented all applicable changes and have addressed all OFIs by July 1, 2002. It is our plan to verify the action your organization has taken to address the OFI's during annual audit activity. As such, we will be requesting that each registration body provide a brief overview of action taken along with supporting documentation (eg. quality manual, CAN-P-10B matrix) prior to annual audit activity. We would also like to take this opportunity to remind you that the SCC reserves the right to verify how IAF related OFI's have been addressed, at any time.

3.3 IAF RESOLUTION 2001 – 30 – WITNESS AUDITS

The following Resolution was adopted at the 2001 Annual Meeting in Kyoto in November:

"*IAF Resolution 2001-30 - Witness Audits - The Annual meeting supports the principle of random sampling for accreditation body witness audits of accredited certification / registration body activities, and that this be treated by certification / registration bodies as an obligation, not a favour. The Annual Meeting directs the Board to issue guidance requiring IAF Accreditation Body Members to require accredited certification / registration bodies to have enforceable arrangements with organizations holding an accredited certificate, to ensure access to witness the certification / registration bodies audit team performing an audit at the organization's site."*

This change has been incorporated into Annex 1 of the IAF Guidance on the application of ISO/IEC Guide 61 Issue 2 Version 2. The IAF has indicated the application date of Issue 2, version 2 as 2002-07-01. The SCC will cooperate with other Accreditation Bodies and Registration Bodies to ensure the smooth implementation of this new requirement for you and your clients.

3.4 NOTIFICATIONS AND PROVISION OF FALSE OR MISLEADING INFORMATION

It has come to our attention that some registration bodies are not providing notification of organizational changes, not providing complete information, or providing misleading information. We would like to remind Registration Bodies of CAN-P-1517A Clause 3.5.2 which states " It is the responsibility of the Registration Body to advise SCC of any pertinent information or intended change in the organization such as legal status, structure, policies, procedures, resources, key personnel or facilities, which may affect conformity with the criteria and requirements for accreditation or their scope of accreditation".

Failure to provide notification to the SCC of changes, or the provision of false or misleading information may result in the immediate suspension of accreditation. In addition, any time taken by SCC to address non-conformities to Clause 3.5.2 or misleading or false information will be billed back to the registration body in accordance with the published fee structure.

3.5 ISO9001:2000 TRANSITION

As you know, the transition period for organizations to upgrade their registrations from the ISO9001/2:1994 to the new ISO9001:2000 standard has already begun. By December 14, 2003, all organizations registered to the 1994 version must be evaluated by their registrar against the 2000 version, and re-registered as conforming to ISO9001:2000.

The SCC urges you to publicize this matter as widely as possible, so that all participants in the marketplace are aware of the need to take action to upgrade QMS certificates prior to the December 14, 2003 deadline.

In order to assist you in this endeavour, in late May 2002, the SCC provided all members of CCAC with a letter which we encouraged you to circulate to all of your firms (currently) registered to the ISO90001/2:1994 standard. Further suggestions for its use included direct mailing campaigns targeting firms which had not made the transition, attaching a copy of the letter to your audit reports, posting of the document on your website, etc.

Should you require additional copies of this letter, or would like to receive it in electronic format, please do not hesitate to contact Monica Pantusa, mpantusa@scc.ca.

Reminder:
ISO9001:2000 transition witness audits are to be performed by July 31, 2002. In addition, please note that certificates to ISO9001:2000 should not be issued unless Head Office assessments and required witness audits have been completed. For further information, or to schedule a witness audit, please contact Sohini Famili at (613) 238-3222, ext. 424, by email – sfamili@scc.ca.

SECTORS

3.6 TS16949:2002 PASSED INTERNATIONALLY

Wheels in motion – an update on automotive industry standards and trends

TS16949 will replace QS9000 as the quality standard for the international automotive industry. QS-9000 has been given an extension of 3 years beyond 15th December 2003 (the expiry date of ISO9001:1994). Clients certified to QS-9000 will therefore have until 14th December 2006 to upgrade to ISO/TS16949:2002 although this may be subject to specific vehicle manufacturer requirements. New certification to QS-9000 will still be possible in the period up to 14th December 2006, but all QS-9000 certificates will become obsolete from 15th December 2003.

Certificates for QS-9000 will require amendment to be valid past 15th December 2003. IASG Sanctioned Interpretation issued on this subject will be effective from July 1st 2002. All new certificates from 1st July 2002 will be issued containing new wording. All existing certificates will be reissued before 15th December 2003 to include the new wording.

New certificates for QS-9000 can continue to be issued throughout the extended period, but must be transferred over to ISO/TS16949 by 14th December 2006. Again QS-9000 will cease to exist on 15th December 2006.

What will be the impact of ISO 9001:2000 on QS-9000 and ISO/TS 16949:1999?

ISO9001:1994, on which QS-9000 is based becomes obsolete on 15th December 2003. However, QS-9000 Supplier Quality Requirements Task Force (SQRTF) have been granted an extension of 3 years by ISO to continue to use ISO9001:1994 in conjunction with QS-9000.

QS9000

3.7 IASG QS-9000 Sanctioned Interpretation C9

Effective July 1, 2001, IASG QS-9000 Sanctioned Interpretation C9 was implemented to clarify the meaning of "the goal of subcontractor compliance" under Subcontractor Development of element 4.6.2.1 of QS-9000 3rd Edition. The Sanctioned Interpretation C9 is intended to be used in conjunction with all elements pertaining to subcontractor development within QS-9000 3rd edition, which remains in full effect.
The full text of the sanctioned interpretation for 4.6.2.1 is available on the AIAG website: http://www.aiag.org, for your convenience the link to the document is as follows: http://www.aiag.org/forms/QS-9000Info-07-01-02Final.pdf.
Any questions regarding the document should be forwarded to Karen Whitemore, 248 -358-3570.

3.8 IASG SANCTIONED QS-9000:1998 THIRD EDITION INTERPRETATIONS

(Previously Released: July 1, 2001)
Effective date: July 1, 2002
The International Automotive Task Force (IASG) has released a new Sanctioned Interpretation to the QS-9000:1998 Third Edition with an effective date of July 01, 2002.
You may obtain a copy of these interpretations via the AIAG, http://www.aiag.org/, at the following link: http://www.aiag.org/forms/07-01-02Final.pdf.
Questions should be submitted through http://www.QS-9000.org.

3.9 QUEST FORUM LEADERSHIP OPPORTUNITIES

During the July Work Group meetings in Milwaukee, WI three Work Groups will be holding elections for Chair and Vice Chair positions. **Nominations are being accepted from now until July 29, 2002**. Nominations must be accompanied by a written letter from the management of the candidate's corporation, association or organization, committing that entity to provide support for the candidate in carrying out the duties of the position (e.g., travel, time, incidental secretarial and mailing support).

Applications and/or any questions regarding the positions should be directed to:
Kim Hauswirth, ASQ,
QuEST Forum Administrator Program Manager,
khauswirth@asq.org,
tele: (414) 765-7203,
fax: (414) 765-8665.

CMDCAS

3.10 CMDCAS Interpretations

On June 20th, 2002 the CMDCAS Implementation Group met to discuss several items of relevance to the CMDCAS program. At that meeting several interpretations were provided for information and implementation by Registration Bodies as such:

3.4.1 Issuance of ISO 13485/8 certificates

Registration Bodies have requested some clarification regarding the issuance of ISO 13485/8 certificates specifically in light of the transition guidance related to ISO 9001:2000. The following questions have been posed and SCC responses provided for your information.

Q: As ISO and the IAF have indicated that ISO 9001:1994 certificates should no longer be issued after 2003-12-15, how should certificates referencing ISO 9001:1994 and ISO 13485 be addressed when the transition period ends?

A: ISO 9001:2000 and ISO 13485 certificates can be issued independent of each other as long as all required information (eg. identification of standards, Term of registration) is identified on the certificate.

Q: How should ISO 13485/8 certificates not referencing ISO 9001:1994 or ISO 9001:2000 be issued after 2002-12-15?

A: As ISO 13485/8 are stand alone quality system standards, registration certificates can be issued to them, as long as all required information is referenced.

Q: How should certificates be issued for simultaneous registration to ISO 9001:2000 and ISO 13485/8:1996?

A: It depends on registration body's procedures and the term for each registration. ISO 13485/8 will be revised shortly to become consistent with the ISO 9001:2000 standard. When it is finalized, the International Technical Committee 210 will provide transition guidance. In the meantime, it is suggested that separate certificates for ISO 13485/8:1996 and ISO 9001:2000 be issued.

3.4.2 Regulatory Profile

Registration Bodies are requested to note that activities related to the Regulatory Profile are no longer required as it has been dropped as a Health Canada CMDCAS requirement.

3.4.3 Mandatory Annual Audit Witness audit

As part of the requirements to maintain CMDCAS sector qualification, registration bodies will be subject to one witness audit annually. As with other sectors, you will be requested by SCC to provide a list of upcoming ISO 13485 audits (related to CMDCAS) to select an audit for witnessing and standard witness audit procedures will be followed. Please note that Health Canada may accompany the SCC audit team for CMDCAS witness audit activities.

3.4.4 Subcontracting

It has come to our attention that some registration bodies may be entering into sub-contracting arrangements with notified bodies or other registration bodies for CMDCAS related audit activities. While these arrangements are acceptable under the CMDCAS program, this practice will not be permitted until the SCC and Health Canada have reviewed the arrangements and are confident that they meet the requirements of Q90RO. Failure to provide notification of these arrangements and documentation for review prior to your implementation of the sub-contracting arrangement may result in the suspension of the CMDCAS sector qualification. For those registration bodies currently in process, this information is required as part of the sector qualification process and final approval of the sector qualification will not be provided until a review of the arrangement has been performed.

3.4.5 Role of related bodies in CMDCAS activities

As registration bodies are aware, accreditation and sector qualification is provided to legal entities. As such, related bodies may not offer registration under the CMDCAS program. CMDCAS related activities may be performed by qualified auditors of related bodies, however, the registration must be controlled by the accredited and CMDCAS qualified entity.

3.4.6 Upgrade audits from ISO 9001/2 or EN 46001/2 to ISO 13485/8 that will be used to satisfy the Canadian medical Devices Regulation

It is acceptable under the CMDCAS program for registrations to be upgraded from ISO 9001/2:1994 and EN 46001/2. To do so, Registration Bodies should first review the gaps between the existing registration and ISO 13485 requirements and provide a rationalization as to why certain elements may be excluded. This information should be documented in the document review report and reflected in the audit plan and audit report. In addition, registration bodies should verify that the Canadian Medical Devices Regulation has been addressed within the client's management system. Evidence must be provided that all ISO 13485 elements have been assessed and implemented.

It is anticipated that these interpretations will be posted on the CMDCAS area of the SCC website at the following URL: http://www.scc.ca/standards/cmdcas/index_e.html.

Standards Council of Canada
Conseil canadien des normes

(Date)

(Company Name)
(Address)
(City/Province/Postal Code)

Attention: (Name)

Dear (Name)

Subject: SCC Assessor Feedback & Post Audit Questionnaire

200-270, rue Albert St.
Ottawa, ON (Canada)
K1P 6N7

Tel.: +1 613 238 3222

Fax.: +1 613 569 7808

E-mail/Courriel
info@scc.ca

Internet:
http://www.scc.ca

Further to our recently completed audit activity, attached please find our *SCC Assessor Feedback & Post Audit Questionnaire,* which we are requesting that you complete for each SCC assessor involved in your audit.

The objective of this confidential survey is to assist us in evaluating both the quality of audit services conducted on behalf of the Standards Council of Canada (SCC) and the professionalism of the Task Group on Quality/Environmental Management Registration Systems Organizations (TG Q/EMSRO) representative conducting the audit activity.

Our intent is to use the feedback which you provide to enhance the overall quality of our Program(s) by improving the service provided to our clients, as well as evaluating the efficiency and effectiveness of the TG Q/EMSRO members. As such, please be as candid as possible in responding to the attached. Only by understanding the viewpoint of those that undergo an audit activity will we be able to ensure that we are providing the best possible service to you.

Upon completion of the survey, kindly return it by email or fax:
Monica Pantusa
Program Officer, Management Systems
mpantusa@scc.ca
Fax: (613) 238-3222

Your assistance is greatly appreciated,

Monica Pantusa
Program Officer, Management Systems
613-238-3222, ext. 449
mpantusa@scc.ca

Canada

Standards Council of Canada
Conseil canadien des normes

The objective of this survey is to assist us in evaluating both the quality of audit services conducted on behalf of the Standards Council of Canada (SCC) and the professionalism of the Task Group on Quality/Environmental Management Registration Systems Organizations (TG Q/EMSRO) representative conducting the audit activity. Our intent is to use the feedback which you provide to enhance the overall quality of our Program(s). Your assistance is greatly appreciated.

Name of Registration Body: _____ ***Name of Assessor:*** _____

Address of Assessment/Visit: _____ ***Role:*** ***Lead [ ] Member [ ]***

_____

_____

Date of Visit: _____

Purpose of Visit: _____

Indicate the extent to which you agree or disagree with the following statements by circling the appropriate code as follows:

SA = Strongly Agree A = Agree D = Disagree SD = Strongly Disagree N/A = Not Applicable

Section 1: Auditor Performance

							Comments:
1.	Auditor demonstrated knowledge of program Criteria (CAN-P-10/1517/IAF Guidance).	**SA**	**A**	**D**	**SD**	**N/A**	_____ _____
2.	Auditor demonstrated courtesy, professionalism And a constructive positive approach.	**SA**	**A**	**D**	**SD**	**N/A**	_____ _____
3.	Auditor kept you informed and discussed audit findings with department personnel.	**SA**	**A**	**D**	**SD**	**N/A**	_____ _____
4.	Audit results were clearly and fully explained.	**SA**	**A**	**D**	**SD**	**N/A**	_____ _____
5.	The audit resulted in minimal disruption to operations in the department/organization.	**SA**	**A**	**D**	**SD**	**N/A**	_____ _____

Section 2: Lead Auditor

Please complete this section (questions6-9) only if the individual being assessed was the Lead Auditor during the audit activity.

6.	Lead Auditor was well prepared for the assessment (i.e. demonstrated effective planning, preparation and briefing.)	**SA**	**A**	**D**	**SD**	**N/A**	_____ _____
7.	During the opening meeting, the Lead Auditor clearly explained the audit plan (objectives, scopes, timing and process.)	**SA**	**A**	**D**	**SD**	**N/A**	_____ _____
8.	The Lead Auditor effectively managed the audit, and was able to keep the audit team within the scope.	**SA**	**A**	**D**	**SD**	**N/A**	_____ _____
9.	During the closing meeting, the Lead Auditor presented audit observations in such a manner as to ensure that results of the audit were clearly understood.	**SA**	**A**	**D**	**SD**	**N/A**	_____ _____

Standards Council of Canada
Conseil canadien des normes

Section 3: Comments

1. a) What do you feel were the auditor's most significant strengths?

   _____
   _____
   _____

   b) Most significant weaknesses?

   _____
   _____
   _____

2. Overall, how would you rate the performance of the auditor? **Excellent** **Good** **Fair** **Poor**

3. Overall, do you believe that the audit was useful, helpful?

   _____
   _____
   _____
   _____

4. Additional comments and/or suggestions:

   _____
   _____
   _____
   _____
   _____
   _____
   _____

Optional:

_____ _____ _____

Signature Title

ISO/TC 176
Quality Management
And Quality Assurance

Secretariat: Canada (SCC)
Secretary: G. Gillis

ISO/TC 176 N696

2001-08-10

To : Michael Smith, Secretary, ISO/TMB

Re : ISO/TC 176 Interpretation Process

In consideration of ISO/TC 176's interpretation process, ISO/TMB is asked to approve the following:

It is recommended that the ISO/TC 176 interpretation process of the ISO 9000 quality management system standards be granted a one year extension as a pilot project for validation of the process in view of improvements made.

Background

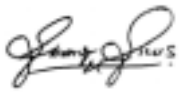
At its 18th meeting, July 2000, ISO/TC 176 recommended the adoption of a formal interpretation process for the ISO 9000 quality management system standards. The ISO TMB, at its September 2000 meeting, noting some concerns with the robustness and timeliness of the recommended process, approved it as a pilot project for a one year period.

ISO/TC 176's Working Group on Interpretations now has 43 experts representing 28 Member Bodies. Of these experts, 50% have been involved in the preparation of the current editions of the ISO 9000 standards; there are also representatives from a wide range of interested parties. All the experts have solid experience with ISO 9000 standards. During the pilot period, 11 interpretations were processed, 10 of which were approved at P-Member ballot.

At its recent Birmingham plenary, ISO/TC 176 conducted a review of the results obtained. Opportunities for improvement of the process were identified and revisions were introduced, with a view to improve the robustness of the process without reducing its timeliness. As a consequence, it was felt that additional time is needed to test and validate the revised interpretation process.

In order therefore to validate the improvements made to the interpretation process, ISO/TC 176 recommended unanimously, at the Birmingham meeting, that the modified process should be granted a one year extension as a pilot project (see resolution 4/2001 attached).

Yours truly,



Grant Gillis
ISO/TC 176 Secretariat

CC: P. Caillibot

CANADIAN STANDARDS ASSOCIATION

Secretariat administered by:
Canadian Standards Association, 178 Rexdale Blvd., Toronto, ON, Canada M9W 1R3
e-mail: grant.gillis@csa.ca TP+1-416-747-2272 TF+1-416-747-2473
Websites: www.csa.ca www.tc176.org

Attachment

Resolution 4E (2001) – Report of the Working Group on Interpretations

Noting that the interpretations process was approved by the ISO TMB (Resolution N55/2000) as a pilot project for a one - year period,

Noting that the process has been improved upon, but also

Noting the recommendation of the Working Group that additional time is required for correction and validation of the process;

ISO/TC 176 resolves to:

- not publish any official ISO/TC 176 interpretations at this time, but to treat them as information to the requester,
- ask ISO TMB to extend the pilot period for a further year, and
- during the extended pilot period, to conduct an independent assessment of the process.

IAF Welcomes Closer Co-operation with ISO

The Executive Committee of the International Accreditation Forum, Inc. (IAF) met in Vancouver at the end of May 2002. The Executive Committee re-affirmed its commitment that IAF will work tirelessly to ensure that conformity assessment activities meet the expectations of industry and consumers and operate with the highest integrity and competence.

The Executive Committee welcomed the release of a Communiqué by the Joint Working Group on Image and Integrity of Conformity Assessment (attached). The Joint Working Group, made up of representatives of IAF, the International Laboratory Accreditation Cooperation (ILAC) and the Conformity Assessment Committee (CASCO) of the International Organization for Standardization (ISO) was formed in December 2000 with the task of suggesting measures which would protect the customers and users of conformity assessment services from unethical or inappropriate practices.

The Executive Committee also welcomed the decision by the ISO Council at its meeting on 25-26 April in Geneva (Council Resolution 11/2002), on ISO cooperation with IAF. The ISO Council welcomed the agreement between IAF and ISO to exchange information about complaints received by ISO and/or IAF relating to certification/registration to ISO 9000, ISO 14000 and other ISO related documents, and to share information and closely monitor actions taken in response to the complaints, and noted that IAF and ISO “share the same goal to improve the integrity of accreditation and conformity assessment to eliminate malpractice, unethical and dishonest practices.”

The IAF Executive re-affirmed its view that the reputation of the conformity assessment system relies upon the integrity and competence of accreditation bodies. IAF requires its Accreditation Body Members to apply rules which are designed to identify and stamp out any activity by accredited organisations which could damage the integrity of accredited activities.

IAF Members are required to comply strictly with the International Standards or Guides relevant to their operations and to guidance issued by IAF on the application of those Standards or Guides. IAF Accreditation Bodies conduct regular surveillance of the operations of the organisations they accredit to ensure that the services they provide to industry and consumers continues to meet their needs as well as being provided with integrity. Members of the IAF MLA are also subjected to regular surveillance of their accreditation activities by IAF itself to ensure that their activities continue to meet the high standards IAF requires.

IAF warns consumers and industry against using the services of organisations which purport to be accreditation bodies or certification / registration bodies but which are not Members of IAF or of ILAC, or accredited by Members of IAF or of ILAC, as they may not adhere to the high standards of integrity required of Members of IAF and ILAC.

IAF and its Members work tirelessly and continually to ensure that the activities of its Members and the organisations they accredit enhance the confidence of industry and customers in the outcomes of accredited activities. Further, IAF has and will continue to review the IAF Guidance documents where experience has shown that changes are needed to ensure that the integrity of certification is maintained and enhanced. IAF constantly reviews its strategic policies on accreditation to ensure that accreditation policies prevent malpractice.

IAF requires all it's Accreditation Body Members to have in place effective complaints procedures to ensure that all complaints that are made to the body are thoroughly investigated and corrective action taken. Accreditation Body Members of IAF are required to ensure that the bodies they accredit also have in place effective complaints procedures.

In that regard IAF itself has an effective Complaints Procedure. All complaints lodged with IAF are fully investigated, and, where inappropriate actions by any Member are demonstrated, action to prevent repetition of inappropriate action is taken. But IAF recognises that complaints procedures can only deal effectively with inappropriate behaviour when it is reported, and evidence sufficient to justify action is made available. IAF is concerned that unsubstantiated criticism is too often made publicly without any evidence to justify the criticism.

IAF encourages any person or organisation which has evidence of inappropriate behaviour by any conformity assessment organisation to provide that evidence either to IAF itself or to any Accreditation Body Member of IAF. IAF assures all persons with information which suggests inappropriate behaviour by an organisation accredited by a Member of IAF, or certified by a body accredited by an IAF Member, that action will be taken on all information provided. IAF is determined to eliminate any practice which brings the conformity assessment system into disrepute.

Issue by the IAF Secretary

30 June 2002

COMMUNIQUE

19 April, 2002

Co-operation between ISO/CASCO, IAF and ILAC for protecting Image and Integrity of Conformity Assessment

Background

Representatives of the International Accreditation Forum, Inc. (IAF), International Laboratory Accreditation Cooperation (ILAC) and the Conformity Assessment Committee (CASCO) of ISO formed the IAF-ILAC-ISO/CASCO Joint Working Group on Image and Integrity of Conformity Assessment in December 2000, to discuss what contribution IAF, ILAC and CASCO could collaboratively make to protect the customers and users of conformity assessment services from unethical or inappropriate practices. The JWG recognizes that, whilst those conformity assessment bodies[1)] accredited by Members of IAF and ILAC are committed to operate ethically and in accordance with ISO/IEC Guides and Standards, there are some conformity assessment bodies that do not operate ethically and so damage the image and integrity of conformity assessment.

In this regard, the JWG has identified three kinds of problems:

- malpractices (unethical and dishonest practices) of conformity assessment bodies
- misleading advertising of the status of conformity assessment results, including misuse of marks of conformity
- confusion in the market place between “certification “ and “accreditation”

and also identified a number of measures to help users of conformity assessment services to select conformity assessment bodies which operate ethically and competently. The implementation of the measures identified is in progress. This communiqué is to highlight the common commitment of ISO, IAF and ILAC to ensuring that the users of conformity assessment services are able to find and employ ethical and competent conformity assessment bodies, and to draw attention to existing systems for handling complaints relating to conformity assessment services, which is one of the measures proposed to deal with the identified problem of malpractice by conformity assessment bodies. Further communiqués and other publications will be issued as the work being undertaken by the JWG progresses.

Common View

ISO, IAF and ILAC share the same goal to help users of conformity assessment services to select conformity assessment bodies which operate ethically and competently, and to eliminate malpractice in conformity assessment.

---

1) Conformity assessment bodies include testing and calibration laboratories, inspection bodies, product certification bodies, management system certification/registration bodies and personnel certification bodies.

Existing Systems for handling Complaints relating to Conformity Assessment Services

Accredited conformity assessment bodies must have complaint handling systems, based on relevant ISO/IEC Guides and Standards. Customers of conformity assessment services dissatisfied with the service they receive are encouraged to lodge their complaints with the relevant conformity assessment bodies. When accreditation bodies have proof that an accredited conformity assessment body has behaved inappropriately, they will take the necessary action, including the suspension or withdrawal of accreditation, according to their documented complaint handling procedures.

IAF and ILAC together with their Members and ISO have procedures in place to receive complaints about the practices of Accreditation Bodies and accredited conformity assessment bodies, to investigate these complaints (via the relevant Accreditation Body where the complaint is against an accredited conformity assessment body) and advise on the appropriate action to be taken.

In particular, ISO and IAF have agreed to share information about complaints received by ISO and/or IAF relating to ISO 9000 certification/registration and to share information on actions taken by ISO and/or IAF in response to the complaints, as appropriate.

Participants

Chairman:

Mr. J.L. Donaldson (CASCO Chairman)

Members:

IAF:

Dr. T. Ohtsubo (IAF Chair)
Dr. T. Facklam (Vice-chair, IAF and Convenor of ISO/CASCO WG 17, *Certification of persons*)
Mr. D. Misczynski (IAF Board Director)
Mr. S. Sutherland (IAF Board Director)
Mr. R. Brockway (Chair, IAF Technical Committee)

ILAC:

Mr. M. Peet (ILAC Chair)
Mr. D. Pierre (Vice-chair, ILAC)
Mr. A. Squirrell (ILAC Secretary)
Mr. P. Unger (Chair, ILAC Arrangement Management Committee)

ISO/CASCO:

Mr. M. Wittner (Convenor of CASCO SGSP)
Mr. H. Yoshimura (Convenor of CASCO Market Feedback Panel)
Mr. R. Rodriguez (Convenor of CASCO Communication Group)
Mr. L. Tronel (Convenor of CASCO WG 5, *Definition*s)
Mr. K. Mitsui (Convenor of CASCO WG 12, *Marks of conformity*)
Mr. D. Snyder (Convenor of CASCO WG 20, *Standards and Conformity Assessment*)

Press Release

IAF Survey of Acceptance of Accredited Certificates 2001

The International Accreditation Forum, Inc. (IAF) announces the release of the results of a Survey of the extent to which certificates of conformity to the ISO9000 series of Quality Management System standards were accepted by customers in international trade, conducted from May to July 2001.

The primary purpose of the survey was to check the progress in achieving acceptance of accredited certificates since the previous survey which was conducted in 1997. The 1997 survey indicated that in 99.9% of cases in international trade accredited certificates were accepted by the customer.

The 2001 survey results showed that, where the accredited certificate was covered by the IAF Multilateral Recognition Arrangement (MLA), less than one certificate in 300,000 was not accepted by the customer. As the 2001 survey covered approximately 67% of all ISO9000 certificates in existence, the results are credible.

IAF welcomed the results of the survey as showing that the operations of the IAF MLA were achieving its primary purposes of enhancing the credibility of accredited certificates and of facilitating international trade.

Copies of the survey results may be obtained from –

IAF Secretariat
2 Marcus Clarke Street, # 1801,
Canberra City ACT 2601,
Australia
Facsimile +612 6222 2761
email <secretary@accreditationforum.com>

OFFICE OF THE
EXECUTIVE DIRECTOR

BUREAU DU
DIRECTEUR GÉNÉRAL

Standards Council of Canada
Conseil canadien des normes

May 2002

To ISO 9000 Registered Companies:

As you probably know, the transition period for organizations to upgrade their registrations to the new ISO 9001:2000 standard is under way. The International Accreditation Forum (IAF) has established a three-year period to allow organizations to achieve this transition within their normal surveillance cycle, thus avoiding additional expense.

The transition period ends 14 December, 2003. By that date, all organizations registered to the 1994 version must be evaluated by their registrar against the 2000 version and re-registered as conforming to ISO 9001:2000. Although three years seemed like ample time at the outset, the deadline now seems very close, particularly if an organization wishes to avoid additional expenses.

We urge you to carefully evaluate your organization's transition plan and timetable.

For many organizations, some additional audit activity will be required to verify conformance with the new requirements in the 2000 revision. This may be accomplished as a separate stand-alone visit, added to regular surveillance visits, combined with registration renewal, or spread over a number of visits. Careful scheduling between you and your registrar will be required. As the deadline approaches, however, your registrar's ability to accommodate your needs may decrease because of increased demand.

It is to your advantage to start this transition process as soon as practical. You may need to include time for training. Scheduling soon could allow you to combine transition audits with regular visits, resulting in fewer audit days and reduced travel expenses. In addition, your preferred registrar auditor may be more likely to be available.

IAF and the Standards Council of Canada strongly encourage you to begin implementing your organization's transition to ISO 9001:2000 now. You can avoid the frustration and inconvenience that may arise as the 14 December, 2003 deadline looms. Our accredited registrars assure us they are prepared now to offer you the flexibility and convenience to ease your organization's transition.

The Standards Council of Canada is a Crown corporation with the mandate to promote efficient and effective voluntary standardization, and is Canada's representative at ISO and a signatory to the IAF Multi-lateral arrangement for Quality Management Systems. The Standards Council coordinates and oversees the efforts of the National Standards System and offers a variety of standardization-related programs and services. For more information on the Standards Council of Canada visit www.scc.ca, or via e-mail at info@scc.ca.

Sincerely,

Peter Clark

200-270, rue Albert St.
Ottawa, ON (Canada)
K1P 6N7

Tel.: +1 613 238 3222

Fax.: +1 613 569 7808

E-mail/Courriel
info@scc.ca

Internet:
http://www.scc.ca

Canada

INFORMATIONAL UPDATE - CONCERNING QS-9000 3RD EDITION SECTION 4.6.2.1 SUBCONTRACTOR DEVELOPMENT AND SANCTIONED INTERPRETATION C9

Released with commentary on published QS-9000:1998 manual and
July 1, 2002 Sanctioned Interpretations. Edited by P.B. Lake, 05/28/02, IASG

Contained within this document are the following segments headed as:

Background
SQRTF Statements
Element 4.6 Purchasing, C9 Supplier Development (4.6.2.1) (07/01/01)
Important Added Points Concerning C9
Q&A: Questions and Answers On C9
Second Party Customer Approval Guidelines
Applicable QS-9000 3rd Edition Reference Language

Background

This information comes from a joint statement from Hank Gryn of DaimlerChrysler, Russ Hopkins of Ford Motor Company and Joe Bransky of General Motors Corp., representatives to The Supplier Quality Requirements Task Force, SQRTF, and conclusions reached at the March 2002 IASG meeting.

SQRTF Statements

Effective July 1, 2001, IASG QS-9000 Sanctioned Interpretation C9 was implemented to clarify the meaning of "the goal of subcontractor compliance" under Subcontractor Development of element 4.6.2.1 of QS-9000 3rd Edition. The Sanctioned Interpretation C9 is intended to be used in conjunction with all elements pertaining to subcontractor development within QS-9000 3rd edition, which remains in full effect.

The full text of the sanctioned interpretation for 4.6.2.1 is shown below:

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.

The sanctioned interpretation stated above should be used with 4.6.2.1 of QS-9000 (see last section **Applicable QS-9000 3rd Edition Reference Language**). There are two options to meet the goal of subcontractor compliance:

1) Subcontractor is certified 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, by December 31, 2002; or

2) Subcontractor assessment to QS-9000*, Section 1, by the OEM customer, an OEM customer-approved second party, or an accredited third party certification body/registrar by December 31, 2002.

*DaimlerChrysler and General Motors Corporation will accept subcontractor assessments to QS-9000 or ISO/TS 16949. Ford Motor Company will accept subcontractor assessments to Q1 2002 Manufacturing Site Assessment, QS-9000 or ISO/TS 16949.

Important Added Points Concerning C9

Here are some additional important points:

A. An OEM customer-approved second party audit can be performed by any QS-9000 certified Tier I supplier after obtaining customer approval to conduct the audit. The supplier must obtain approval from each customer who receives product from the supplier containing products or services from the subcontractor.

B. Subcontractor Development - 4.6.2.1 and C9 of the IASG QS-9000 Sanctioned Interpretations are auditable requirements. A supplier shall have the following documentation on file:

1) Record of customer approval of audit

2) Audit review and results

Q&A: Questions and Answers On C9

1. *Does 4.6.2.1 and C9 apply to all subcontractors, including both direct and indirect materials and service providers?*

No. See "Subcontractor" definition in QS-9000 3rd Edition, page 133, also shown below.

2. *Does 4.6.2.1 and C9 apply to all tiers of subcontractors?*

No. Section 4.6.2.1 and C9 only apply to those subcontractors of suppliers who have QS-9000 certification.

3. *Do subcontractors who act as distributors for parts manufacturers, or the parts manufacturers who provide parts to a supplier through a distributor, affected by 4.6.2 and C9?*

Neither is affected. Distributors who do not add manufacturing value to parts or materials are not subject to the requirements of 4.6.2 or C9. Once the supply chain is broken by non-applicability of distributor, 4.6.2 and C9 no longer applies to the distributor

or the parts manufacturers for which it distributes.

4. *Many of my sub-contractors are small "mom and pop" shops who cannot afford to get registered. Must we stop using them?*

   No. If you refer to QS-9000 3rd Edition, Appendix I.4, page 112, also shown below, you will see that small, low impact subcontractors are addressed by permitting waiver by the supplier of certain specified QS-9000 sub-elements, such as C9 (4.6.2).

5. *I have a large, Fortune 500 company that is a subcontractor in that it supplies a few relatively insignificant parts. I cannot make them get registered - must I find an alternative source?*

   Registration is not required. OEM approved second party assessment may be utilized or Appendix I.4, page 112, may apply if the subcontractor supplies a low volume part or ingredient.

In either item 4 or 5 mentioned above, any exceptions or waivers made by the supplier of a subcontractor, based on QS-9000:1998 Appendix I.4, must be documented with specifics about the subcontractor, and the supplier's justification. Both must be made available to the supplier's registrar.

6. *Can I conduct a 2nd party audit of my subcontractor in lieu of requiring registration?*

   YES, as long as the following conditions are met and documented:

   1) All of your QS-9000 subscribing customers of the parts you supply using the sub-contractor's parts or material have given their written approval to utilize a second party audit process;

   2) The second party audit process meets the "OEM-Approved 2nd party requirements" as defined below, and

   3) You can provide your QS-9000 registrar documentation that the "OEM-Approved 2nd party requirements" have been met as defined below.

Second Party Customer Approval Guidelines

The following is the 2nd party customer approval criteria and authorization jointly agreed by DaimlerChrysler, Ford Motor Co. and General Motors Corp., "DaimlerChrysler, Ford Motor Company and General Motors Corporation Second Party Recognition for Compliance to QS-9000, 3rd Edition, 4.6.2.1, and Sanctioned Interpretation C9".

OEM-approved 2nd Party requirements:

1. The 2nd Party must be QS-9000 registered.

2. The 2nd Party cannot be on QS-9000 Probation.

3. The 2nd Party must utilize a qualified Lead Auditor, or qualified Internal Auditor with evidence of their successful completion of training, such as AIAG "Internal Auditing for QS-9000," or evidence of a minimum of five internal QS-9000 audits under the

supervision of a qualified Lead Auditor.

4. The 2nd Party must audit annually each qualifying subcontractor for whom it has performed the 2nd Party service, and maintain records of these audits.

5. The duration of these audits must conform to the full application of the Audit Day Requirements table of Appendix H in QS-9000, 3rd Edition.

6. Any of the QS-9000 accredited Registrars (Certification Bodies) may be utilized as an OEM-approved 2nd Party.

Applicable QS-9000 3rd Edition Reference Language

The following contains the full text of Subcontractor Development - 4.6.2.1 and Appendix I, No. 4, followed by the definition of "Subcontractor":

Subcontractor Development - 4.6.2.1

The supplier shall perform subcontractor (see Glossary) quality system development with the goal of subcontractor compliance to QS-9000 using Section I of QS-9000 as their fundamental quality system requirement. Assessments, if part of subcontractor development, should occur at supplier specified frequency. Subcontractor assessments to QS-9000 by the OEM customer, an OEM customer-approved second party, or an accredited third party certification body/registrar (see Appendix B) will be recognized in lieu of audits by the supplier.

NOTE: Acceptance of the above audits or ISO 9001/9002 registration is not intended to limit more specific supplier/subcontractor quality system and product development.

NOTE: The prioritization of subcontractors for development is dependent upon the needs of the subcontractor relative to the requirements of QS-9000 and the importance of the product or service they supply.

The use of customer-designated subcontractors does not relieve the supplier of the responsibility for ensuring the quality of subcontracted parts, materials and services.

Appendix I. 4. Subcontractor Development

When a subcontractor is so small as to not have adequate resources to develop a system according to QS-9000, Section 1, certain specified QS-9000 sub-elements may be waived by the supplier of their subcontractor. The majority 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.

Definition of "Subcontractor" as it appears in QS-9000 Third Edition, Page 133:

Subcontractors are defined as providers of production materials, or production or service parts, directly to a supplier to Chrysler, Ford, General Motors or other customers subscribing to this document. Also included are providers of heat treating, painting, plating or other finishing services.

FINIS

IASG SANCTIONED QS-9000:1998 THIRD EDITION INTERPRETATIONS

(Previously Released: July 1, 2001)

Effective date: **July 1, 2002**

(<u>Underlined</u> are the changes/additions to the Interpretations in the previous 07-01-01 release.)

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.

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).
- 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 obtained from the American Society for Quality, ASQ, at 1-800-248-1946 or 414-272-8575, or obtain a copy from the ASQ QS-9000 Web Site at http://qs9000.asq.org/compdir.shtml.

In Europe contact Carwin Continuous, Ltd. at Telephone 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

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 4.11 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:

“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)

1. 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 does 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/.

ii. 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 https://web.bli.ford.com/. Note: if access to https://web.bli.ford.com/ is not available, Ford tier 1 suppliers can provide the necessary documents from the web site.

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 global automotive 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).

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 “site-specific” 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 ASQ 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 ASQ database of all probation, and of all registration de-listings for failure of the supplier to comply with QS-9000 requirements.

I. 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.

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.

FINIS/pbl