

## **ACCREDITATION, REGISTRATION, CERTIFICATION: WHAT THEY ARE ©**

**Donald W. Wilson, P.Eng.**

**Standards Council of Canada, Suite 1200, 45 O'Connor St. Ottawa, Ontario K1P 6N7**

### **Summary**

This paper describes the various elements of conformity assessment, that is any activity concerned with determining directly or indirectly that relevant requirements are fulfilled. The nature of accreditation, certification, and registration and an appreciation of the delivery of each will be explained. The role of the Standards Council of Canada and those to whom the SCC provides services will be described. The opinions expressed are those of the author and do not necessarily represent the views of the Standards Council of Canada.

### **1. Introduction**

For a number of years, there has been ongoing work performed by conformity assessment experts in all parts of the world, brought together by the International Organization for Standardization, popularly referred to as ISO. The ISO Committee for Conformity Assessment, ISO/CASCO is the group responsible for the development of the various guides, nineteen in number, that help shape conformity assessment programs world-wide. The CASCO working groups have established initial guides for a number of key conformity assessment activities, then returned several years later to update these guides to reflect current thinking with respect to conformity assessment. The Standards Council of Canada both contributes to the work of ISO/CASCO and is one of the leaders in implementing the guides as they are produced.

### **2. Discussion**

#### **The Standards Council of Canada (SCC)**

The SCC is a federal Crown corporation with the mandate to promote efficient and effective standardization and the overseer of Canada's National Standards System. Located in Ottawa, the Standards Council has a 15-member governing Council and a staff of approximately 70. The organization reports to Parliament through the Minister of Industry. The Standards Council has the mandate to coordinate and oversee the efforts of the National Standards System, which includes organizations and individuals involved in voluntary standards development, promotion and implementation in Canada.

The appointed Standards Council is supported by a number of Advisory Committees made up of volunteers. The structure is currently being revised to streamline the existing structure and to provide a better-integrated structure for providing support to the Standards Council appointed Board. The new structure is expected to be in place January 1<sup>st</sup>.

The new structure will include the following:

- Advisory Committee on Conformity Assessment (ACCA);
- Advisory Committee on Standards (ACS) - with several key groups within its structure including the Canadian National Committee on IEC, the Canadian National Committee on ISO and the Committee on Public Issues and Consumers (CPIC);
- Advisory Committee on Trade (ACT);
- Provinces and Territories Advisory Committee (PTAC) - a statutory committee;
- Standards Development Organization Advisory Committee (SDOAC) - a statutory committee;

More than 14,000 Canadian volunteers contribute to committees that develop national or international standards. As well, the Standards Council has accredited some 250 organizations. Some of these develop standards, while others are conformity assessment bodies, which determine the compliance of products or services to a standard's requirements. Those organizations accredited by the SCC are considered participants in Canada's National Standards System.

The list of accredited organizations includes:

- auditor certifiers and course providers (Quality and Environmental auditors);
- calibration and testing and laboratories.
- certification organizations;
- environmental management systems (EMS) registration organizations that perform registrations to the ISO 14001 standard;
- quality management systems (QMS) registration organizations that perform registrations to the ISO 9001 or 9002 models; and
- standards development organizations.

#### International Standardization

The Standards Council co-ordinates the contribution of Canadians to the two most prominent voluntary international standardization organizations - the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). These two bodies publish standards in a wide variety of fields, including information technology, medical technology, the environment and quality management.

ISO and IEC standards are often adopted by countries as voluntary standards, or included in national rules and regulations. Many trade agreements, including the World Trade Organization (WTO), call upon signatories to adopt international standards wherever possible. The Standards Council encourages the adoption and application of international standards.

The Standards Council is also involved in efforts to establish mutual recognition of its accreditation programs for conformity assessment organizations with similar bodies in other countries. This effort facilitates the movement of goods and services across borders.

### National Standards of Canada

Accredited standards-development organizations may submit standards to the Standards Council for approval as National Standards of Canada. This designation indicates that the given document meets criteria that are important to many standards users.

As an example, a National Standard of Canada must be developed by consensus of a balanced committee representing producers, consumers and other relevant interests. It must undergo a public review process, be available in both official languages and must not be framed in such a way that it will act as a restraint to trade. Further, the standard should be consistent with or incorporate appropriate international standards as well as pertinent national standards. The globalization of standardization efforts has resulted in a strong push to adopt, or at least adapt, international standards for use in Canada. Many industrialized members of ISO and IEC take the same approach.

### Standards Information

For the benefit of Canadians generally, the SCC operates a Technical Document Centre (TDC) at its Ottawa offices. The TDC houses the country's most comprehensive and up-to-date standards collections. The following are available:

- Full-text Canadian standards from Le Bureau de normalisation du Québec (BNQ), Canadian Gas Association (CGA - now part of CSA), Canadian General Standards Board (CGSB), Canadian Standards Association (CSA) and Underwriters' Laboratories of Canada (ULC);
- The only historical collection of Canadian Standards in Canada;
- Full-text international standards from ISO and IEC;
- Full-text foreign national standards from Great Britain (BSI), Germany (DIN), the United States (ANSI and ANSI-adopted), France (AFNOR), Japan (JIS) and more;
- Full-text draft European standards developed by the Committee for European Standardization (CEN); and
- More than 500 subscriptions to periodicals, newsletters and catalogues published by Canadian, international and foreign standards bodies.

The SCC offers a variety of contact information, brochures and articles on standards organizations around the world as well as information on current hot topics. Documents may be consulted free of charge. Because of copyright restrictions, most documents may not be reproduced. Please note that the TDC does not participate in inter-library loan programs. Should anyone require assistance with the identification of appropriate standards,

the SCC Information Officers offer research services. It should be noted that a fee might apply to some research services.

The TDC allows the Standards Council to provide customers with the latest information on standards and technical regulations used in Canada and around the world - including such important markets as the European Union, the United States and Asia-Pacific. It is significant to note that much of this information is available through SCC.CA, the Standards Council's new Internet-based information service, the source for much of the information contained in this paper.

The SCC also operates Canada's Inquiry Point for the World Trade Organization on behalf of the Department of Foreign Affairs and International Trade. This service keeps callers informed on standardization issues in other countries and in Canada.

#### Conformity Assessment in Canada

The SCC's accreditation programs for conformity assessment activities include:

- Auditor Certifiers and Auditor Course Providers (Quality and Environmental);
- Calibration and Testing and laboratory services;
- Certification of Products;
- ISO 9000 Registration (including QS-9000); and
- ISO 14000 Registration (including SFM).

It is important to note that the SCC is obliged to recover all its costs in the accreditation programs. While approximately 50% of the SCC revenues are obtained from government appropriations, the other half is recovered from the SCC's accreditation program clients. The aim of all programs is to fully recover both direct and indirect costs and to avoid spending any public funds on the accreditation activities. Largely, the accreditation programs meet this requirement or will do so soon.

Before beginning to consider the various conformity assessment programs that are part of the SCC's accreditation activities, let us have a look at the principal definitions in use in the SCC's programs:

- **accreditation:** means the formal recognition, by SCC, of the competence of an organization to carry out specific functions;
- **certification:** means a procedure by which a third party gives written assurance that a product conforms to specified requirements;
- **registration:** means a procedure by which a registration organization indicates the relevant particulars of a supplier's assessed quality system in an appropriate, publicly available list; and
- **test:** means a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

It should be noted here that there appears to be an inordinate amount of confusion regarding the words defined above. Many throw these words around quite indiscriminately and it leads inevitably to confusion. It doesn't help to know that "registration", the term in common use in North America is referred to in most of the rest of the world as "certification". One of the reasons why we in North America differentiate between registration and certification is the likelihood of confusion between the recognition of a Quality System to ISO 9001, for example, and certification of a product. We thus avoid the linkages by using a different word! Nonetheless, it would be wise for anyone working in a larger market to be aware of the subtle difference in usage.

The accreditation activities undertaken by the SCC are illustrated in Figure 1 that appears at the end of this paper. That figure represents a concept of a conformity assessment structure and indicates the relationship between various participants in this aspect of Canada's National Standards System. The SCC accreditation programs will be described following the order listed above:

- Auditor Certifiers and Auditor Course Providers: The SCC has a program for the accreditation of those organizations that certify auditors. In Canada, there are two principal certifiers of auditors;
  - The Canadian Environmental Auditing Association: Certifier of Environmental Auditors; and
  - The National Quality Institute: Certifier of Quality Auditors.

These organizations have worked closely with the international auditor certification community in evolving their program requirements. The SCC has similarly taken note of international developments while developing its accreditation criteria.

With respect to Auditor Course Providers, the SCC has a program for the accreditation of such organizations should they wish national recognition of the work they do. Both programs are in their early stages of implementation. The Quality and Environmental programs are managed by a single SCC manager, though the accreditation applications currently follow separate Quality and Environmental routes before going to Council for approval. There are no auditor certifiers nor course providers accredited though applications are in process.

- Calibration and Testing Laboratories: The SCC began accrediting laboratories in 1981 and runs an active Program for the Accreditation of Laboratories - Canada, known as PALCAN. The staff manages the program, made up of a wide range of testing activities - from Dairy to DNA to Drug Abuse with many, many others in between. There are about 215 accredited laboratories in PALCAN. These are stand-alone laboratories, not a number of laboratories within one complex and are part of a program that currently operates on a 4-year cycle, with PALCAN visits approximately every two years, once accreditation has been achieved. PALCAN accredits laboratories to its CAN-P-4, a verbatim adoption of the international ISO/IEC Guide 25, a document published in 1990. A successor document, to be

published in January 2000 as an international standard, ISO/IEC 17025, will add to the quality management aspects while also sharpening up the technical requirements of the laboratory accreditation process. The SCC has two principal partners who deliver a great deal of the services within the PALCAN structure. The first is the Canadian Association of Environmental Analytical Laboratories (CAEAL) that provides assessment services to 90 laboratories accredited by the SCC. The second is the National Research Council (NRC), that provides like services to 15 calibration laboratories accredited by the SCC. Qualified (and frequently certified) quality and technical assessors conduct the visits to the laboratories. The PALCAN Senior Program Officers manage all the files and conduct annual visits to assure the continued effectiveness of the partner programs. Another form of partnership relates to the joint programs run by PALCAN in co-operation with regulatory authorities such as the Canadian Food Inspection Agency, the Pest Management Regulatory Agency and the Canadian Paramutual Agency - to name three. The regulatory bodies have turned over their own accreditation programs to the SCC while retaining contact with the laboratories by providing the technical assessors who accompany PALCAN assessors on laboratory visits. This program continues to expand as more agencies and associations recognize the value of linking up with Canada's internationally-recognized laboratory accreditation body. When the accreditation is approved, the testing laboratories along with their accredited scopes, are listed on the SCC website. The calibration laboratories accredited by the SCC are listed on the NRC website and the CAEAL labs also have a site where their accreditation information is available. Costs of accreditation vary with the size and complexity of the laboratory program, but \$12,000 to \$15,000 is typical. Annual fees also are paid based upon the number of program areas involved along with the number of tests for which the laboratory is accredited.

- Certification of Products: The SCC began its accreditation of Certification Organizations (CO's) as certifiers of products nearly 20 years ago. There are currently 18 accredited 18 organizations, evenly split between Canadian and U.S.-based firms. Initial assessments are conducted using the SCC criteria document, CAN-P-3. In about six months this document will be updated when the SCC adopts verbatim the ISO/IEC Guide 65, published in 1997. The new document brings the CO accreditation program more in line with those programs run for Registration Organizations (see below). As part of the processing of the application, the applicant is required to establish a working relationship with the Regulatory Authorities concerned for the certification of the products handled by the applicant. In addition, they are required to identify the scope of their planned operation so that the SCC can list the scopes for its accreditation of the CO. The applicant also must register the certification mark that they intend to use in Canada with the government Trademarks Office. Once the CO has met all the Regulatory, Trademark Office and SCC requirements, the SCC Council will assess the application and approve the accreditation. The SCC lists the new CO and its scopes on its website and in its formal directory of CO's;

- Registration of Quality Systems: Since 1992 the SCC has operated a program for the accreditation of Registration Organizations (RO's) who register supplier Quality Systems conforming to ISO 9001 or 9002, with the first three RO's accredited in 1993. There are currently 15 RO's accredited by the SCC to register Quality Systems, with the majority Canadian-based. Approximately 5,000 suppliers have been registered by these organizations, operating primarily in Canada and the U.S. The SCC accredits RO's to ISO/IEC Guide 62, adopted verbatim by the SCC as its latest version of CAN-P-10. Following the successful completion of a comprehensive assessment by an independent team, and any required corrective action by the applicant, the SCC staff forward a recommendation for accreditation to Council for approval. The recommendation includes a definition of the scopes of accreditation for the applicant. Included in this program is a specific assessment conducted in support of the automotive quality initiative as defined in the sector-specific document QS-9000, for which the SCC has been recognized as an acceptable RO accreditor. Registration costs vary, depending upon the complexity and extent of a supplier's operation. Typical registration costs range from \$10,000 to \$25,000. Accredited RO's are listed on the SCC website.
- Registration of Environmental Management Systems: Since 1996, the SCC has operated a program for the accreditation of RO's registering EM Systems to ISO 14001. This program follows SCC criteria since the international document, ISO/IEC Guide 66 is not yet approved. There are seven applicants at present, with 4 accredited at the time of preparing this paper (end of October, 1998). The number of clients seeking registration of their Environmental Management Systems is quite limited at this time, though there is a growing interest. Many of the RO's report their clients wish to receive both ISO 9001 (or 2) registration *and* ISO 14001 registration as part of the same visit. While this complicates their lives, the registrars deserve credit for their ability to respond to such requests. As many will know, ISO is exploring a way to bring QS and EMS closer together. Both the Quality and EMS Technical Committees (TC 176 and TC 207) have agreed to investigate the compatibility of their two management system standards. It is expected that ISO will be able to bring the two families of standards closer together over the next several years. Of particular interest to those working in the wood industry is the National Standard of Canada for certification of forestry lots, CAN/CSA Z809. Several of the RO's have shown an interest in registering (certifying?) forest properties to that standard and some assessment work has begun. In parallel, the Canadian Environmental Auditing Association has developed certification criteria for the Certified Environmental Auditors (CEA's) performing these assessments. While it is early days, it is possible that the RO's forestry clients will seek both ISO 14001 and Z809 assessments as a package from the accredited RO's. It is expected that the RO's fees may be higher than for QS registrations. This is because of the complexity of the EMS assessments and the need to give careful consideration to regulatory issues.

## The SCC's International Affairs

As one would expect, the SCC is very involved and committed to international bodies that help tie the accreditors programs together. These ties are important to Canada and to standardization efforts in this country. Participation in these international organizations is done with the knowledge of and inputs from the various interested parties in Canada. One such group is the Canadian Conformity Assessment Conference (CCAC). The CCAC has two components; one is made up of accredited RO's, the other accredited CO's. The groups meet regularly with SCC managers and deal with issues affecting their accreditation and with international aspects of their operation within the National Standards System. The following are the principal organizations with which the SCC has connections:

- Asia Pacific Laboratory Accreditation Co-operation (APLAC): Most of the economies of the Asia-Pacific belong to APLAC. This regional body acts on behalf of its members in terms of information services and MLAs. APLAC provides a MLA for those laboratory accreditors willing to be subjected to a peer review evaluation. As a member of APLAC, the SCC has asked to be assessed in order to be able to sign the MLA. The accomplishment of this will provide valuable mutual recognition between fellow-signatories across the Asia-Pacific region. Such recognition will facilitate the exchange of testing information that will greatly facilitate trade within the region. The APLAC pre-assessment of the SCC is complete; the assessment is expected in May 1999;
- European co-operation for Accreditation (EA): The SCC has begun the process leading to recognition by EA – a process that can take up to three years to achieve. This group is important as the European regional group that has some influence on inter-region recognition. Such recognition could be critical with the approval earlier this year of the Canada-EU Mutual Recognition Agreement. The EA is a new organization formed in 1997 by the amalgamation of the EAC and EAL - the European organizations dealing with management systems and laboratory accreditation;
- Inter American Accreditation Co-operation (IAAC): This is a new organization formed in 1995. The IAAC operates out of Brazil and embraces all the South American countries, Mexico and the U.S. The SCC has been attending its meetings but is not yet a member of the IAAC. This regional organization is similar to EA in that its program addresses both laboratory and management systems accreditors;
- International Accreditation Forum (IAF): This organization is being incorporated in the U.S. and seeking an executive to run its day-to-day affairs. The IAF has been functioning for several years and only recently has decided to incorporate as an entity. The purpose in doing so is to establish itself more firmly in the global standardization system and to develop links with ISO and IEC. The IAF administers a Multilateral Arrangement (MLA) that is intended to provide recognition of all signatories each to each other. As a result of the MLA, all RO's accredited by one signatory will be on an equal footing with those accredited by another signatory. The first six groups, including the SCC, signed the MLA in January 1998. That



group includes accreditation bodies from Australia and New Zealand, from China, from Japan, the U.S. and the European Union (11 accreditors). A total of 16 accreditors have signed the MLA and a number of others are expected to have signed at the IAF meeting held at the end of October. In preparation for the MLA approval, the SCC underwent a peer review – an evaluation by IAF assessors from two other accreditors. The assessment was comprehensive and demonstrated both IAF's ability to assess member accreditation programs and the SCC's to have a documented quality program complete with procedures needed for the effective operation of its RO accreditation program;

- International Auditor Training and Certification Association (IATCA): The SCC is a member of IATCA as an accreditor of Auditor Course Providers. This body has been in existence since 1994 and has sought since its formation to develop criteria for the certification and training of auditors. IATCA originally was concerned only with Quality assessors, but is now busy developing criteria for the certification and training of Environmental auditors. IATCA has a MLA structure for mutual recognition. The SCC is currently not participating in this program but rather is seeking IATCA acceptance of the results of an SCC accreditation of auditor certifiers and course providers in Canada. It is noted that the SCC accreditation documents have been patterned on the approved IATCA documents;
- International Electrotechnical Commission (IEC): The SCC sponsors the Canadian National Committee of IEC, the member group of IEC. This too is an important link in the international activities of IEC. In addition, the SCC provides a member for IEC's Conformity Assessment Board (CAB);
- International Laboratory Accreditation Co-operation (ILAC): This group is the oldest, most experienced of international bodies, and has as its focus laboratory accreditation. The SCC has been a member of ILAC since it began meeting. ILAC sets most of the operational protocols for laboratory accreditation and makes a major contribution to the ISO/CASCO working group developing the relevant guide/standard used for laboratory accreditation;
- International Organization for Standardization (ISO): The SCC is Canada's member of ISO. In addition to our linkages with the ISO as a member body, the SCC is a member of the ISO Council and the Technical Management Board. In addition, Canada provides the Chair of the Technical Management Board and the Chairs of two key Technical Committees of ISO, TC 176, responsible for the ISO 9000 series and TC 207, the committee responsible for the ISO 14000 series;
- National Council for Laboratory Accreditation (NACLA): This body incorporated last month and is a U.S.-based group that is seeking to bring together a large number of accreditors that are acting independently and to differing criteria. The objective is to reduce the number of accreditations needed by laboratories in the U.S. The SCC and Mexico's SECOFI are represented on the Board of NACLA;
- North American Calibration Co-operation (NACC): The SCC is a member of this body, a grouping of accreditors of calibration laboratories from Mexico, the U.S. and Canada. There will be an MRA in this group also, with assessments getting under

way in 1999. It is expected that the APLAC assessment team for the SCC visit next year will have a member from NACC and approval by APLAC will lead to NACC approval also. For two years beginning January 1998 the SCC is providing the Chair of NACC; and

- Pacific Accreditation Co-operation (PAC): This regional body, formally established in 1995, works closely with the IAF and other regional bodies and provides its members with an opportunity to share experiences and thus to learn from each other. Since one of the assessors who visited the SCC in 1997 was from a PAC member accreditor, the IAF approval of the SCC permitted automatic approval and signature of the PAC MLA. The SCC was among the first four accreditors to sign that document in January of this year.

### The Canadian Standards Strategy

One of the initiatives that emerged from the planning for the Standards Council's Strategic Plan was the need for a Canadian Standards Strategy. At the end of August, the first meeting was held of a Stakeholders Advisory Council (SAC), a group formed by the Standards Council to study the current standardization situation in Canada and to propose a Standards Strategy. The SAC will factor in the international and global aspects of standardization that could have a bearing on the operation of the National Standards System and examine Canada's trade objectives in building the Strategy. The SAC has much work to do, but at the end of it, Canada will have a Standards Strategy that will shape standardization efforts for years to come.

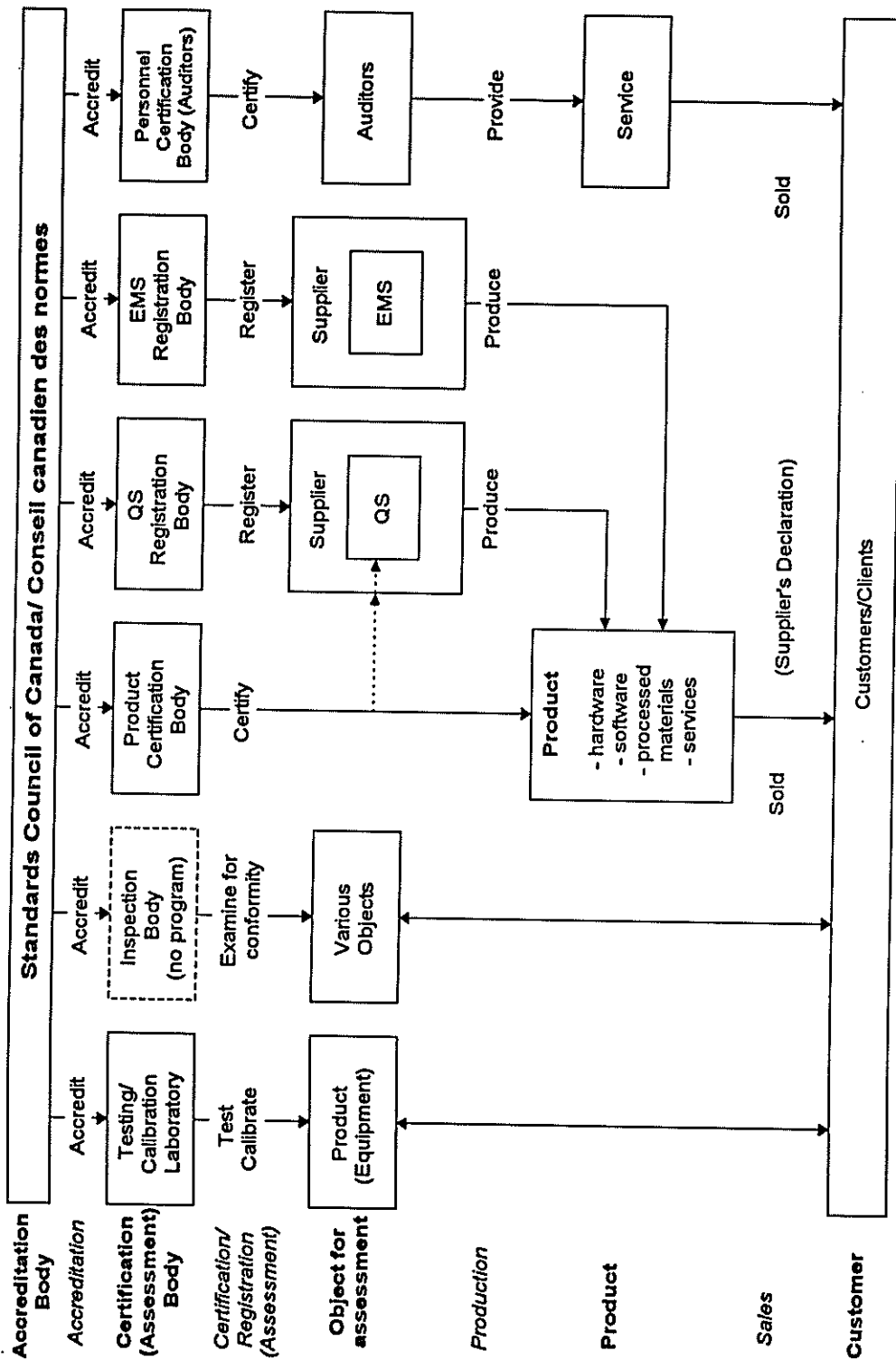
### **3. Conclusions**

Readers will now be better informed of the work of the Standards Council of Canada. The SCC's strong support for conformity assessment in Canada demonstrates a determination to ensure Canada's interests are preserved. Development and support of the linkages with international standardization organizations will help to contribute in a positive way to the design of a Canadian Standards Strategy of which these links will play an important role. Such efforts are both a challenge and an opportunity.

The permanent staff members of the SCC, together with the many volunteers working in the SCC programs, are devoted to the evolution of an effective and ever-improving National Standards System. At the same time, these same people keep a watchful eye on the many international challenges that are a fact of life in these days of constant change.

Anyone wishing further general information including some of the specifics of the various programs is encouraged to visit the SCC website at: <http://www.scc.ca>.

Ottawa, October 31, 1998.



Note: Adapted from an ISO/CASCO conceptual structure of conformity assessment

Figure 1 - Accreditation, certification and related concepts