FINAL

EVALUATION OF THE CANADIAN STANDARDS ASSOCIATION HEALTH CARE TECHNOLOGY PROGRAM

Submitted to:
Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Prepared by:
Hussein Rostum
PricewaterhouseCoopers
99 Bank Street, Suite 800, Ottawa, Ontario K1P 1E4

August 31, 1998

TABLE OF CONTENTS

Page

EXECUTIVE SUMMARY

PricewaterhouseCoopers (PwC) was contracted by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) to undertake an independent evaluation of the Canadian Standards Association Health Care Technology Program. The following report provides the analysis and findings of this study.

Conclusions

- The Canadian health care system is undergoing tremendous change. As pressures to reduce costs yet maintain quality increase, administrators, health care providers, policy makers, and consumers are searching for new, innovative, and cost effective ways to deliver health care.

- The need for voluntary consensus standards in health care is increasing and will continue to do so for the foreseeable future. The CSA HCT program is capable of fulfilling only a small part of this need, but there was overwhelming support for its continuation.

- CSA is a facilitating standards development organization and its expertise is in organizing committees for standards development and in providing an infrastructure for conformity assessment to standards.

- International liaison and harmonization of standards is essential, bearing in mind Canada's dependence on imported health care products and the support required for the domestic manufacturing industry.

- People in the manufacturing industry, governments, and health care institutions who were contacted expressed enthusiasm for the CSA HCT program and for CSA. There were many suggestions for future standards and recognition that CSA needs more resources.

- The arrangements for determining priorities for the program need clarification. Clearly there are misunderstandings on both sides of the roles of the CSA and CCOHTA. Improved communications between the organizations is essential.

- Voluntary consensus standards may not be appropriate for all areas of health care at the present time. For example, standards for drugs and pharmaceutical products, which require extensive trials and tests, would be difficult to incorporate in the current process.

- The shift of health care services to the community is introducing new and previously institutionally-based technologies into the home environment. Standards need to be developed and/or revised to take into consideration the surrounding environment, socioeconomic circumstances and education/training needs of this new group of health care technology users.

- Funding sources for the CSA HCT program are not directly involved in the direction of the program, but CSA has a HCT strategic steering committee which guides the program, and all provinces are invited to actively participate on this committee, and to provide guidance and direction to the program.

- The standards that have been developed to date by the CSA HCT program are well used and well recognized.

- Many comments in the survey of stakeholders related to the need for better dissemination and marketing of standards, particularly to health care facilities outside major urban centres.

- The emphasis on a consensus approach for the National Standards System of Canada was cited by many users as the key to CSA's success in terms of being able to develop standards which are practical/usable, engender compliance on the part of industry, and have "clout" and "buy-in" due to the multi-disciplinary nature of their development.

- There is a need to develop alternative approaches to evaluating the implementation of standards. Clearly, two critical questions that need to be answered on an ongoing basis for purposes of accountability to the CSA HCT program are:
  - ✓ To what degree are the standards being used?
  - ✓ What is their impact?

  The first question is quantifiable (for example by sales figures of the standards). The second question is more difficult to answer, but CSA is one of the first SDOs in the world to develop an assessment tool (SVAT) to examine this question.

Recommendations

- The program should recognize the need for more international liaison and harmonization of health care standards and increase its support for international standardization efforts.

- There is a need to re-examine the scope of the CSA HCT program, in light of the many health care standardization opportunities that are emerging due to significant changes in this field, and the technological infrastructure that supports it.

- Program participants and contributors should focus on developing a program "charter", to arrive at an agreed set of objectives and to scope the program. The primary participants in this process should be the CCOHTA Board of Directors, CSA, and the CSA Strategic Steering Committee on Health Care Technology.

- The program charter should define the program objectives within the framework of health care technology needs as agreed upon by the financial contributors to the program. The objectives need to be defined from a long-term perspective, over a three to five year period to reflect the life-cycle of standards development activities. Strategic goals of the program should be defined in these terms, so that the program is not "re-invented" each year. It should be noted that the business of developing standards for many technologies often last longer than one year, in many cases up to five years. Strategic milestones that reflect this aspect of standards development should be indicated in the program charter.

- It is a good idea to develop such a program "charter" with the assistance of a third-party facilitator, experienced in conducting workshops which could bring the various players in the program together, to design an appropriate program definition and scope. At the end of this process the outcome should be a stable program charter which delineates the

following: objectives, a detailed "in/out of scope" statement, strategic milestones, and reporting relationships and authorities.

- The program charter itself should not address year to year goals and specific annual resources for projects and work items. However, a broad basis of the context and rationale for the program should be identified in the program charter, and approved by the CCOHTA Board of Directors, so that the terms of reference for annual expenditures and related Workplan items are clear to all parties involved. An absence of agreement on program scope is detrimental to the future of the program, especially within the current climate of broad and significant health care technology standardization needs.

- A retrospective statement on completed projects, and work in progress, should be given a separate treatment within the body of the Workplan, with highlights and individual project achievements. A list of standards developed is not sufficient as an accountability item in the Workplan.

- The approach for estimating the "values" of standards is not sufficiently explained in the Workplan. The approach need not be explained within the Workplan itself, but the CCOHTA Board of Directors deciding on funding and priorities need to be provided with a convincing explanation of the SVAT methodology, recognizing that this methodology is a work in progress and that this tool may be breaking new grounds as a value assessment methodology. CSA is working on this tool and trying to improve their process for assessing priorities and standards values, but if this methodology is to be used for achieving appropriations of public funds, it should be validated.

- The SVAT tool is only as good as the information it uses. Because SVAT depends on health care data for its results, and because consistent data is currently not available across all of the fields covered by the Workplan, the use of this tool to assign value estimates to CSA's prioritization process is somewhat presumptive at this point. Nonetheless, CCOHTA could help CSA develop some of their information sources and needs. CCOHTA doesn't get paid by the provinces to do this, so it will require increased funding to undertake such support.

- As part of the program charter (see above), CSA and CCOHTA should decide jointly on an approved format (table of contents) for annual workplans, that includes all the necessary items for decision making by the CCOHTA Board of Directors, and for accountability purposes. A model workplan can be discussed during a joint workshop, and finalized through a process involving program participants and funders.

- The benefits that are listed in the project statements within the 1998/99 Workplan, for the CSA HCT program, seem reasonable, and intuitively convincing. However, the manner in which these benefits are presented create some difficulty in deciphering them (e.g., from the small print in the workplan attachment across the many project proposals). We suggest that a summary table which separates benefits into categories (by project), and filled in as applicable to the issue (standard) at hand, and as discovered through the CSA analysis of benefits. Categories of benefits could include the following:
    - ✓ direct economic benefits (or cost savings)
    - ✓ indirect economic benefits (or cost savings)
    - ✓ health status/clinical outcome benefits
    - ✓ quality of life/quality of care benefits

- ✓ regulatory benefits
- ✓ industry benefits
- ✓ other benefits (tangible/intangible).

- Priority projects listed in the 1998/99 Workplan do not reflect the broader changes in the scope and location of health care provision in today's health care system as discussed in this report (e.g., community-based versus institutional health care needs). However, CSA responds to specific requests for standards from clients in the public sector, industry, and health care providers. To a great extent, these clients set the agenda for CSA standards development activities. In this respect, CCOHTA and CSA could improve their communications with each other by undertaking the following:
  - ✓ communicate on an ongoing basis, regarding program activities, including proactive involvement by CCOHTA members in the early stages of developing the annual workplan submission;
  - ✓ CCOHTA act as a conduit to facilitate information dissemination to the provinces and territories about the Program, new initiatives, published standards, etc., and facilitate information input into the Program and exchange of information regarding needs that the provinces and territories have identified;
  - ✓ have CSA and the CSA HCT program mentioned on the CCOHTA website, in CCOHTA publications, etc., to identify and emphasize a cooperative link between CCOHTA and the CSA HCT program.

1. INTRODUCTION

PricewaterhouseCoopers (PwC) was contracted by the **Canadian Coordinating Office for Health Technology Assessment** (CCOHTA) to undertake an independent evaluation of the **Canadian Standards Association Health Care Technology Program**. The following report provides the analysis and findings of this study.[1]

1.1 Background

1.1.1 Canadian Standards Association

The Canadian Standards Association (CSA) is Canada's largest standards development and certification organization. It is an independent, non-government, not-for-profit association with headquarters in Toronto. Established in 1919, CSA has a long record of handling safety, performance and quality issues through the development of consensus standards as well as product testing, certification and quality systems registration services. CSA standards are developed and written by consensus through its technical committees comprising volunteer experts who represent a range of constituencies. The standards produced by CSA technical committees are voluntary; but may be enforced by law when referenced in provincial or federal regulations. CSA is an important part of the National Standards System (NSS) of Canada. The NSS is overseen by the Standards Council of Canada, which is mandated by federal legislation and reports to Parliament through Industry Canada.[2]

1.1.2 The CSA Health Care Technology Program

CSA published its first health care standard in 1963, and established its Health Care Technology (HCT) Program in 1973. From an initial emphasis on standards in the electromedical field, the HCT program now has defined a broad role as follows:[3]

- to coordinate and manage a consensus standards development process;
- to enable users to understand particular standards by providing standards-related information and interpretations;
- to encourage and assist stakeholders in identifying issues where CSA's standards development capability can offer effective consensus solutions; and,
- to respond to the needs of health care providers and Canadian manufacturers in developing standards which are specific to Canadian needs, yet harmonized wherever possible with international standards.

The CSA HCT program is funded, in part, by the provincial and territorial governments of Canada; and, until 1994, was accountable to the Federal/Provincial Advisory Committee on Institutional and Medical Services (ACIMS) and later to the Federal/Provincial/Territorial Advisory Committee on Health Services (ACHS). In March 1994, accountability of the program was transferred to the CCOHTA, who took on the responsibility of approving the annual activities and budget of this Program and recommending the budget levels of the Program to the Conference of Deputy Ministers of Health.

[1] It should be clear that this study is not intended to be either a "financial audit" of the program, or an "audit" of management practices. It is a program evaluation with specific objectives as indicated in the *Request for Proposals (RFP) for an Independent Evaluation of the Canadian Standards Association Health Care Technology Program*, Canadian Coordinating Office for Health Technology Assessment, Ottawa, February 4, 1998.

[2] See Section 2 for a description of the National Standards System (NSS).

[3] These objectives of the CSA HCT program are as listed in the 1998-99 Program Workplan, and as identified in the *RFP* for this evaluation study.

1.2 The 1998-99 CSA HCT program Workplan

CSA submitted an HCT program Workplan for 1998-99 (fiscal year) on October 1, 1997, for consideration by the CCOHTA Board of Directors. This workplan included 26 proposed projects with a budget of $880,525, plus a proposal for a performance measurement project worth $65,000. Thus, the total CSA HCT program funding requested by CSA for fiscal year 1998-99 was $945,525. The CCOHTA Board reviewed the workplan and the associated budget on October 6, 1997. The Board decided not to recommend any provincial/territorial government support for the CSA request for funding in 1998-99, "until an external evaluation of the CSA approach to standard setting, update and assessment is conducted, and until the process of identifying the 'value for money', selection of projects and prioritization of projects is transparent to the Board."

1.3 Objective of the Evaluation

This report provides an independent evaluation of the CSA HCT program. The overall objective of the independent evaluation is to assess the effectiveness of the CSA HCT program.

The key issues addressed by this study are focused on the following areas of evaluation interest:

- the rationale of the CSA HCT program;
- the success of the program in meeting its objectives;
- the results of the program and their benefits;
- the participation of health care technology stakeholders in the standards development process funded by this program; and,
- alternative approaches.

To ensure an appropriate focus for the study was maintained during the project, the evaluation questions identified in the Statement of Work[4] were structured into a pre-evaluation assessment matrix, which included several questions to pursue in the evaluation (see Annex A). It should be noted that this evaluation is not an *audit* (financial, management or otherwise) of the HCT program.

1.4 Approach

The approach adopted for this study included the following steps:

- Interviews with members of the CCOHTA Board of Directors (see list of interviewees in Annex B).
- Survey of stakeholders (including health care providers, manufacturers of health care technology, standards developers, regulators, and officials from provincial ministries of health (see questions asked in Annex C).
- Health care technology environmental scan (see list of articles, reports and other documents reviewed in Annex D).
- Review of file documents pertinent to the CSA HCT program and history (see list of documents reviewed in Annex D).

[4] *Request for Proposals (RFP) for an Independent Evaluation of the Canadian Standards Association Health Care Technology Program*, Canadian Coordinating Office for Health Technology Assessment, Ottawa, February 4, 1998.

- Inventory of standards -- an inventory of standards developed by the CSA HCT program was tabulated for the years 1993-94 to 1998-99 (see Annex E).
- Analysis of international factors in standards development -- e.g., trends in Health Care standards developed by international organizations such as International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC).
- Review of benefits of health care technology standards (including voluntary and regulatory standards).
- Assessment of the Standards Value Assessment Tool (SVAT) of CSA.
- Comparison of CSA HCT program priorities and activities to health care technology environment scan findings.
- Comparison of regulatory and voluntary standards regimes – their roles and responsibilities.
- Review of health care standards development in other western industrialized countries.

The various components of the study approach listed above represent multiple lines of evidence and provide important insights on the issues and findings with regards to the results and impacts of the CSA HCT program.

1.5 How to Read this Report

An Executive Summary highlights the findings and recommendations of the evaluation. The report was written in a manner to succinctly describe the analysis and conclusions, while including necessary corroborative evidence and detailed information.

A need to make the national standards and regulatory systems of Canada transparent: Section 2 provides a descriptive overview of the Canadian voluntary standards and regulatory systems. It was deemed necessary to include such an overview since, during the evaluation process, stakeholders identified a need for clarification on similarities, differences and relevant applications of these two systems.

Health care technology context: An environmental scan of health care trends and factors impacting on standards development is included in **Section 3**. This section of the report is intended to provide a contextual background for the evaluation of the CSA HCT program. Setting priorities for developing health care standards depends, in part, on the context and need for the standards. Section 3 provides information that is indicative of the increasing significance of standards development for health care technologies.

Analysis of the CSA HCT program results: Section 4 of this report provides the details of the results of the CSA HCT program. This Section is organized based on the issue components listed in 1.3 above – i.e., rationale of the program, achievement of program objectives, results and benefits of the program, participation of stakeholders, and alternative approaches.

Evaluation of the 1998-99 Workplan: Section 5 is focussed on the evaluation of the Workplan (1998-99) of the CSA Health Care Technology Program.

Background information and additional corroborative materials: A set of **Annexes** provides background information (including interviewee lists and references). Additional corroborative materials gathered during the evaluation are available for interested readers (for example, notes from stakeholder interviews, summary tabulations from CSA on standards developed, background reports and documents).

2. NATIONAL STANDARDS SYSTEM OF CANADA AND THE REGULATORY PROCESS

This section of the report describes the regulatory process and the voluntary consensus National Standards System (NSS) of Canada, and compares various characteristics of the two. This is not intended to be an exhaustive description of these systems, but rather to provide a basis for the subsequent evaluation sections of this report by identifying key features of the two systems that are pertinent to this study. Key messages related to the evaluation are summarized at the end of this section.

It is important to include this overview since, during the evaluation process, health care stakeholders identified a need for clarification of these two systems, to provide an understanding of the appropriateness of each system to health care standards requirements, and to make the two systems more transparent within the context of this evaluation. It is important to recognize the complementary nature of these systems of health care standards and regulatory requirements in Canada.

2.1 Complementary Systems: Making Standards and Regulatory Systems More Transparent

Exhibits 2.1 provides an overview of regulatory and standards components and functions, based on the following general elements: mandates and legislative authority; priorities and who develops regulations/standards; enforcement (compliance, conformity assessment); and review process.

There are a number of similarities and differences between the voluntary consensus and regulatory standards systems in Canada. Both systems are well structured and include requirements and criteria for accountability and representation of stakeholders. The government regulatory and the national standards systems of Canada have many components that are similar (as shown in Exhibit 2.1).

Regulations are mandatory requirements that govern products, processes or behaviour. The standards published through the National Standards System of Canada (for example, by the Canadian Standards Association), while not necessarily mandatory, also accomplish similar ends. Both systems require a review process to take place, and both systems require consultation with or participation of appropriate representatives of experts, stakeholders and interest groups.

Parallel functions and generic activities of the regulatory and national standards systems in Canada are summarized below. Obviously, there are many parallels in the development and application of the two types of standards, but there are also some important differences and expectations.

- A regulating department develops, maintains and enforces *regulations* that fall within its jurisdictional purview as limited by the laws of Canada or provincial governments, in accordance with procedural guidelines defined by central agencies. In contrast, a standards development organization in the NSS develops and maintains *consensus standards* in accordance with criteria established by the Standards Council of Canada (SCC).[5]

[5] See *Criteria for a National Standard of Canada* in Annex F.

Exhibit 2.1 Regulations and Standards: System Components

REGULATIONS *(Regulatory System)*	**CONSENSUS-BASED STANDARDS** *(National Standards System)*
MANDATE AND LEGISLATIVE AUTHORITY	
Regulations are authorized under a federal Act of Parliament (e.g., Governor-in-Council regulations, Ministerial regulations); or by provincial legislation.	Accredited SDOs are responsible for coordinating and facilitating the process. Standards Council of Canada (SCC) authorized under Act of Parliament -- SCC accredits SDOs; oversees process; sets guidelines and requirements.
BY WHOM DEVELOPED	
Developed by federal and provincial government departments.[6]	Developed by standards development organizations (SDOs), for example CSA (technical committees).
PRIORITIES	
Subject to Regulatory Impact Analysis Statement (RIAS), for federal government regulations.[7]	Subject to industry and market-imposed checks and balances. Also subject to funding source (client) stipulations. CSA applies SVAT to assess standards.
REVIEW PROCESS	
Public review process, consultation with interest groups and stakeholders.	Consensus and review process, with participation of experts, stakeholders and interest groups.
Reviewed by Central Agencies and Justice Departments.	Regular review and update by technical committees.
Published in Canada Gazette.	Published by SDOs/referenced in Canada Gazette.
COMPLIANCE AND ENFORCEMENT	
Enforced by law, Act of Parliament. Compliance required – checked by inspections and approved by registration process.	Testing and certification or third-party registration may be required. Enforced by law when referenced by regulations.

- Priorities for the development of *regulations* are set according to Departmental mandates and government policies. Priorities for *consensus standards* are set in response to requirements of clients of the SDOs, but Canadian national standards should be capable of making "a significant and timely contribution to the national interest", and government policies provide a framework and strategic context for standards development.

- Budgets for development and maintenance of *regulations*, and their enforcement, are set by government departments. Budgets for activities involving assessment of conformity to *consensus standards* are set by SDOs and certification/ testing bodies, and are responsive to demands for services rendered.

- *Regulatory development* usually begins with the Department making a search (for example, using the SCC) for relevant international or national regulations, or standards that could be referenced. In c*onsensus standards* development international standards and those of other countries are used (adopted or adapted) wherever feasible and available.

[6] However, regulations could also reference standards developed by standards development organizations (SDOs).
[7] RIAS is the federal government method for providing evidence on the impacts of new regulations, and serves as a decision tool in developing regulations.

- Except in emergency situations, the development of a *regulation* includes consultations with all interested parties, either in a series of bilateral discussions or with all parties represented together (e.g., in committees). To establish the criteria for a *standard*, the SDO forms a technical committee that is balanced in accordance with SCC criteria and operates on the consensus principle.

- *Compliance assessment for regulations* is done by government laboratories which could be accredited by the SCC (but, at the present time, mostly are not). Some testing is also contracted to private sector laboratories. *Conformity assessment for standards* may be done by laboratories associated with an SDO, or by other laboratories accredited by the SCC.

- Some *regulatory government departments* have agreements with governments in other countries to test goods before export to Canada. *Standards development organizations* may make arrangements with their counterparts in other countries for testing to Canadian standards.

- By sub-contracting or licensing, *regulatory government departments* "accredit" or "approve" the results of test laboratories. The *Standards Council of Canada* is the national accreditation body for product testing laboratories.

- Government departments may require contractors to conform to one or more specified standards in the ISO 9000 quality management series. The SCC is the sole accreditation body for quality management registrars in Canada.

2.2 National Standards System of Canada

Exhibit 2.2 provides an illustration of the "world" of standards and the interdependent nature of the players involved. Literally thousands of national and international organizations make up this world. Health care standards, just as standards in all other industry sectors, are part of this global infrastructure of standards development organizations.

What is known in Canada as the "National Standards System" (NSS) for voluntary standards is shown in Exhibit 2.2 within the dashed lines. The NSS is based on a federation of accredited standards development, product testing, certification, and quality systems registration organizations. As the largest standards development organization in Canada, CSA is an important part of the NSS. As indicated in Exhibit 2.2, the NSS interacts with a wide variety of stakeholders on both a national and an international basis. The following provides an explanation of the activities of each of the actors in the Canadian NSS.

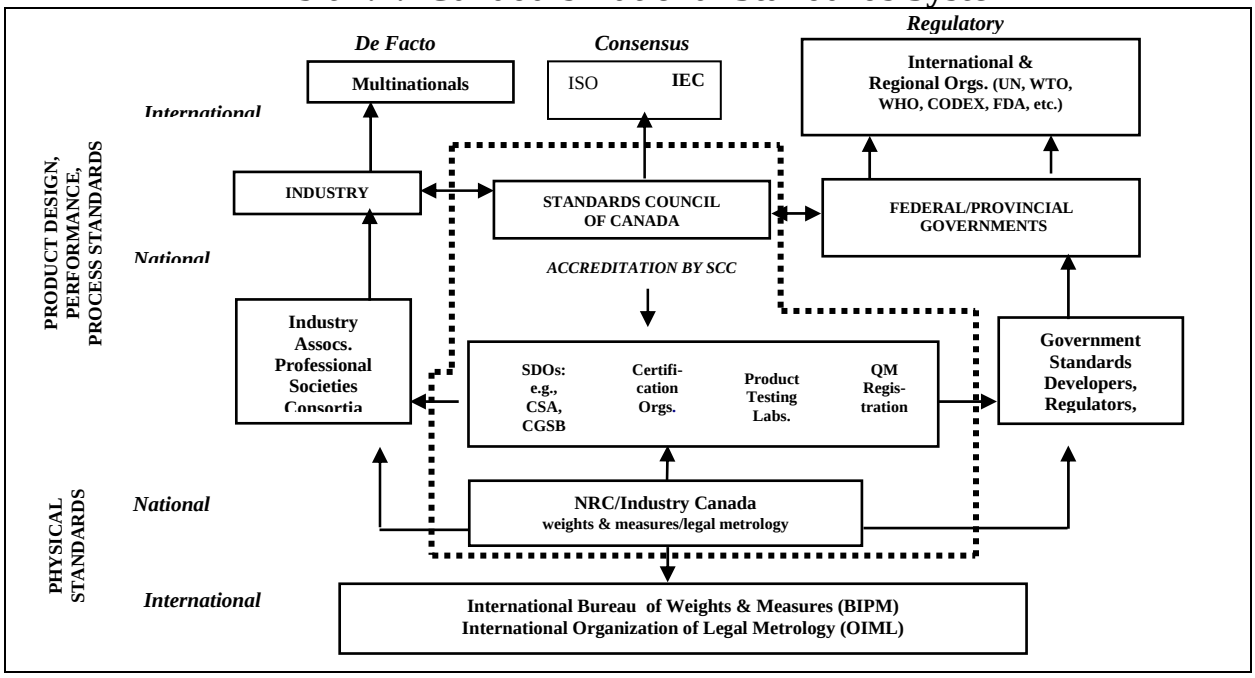
The **Standards Council of Canada** (SCC) is responsible for the overall coordination of this federation. The SCC is a federal Crown corporation whose mandate is to promote efficient and effective voluntary standardization in Canada in order to advance the national economy, support sustainable development, benefit the health, safety and welfare of workers and the public, assist and protect consumers, facilitate domestic and international trade and further international cooperation in relation to standardization.[8] In this latter context, the SCC is: (a) Canada's designated Inquiry Point under the World Trade Organization TBT (Technical Barriers to Trade) Agreement; (b) the designated Canadian standards organization member at

[8] *Standards Council of Canada Act,* House of Commons, Ottawa, 1997.

the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC); and, (c) the Canadian member in other regional and international standards bodies.

The SCC's activities are carried out within the context of the National Standards System. The SCC is manager of the NSS, and the SCC works to ensure that Canadian needs for voluntary consensus standards and related services are met.

Exhibit 2.2: Canada's National Standards System[9]



A **National Standard of Canada** (NSC) is a standard submitted by a Canadian Standards Development Organization for NSC designation by the SCC, which must be satisfied that specified criteria have been met before the NSC designation is given. These criteria are listed in Annex F.[10]

There are five accredited **Standards Development Organizations** (SDOs) within the NSS: Canadian Standards Association (CSA), Canadian General Standards Board (CGSB), Underwriters' Laboratories of Canada (ULC), Bureau de Normalisation du Quebec (BNQ), and Canadian Gas Association (CGA). These organizations coordinate the work of standards technical committees (TCs) whose members represent a cross-section of interests, from producers to users. Standards prepared by these committees can be submitted to the SCC for approval as National Standards of Canada.

The five accredited SDOs of Canada are shown in Exhibit 2.3, together with the areas of standards development activities that they undertake that are related to health care issues.

[9] Based on chart developed in *Review of Standardization Activities and Opportunities*, a report prepared for Standards Council of Canada by Nordicity Group Ltd., July 14, 1998, p. 15.
[10] *Criteria and Procedures for the Preparation and Approval of National Standards of Canada*, (CAN-P-2E, Standards Council of Canada, January 1992).

Exhibit 2.3: The SCC Accredited Standards Development Organizations and Their Areas of Standards Development Relevant to Health Care

Organization	Areas of Standards Development Relevant to Health Care	Description/Role/Comments
Canadian Standards Association (CSA)	• Anaesthetic equipment & respiratory technology • Application of electricity in health care • Assistive technologies for persons with disabilities • Biological evaluation of medical devices • Child resistant packaging • Dentistry • Drug related standards • Extra-corporeal circulation technology • Health care facility engineering & physical plant • Implantable medical devices • Laboratory medicine • Medical gas systems • Medical laser safety • Medical sterilization systems • Quality management for health care products	• CSA is an accredited, not-for-profit, non-statutory, voluntary membership organization engaged in standards development and certification activities. • CSA currently operates 16 technical committees developing health care standards under the CSA's Health Care Technology Program, with provincial government funding. • CSA has developed more than 105 new health care standards and updated at least 38 others over the last five years. • CSA maintains close links with international standards organizations such as ISO and IEC and adopts or adapts international health care technology standards wherever practicable.
Canadian General Standards Board (CGSB)	• Blood grouping reagents • Lifting systems for aircraft boarding • Medical gloves and condoms • Mercury-in-glass clinical thermometers • Portable medical gas systems • Screen type and intra-oral diagnostic X-ray film • Single-use syringes	• CGSB is a federal agency mandated to provide standardization and conformity assessment services in support of government procurement and other government requirements. • Health care standards developed by CGSB to date are related to a few specific health care technologies.
Underwriters' Laboratories of Canada (ULC)	• Building construction materials • Burglar alarm and physical security equipment • Fire fighting apparatus, fire alarms and fire protection equipment • Fittings and associated equipment for flammable fuels and gases • Tanks and associated equipment	• ULC is an accredited certification and standards development organization dedicated to the protection of life and property. • ULC standards relevant to health care facilities are in the areas of physical security, fire protection and related construction standards.
Bureau de normalization du Quebec (BNQ)	• Hospital beds and mattresses • Non-flammable medical gas distribution systems	• BNQ is an accredited standards development organization created by the government of Quebec in 1961. • BNQ has developed a few specific standards relevant to the health care sector.
Canadian Gas Association (CGA)	• Natural gas and propane installation codes • Gas safety valves and regulators • Gas appliances	• CGA is the national standards association of the Canadian natural gas industry. • CGA is accredited by SCC to develop standards related to natural gas networks, appliances and usage.

Certification Organizations (COs) have registered trademarks which give a visible indication that products or services comply with a standard. The SDOs which have also been accredited by SCC for product certification include CSA, BNQ, ULC, and CGA.[11]

Testing Organizations (TOs) determine whether a product or service meets the appropriate standard. At the time of writing this report, there were over 250 accredited testing organizations in Canada.

Quality Systems Registration is a relatively new part of the NSS. Companies wishing to quote that they conform with the ISO 9000 series of standards for quality management must

[11] For a complete list of accredited SDOs, certification and testing organizations, see the SCC website at http://www.scc.ca.

be registered with an accredited registrar. These registrars are frequently closely associated with the SDOs and form an element of the NSS.[12]

The SCC operates a system of **accreditation** under which it ensures the coherence of the NSS by establishing rules for all the above standards bodies and groups (SDOs, COs, TOs, etc.) and by monitoring their performance.

As part of the NSS, another important role of the SCC is to ensure effective Canadian participation in the work of international standardization. For many years Canada has made a significant contribution to the two organizations primarily responsible for international voluntary consensus standardization -- the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). These two bodies publish standards in a wide variety of fields, including medical technology, information technology, the environment and quality management. As Canada's representative member at ISO and IEC, the SCC works on behalf of Canada according to international protocols set by ISO and IEC in standards development and conformity assessment.

Together, all the above Canadian standards organizations form the infrastructure of the National Standards System of Canada. Some of these organizations develop standards, others are conformity assessment bodies which determine the compliance of products or services to a standard's requirements. More than 14,000 Canadian volunteers contribute to committees that develop national or international standards. The NSS provides an appropriate springboard for participation of stakeholders in strategic international activities related to standardization and conformity assessment. The SCC works to ensure that the NSS achieves Canadian needs for voluntary consensus standards and related services.

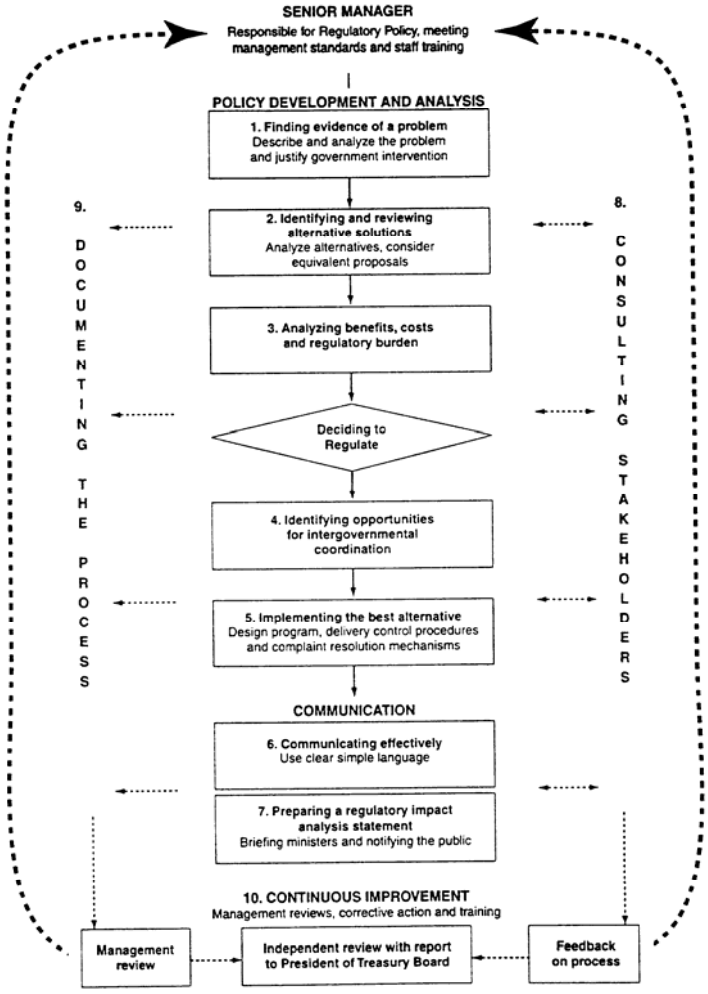
2.3 Regulatory Process

The flow chart shown in Exhibit 2.4 is a simplified illustration of the federal government's system for managing the regulatory process. Provincial regulatory authorities also follow a similar scheme in developing their provincial regulations. Exhibit 2.4 links the steps involved in managing and continually improving the process for developing regulations.[13] (see reference: *Federal Regulatory Process Management Standards: Compliance Guide*, Regulatory Affairs, Treasury Board of Canada, November 1996). This flow chart can be compared to the procedures for preparation and approval of National Standards of Canada in the NSS, as shown in Exhibit 2.5.

The first steps in developing a regulation are to identify the problem that may require government action and to analyze the possible alternatives to creating regulations. Regulatory authorities proposing new regulatory requirements or regulatory changes must have evidence that a problem has arisen, that government intervention is required, and that new regulatory requirements are necessary. When health, safety and environmental risks are involved, regulatory authorities must consider whether the relative and absolute risks posed are such that regulatory intervention is required.[14]

[12] For a current list of accredited quality systems registration organizations, see the SCC website at www.scc.ca.
[13] See *Federal Regulatory Process Management Standards: Compliance Guide*, Regulatory Affairs, Treasury Board of Canada, November 1996.
[14] *Health Protection for the 21st Century*, a discussion paper, Health Canada, July 1998.

Exhibit 2.4: Regulatory Process[15]



It must be demonstrated that the benefits of regulatory requirements are greater than their costs. When regulations address health, social, economic or environ-mental risks, it must also be demonstrated that regulatory effort is being expended where it will do the most good. For all regulatory proposals, a benefit-cost analysis must be carried out to assess potential effects, such as impacts on the environment, workers, consumers and other sectors of society.[16] The Business Impact Test[17] is an example of the type of analysis that must be undertaken to assess the effect that major regulatory proposals will have on the private sector.

Regulatory authorities must determine what, if any, related regulatory requirements already exist and which other departments, agencies or governments are involved. New regulatory requirements must be coordinated with existing ones to avoid duplication and to take advantage of possible efficiencies. When standards are being considered, reference should be made, if appropriate, to existing standards developed within the National Standards System or internationally. Pertinent international and federal-provincial agreements must be respected.

[15] See *Federal Regulatory Process Management Standards*, Regulatory Affairs, Treasury Board Secretariat, November 1996.
[16] *Benefit/Cost Analysis Guide for Regulatory Programs*, Treasury Board of Canada, August 1995.
[17] *The Business Impact Test (BIT)* is a test used to analyze and compare the anticipated impacts of major, alternative regulatory solutions on business.

When the regulator recommends a regulatory solution to Ministers, the regulator needs to prepare a regulatory impact analysis statement (RIAS), which includes taking into consideration the obligations of the regulatory department under NAFTA and WTO agreements. The RIAS is used by Ministers to approve regulations. Since 1986, proposed regulations must be published in draft form for public comment in Canada Gazette I.

Finally, consultation with stakeholders is a critical element in all stages of the regulatory process, because input from people affected by regulations improves the regulations. A final version of the regulation is published in Canada Gazette II. Once the regulation is in force, conformity assessment procedures must be implemented as well. Certification and testing may at this time be done through the use of the National Standards System (particularly if a standard has been referenced); or inspection, testing and enforcement may be done by the department itself.

2.4 Processing a National Standard of Canada

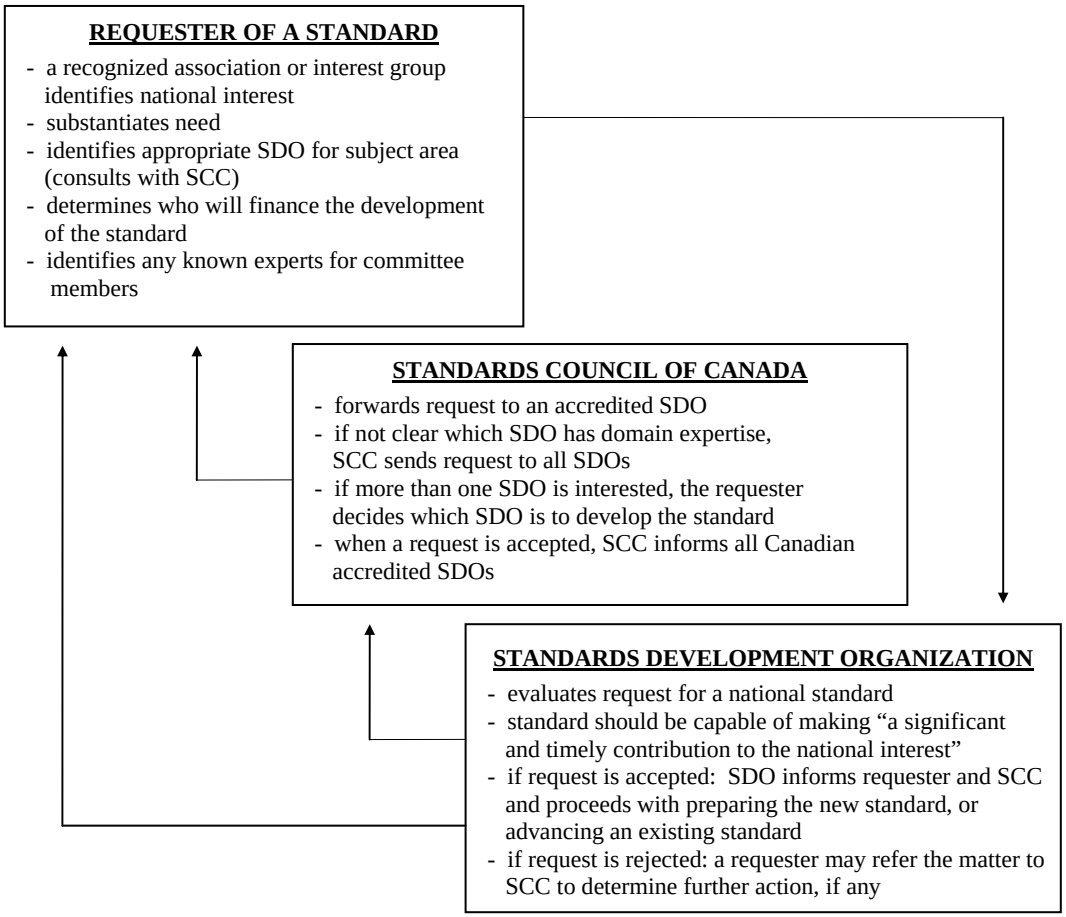
Exhibit 2.5 summarizes the standards development procedures and responsibilities for processing National Standards of Canada (NSCs). A request for the development of a National Standard of Canada may originate from any source. It is preferred that requests originate from recognized associations, government agencies, universities, or represent some co-ordinated group interest. The request should be accompanied with evidence to substantiate that the standard is making or would make a significant contribution to the national interest.

A National Standard of Canada normally will be prepared by an accredited standards development organization. The Technical Committees that develop NSCs are required to have a balance of representation of producers, consumers and others with relevant interests, as may be appropriate to the subject in hand.[18] The Standards Council of Canada is responsible for approving NSCs. Such approval is based upon recommendations, submitted to the SCC by the accredited SDOs, which certify that the standard conforms to specified requirements (as identified in CAN-P-2E).[19] The designation of a standard as a NSC indicates that it conforms to the criteria and procedures established by the SCC. Approval does not, however, refer to the technical content of a standard. This remains the continuing responsibility of the accredited standards development organization.

The format of NSCs are to be in accordance with good standards-writing practices, as identified by the SCC; and may vary, as appropriate, depending on the source, purpose and subject of the standards. NSCs are made available in both official languages, French and English. During its preparation, a NSC is offered for public review.

[18] *Criteria and Procedures for the Preparation and Approval of National Standards of Canada* (CAN-P-2E, SCC, January 1992).
[19] Ibid.

Exhibit 2.5: Processing a National Standard of Canada[20]



2.5 Standards Developed Outside the National Standards System

Government departments ma develop their own standards for regulatory purposes. The right-hand side of Exhibit 2.2 showed that federal government departments (e.g., Health Canada, Environment Canada) and provincial counterparts are involved in setting standards as well as carrying out conformity assessment activities. In this process, Canadian government regulatory departments also interface with international organizations involved in standards issues, and on a bilateral or multilateral basis with government counterparts in other countries.

Standards are also developed outside the National Standards System of Canada by private sector organizations (see Exhibit 2.2). Industry develops *de facto* standards. These standards can be found, for example, in automotive products or in internationally recognized software products. De facto standards may be developed unilaterally by large companies, or by industry associations, professional societies, and consortia. An example of this type of standard is the standard for compact discs, which were produced by a consortium of the principal manufacturers. These standards can be undertaken within a national or an international context.

[20] See National Standards System, *Criteria and Procedures for the Preparation and Approval of National Standards of Canada* (CAN-P-2E, SCC, January 1992); and *Procedures for Processing a Request to Prepare a National Standard of Canada* (CAN-P-1015A, SCC, September 1991).

2.7 Key Evaluation Messages

Key evaluation messages from this Section of the report about the national voluntary standards and regulatory systems of Canada are as follows:

- There is a need to make the regulatory and voluntary standards systems, and how these systems work together to satisfy health care needs, more transparent to all the participants in the CSA HCT program.

- The regulatory and voluntary consensus systems for standards are complementary (not competitive) and share many common elements including, whenever possible, the extensive involvement of stakeholder groups.

- The National Standards System (NSS) provides a framework for the development of reputable voluntary consensus standards in Canada, but standards can also be developed outside this system.

- Both the regulatory and voluntary consensus standards systems of Canada have increasingly become systems which require appropriate rationalization, particularly in terms of social and economic impacts on stakeholder groups, including governments, industry and the Canadian public.

- The Canadian Standards Association is one of the major players in the National Standards Systems of Canada, and is one of five accredited standards development organizations (SDOs). The Standards Council of Canada is the national organization mandated by federal Act of Parliament to oversee the NSS, and to maintain its integrity by setting criteria and accrediting responsible SDOs and other standards organizations.

- All five accredited SDOs have produced standards relevant to health care, but CSA has been the most active and experienced in this field.

- Regulations are enforceable by law while voluntary consensus standards are not, unless they are referenced in a regulation. However, the compliance of a product to a standard may be a contractual requirement imposed by purchasers or users.

- Regulations may reference standards produced within the NSS or internationally; and this is becoming a preferred option for many government regulators.

- Both the regulatory and voluntary consensus systems have extensive international links and obligations, which generally facilitate standards development in Canada.

- A National Standard of Canada is a standard approved by the SCC that was developed by an accredited SDO conforming to requirements established by the SCC. The standard must make a contribution to the national interest.

3. HEALTH CARE TRENDS AND TECHNOLOGY CONTEXT

This section of the report provides an overview of relevant health care trends, and identifies important factors involving standards and regulatory requirements for health care. Key messages and implications for this evaluation study, which emerge from the discussion of the health care trends, are summarized at the end of this section. The evidence included in this section is based on a review of a number of documents on health care programs, policies and trends (see references in footnotes and in Annex D).

Under each of the trends identified below, there is recognition of the degree to which there may be opportunities for future standards development within a given area. It should be noted that these are only general observations regarding standards development opportunities in the health care area, and are not meant to imply that the CSA HCT program, as it is currently scoped, is necessarily the best venue for development of such standards.

3.1 Health Care Trends

The health care system in Canada is undergoing tremendous change. Governments, health care providers and consumers are attempting to define strategies for reducing health care costs, while trying to maintain the quality of care and universal access to health care services. At the same time, the system is trying to keep pace with rapid advances in medicine, which have resulted in a prevalence of and demand for expensive new technologies for the diagnosis and treatment of disease. Many jurisdictions around the world are grappling with these same pressures and are looking to Canada for leadership because of the excellent reputation of our health care system and our long track record with the provision of comprehensive insured health care.

The following details some of the pressures confronting the system and identifies major trends in the provision of health care. The potential implications of these trends for national standards for health care are identified.

3.1.1 Population Trends Impacting on Health Care Delivery

The World Health Organization report for 1998, *Life in the 21st Century - A Vision for All*, indicates that the most important pattern of progress from a population perspective is an unmistakable trend towards a healthier, longer life.

Two main trends, increased life expectancy and declining fertility rates, mean that by 2025:

- worldwide life expectancy, currently 68 years, will reach 73 years;
- the global population, currently 5.8 billion, will increase to about 8 billion;
- the number of people aged over 65 will have risen from 390 million to 800 million; and,
- the proportion of young people under 20 years will have fallen from 40 percent to 32 percent of the total population.

These demographic trends have a profound implication for human health, particularly with respect to the provision of health care for the elderly. In the 21st century, one of the biggest challenges will be how best to prevent and postpone disease and disability, and to maintain the health, independence, and mobility of an ageing population.

One of the ways to meet this challenge is to develop devices that aid in the independent living of seniors. This is already a growing market for device manufacturers, and population projections indicate that it will continue to grow. National standards represent one way for seniors and their families to evaluate the effectiveness and safety of the plethora of devices that are on the market.

3.1.2 Public Perceptions of Health Care

A Canadian national survey of public opinion by Ekos Research Consultants (1994) indicated that 79 percent of Canadians believe that Medicare is the most important social program. Canadians rank health third in a list of 22 values that they believe the federal government should uphold (behind maintaining freedom and preserving a clean environment).

Canadians are concerned about the preservation of the health care system. These concerns stem from government funding caps and reductions, hospital closures, lengthening waiting lists for tests and procedures, and a sense that the quality of the system is being compromised. The Ekos survey reported that 68 percent of Canadians believe that the quality of the health care system has deteriorated over the last two years.

Recent consultations of the National Forum on Health[21] attracted Canadians from coast to coast to come forward to give their views on the future of the health care system. The natural extension of the need to become involved in individual health care decisions is the desire to become more involved in decisions affecting the health care system as a whole. Advisory groups are increasingly including consumer representation on their committees to ensure that public input is received before making additional recommendations on system changes.

Consumers are taking a more active role in maintaining their health and are seeking information to make informed choices on the most appropriate care. This trend towards "consumerism" has placed demands on the system to have readily accessible and understandable information, and to base treatment decisions on evidence.[22] National standards provide one understandable source of information that consumers can use in selecting among therapeutic options.

3.1.3 Reforming Health Care

As funding caps and reductions continue to be applied towards the health care system, the pressure for reform to the system has increased. There is a growing recognition that closing beds and programs without an accompanying systemic view of the impacts of these changes is threatening the quality and accessibility of health care.

The vertical integration of the health care system continues to evolve in Canada and is being actively considered at the provincial and federal levels in the country. A vertically integrated system manages health care across institutional and health sector boundaries (including hospitals, long term care institutions, and community based agencies) and along a continuum from prevention to palliative care. The consideration of a vertically integrated health system has also led to an increased recognition of the value of multi-disciplinary health care provider teams.

[21] *Canada Health Action: Building on the Legacy*, National Forum on Health, 1997.
[22] See section 3.1.7 on "evidence-based decision making".

3.1.4 Home and Community Care

Home and community care have become a focus of concern for the health care system in Canada, as health care needs grow but the capacity to meet them is not fully developed.[23] The establishment of an integrated system means that community based care and home care services will need to increase. The pressure for enhanced home care services originated with a recognition that hospital based care is expensive and, as a result of less invasive therapies and new drug discoveries, many patients could be discharged earlier if appropriate home care could be arranged.

The restructuring of the health care sector has seen hospitals close at a pace faster than the strengthening of the infrastructure for home and community care, creating additional pressure on the system. Strengthening the capacity of the system to provide home-based and community care will remain a strong focus for both the federal and provincial governments for the foreseeable future as hospital budgets continue to be constrained.

Because this area of health care is still relatively uncharted territory, the requirement for standards both of care delivery and the technologies used to support the care will become increasingly important as the infrastructure and systems are put in place.

3.1.5 The Development of Non-invasive Therapies

Funding reductions to the health care system have resulted in health care providers seeking new and more cost effective treatments for medical conditions. Researchers have developed many non-invasive treatments and therapies for conditions that have traditionally required surgical interventions. Non-invasive therapies are less expensive because they require less recovery time for patients and have fewer associated side-effects and complications. The use of lasers as a surgical technique is one example of a less invasive technique which can often be conducted on an out-patient basis.

This is an area of medical innovation that is likely to grow. Rapid advances in this field can be expected over the next 5 to 10 years, both because these treatments are cost-effective but also because patients prefer less invasive medical care.

3.1.6 Shifts in Public Policy Determinants of Health

The traditional illness or medical model of health care has changed in the last twenty years to a more preventive approach regarding illness and the promotion of good health.[24] This view has expanded to acknowledge the important role that non-medical factors play in the health status of the population.[25] Non-medical factors, known as the determinants of health, include the physical environment, income, social status, and employment. The National Forum on Health concluded that a better balance is required between short-term economic imperatives and the long term health and well being of Canadians.[26]

Initially, the focus of government policies was on lifestyle choices (e.g., smoking, drugs, good nutrition) and on healthy public policy (e.g., seatbelt legislation) to promote good health and

[23] *National Conference on Home Care: March 8-10, 1998.* Proceedings prepared by Helen Patriquin of the Nova Scotia Association of Health Organizations.
[24] *A New Perspective on the Health of Canadians—A Working Document*, M. Lalonde ("the Lalonde report"), Government of Canada, Love Printing Service, Ottawa, 1974.
[25] *Achieving Health for All: A Framework for Health Promotion*, Jake Epp ("the EPP document"), Ministry of Supply and Services, Ottawa. 1986.
[26] *Canada Health Action: Building on the Legacy*, op. cit.

prevent illness. More recently, public policy attention has shifted to the societal level, the social and economic determinants of health beyond the immediate control of individuals, professionals, and communities.

The recognition of the important contributions of non-medical determinants of health create opportunities for standards development – for example, standards could consider the impacts of non-medical products and practices on the health status of the population (e.g., the introduction of standards for bicycle helmets).

3.1.7 Evidence-Based Decision Making

The National Forum on Health concluded that a key objective for the health care system should be to move rapidly towards the development of an evidence-based health system, in which decisions are made by health care providers, administrators, policy makers, patients, and the public on the basis of appropriate, balanced and high quality evidence.[27]

The growth in information and communications systems provides an enhanced opportunity to engage in benchmarking, indicator development, health care report cards, outcome measures, clinical practice guidelines and other measurement and best practices techniques which facilitate evidence-based decision making. Applying the best available evidence in the decision making process does not guarantee good decisions or outcomes, but it improves the likelihood of both. Improved decision-making processes can produce better decisions with better consequences, and will enhance the accountability for those decisions.

Two major issues with respect to the enhancement of evidence-based decision making are: (i) the need to balance the privacy of individuals' health information with the information requirements of practitioners, and decision makers and researchers; and, (ii) the need to develop criteria guiding what constitutes the "best" evidence and how to define best practices. National health care standards, developed within an evidence-based framework, could assist the system in addressing both of these challenges and could contribute to the overall knowledge base to improve decision making.

3.1.8 Communications and Information Technology

Rapid advances in communications and information technology have enabled tremendous innovation for health care. Efforts are being made across the country to develop central data repositories, develop open architecture systems that allow information from a variety of systems to be integrated, merge clinical and administrative databases, and develop and introduce smart card technologies.

The introduction of telemedicine enables health care professionals in different locations to connect electronically and consult with each other on medical cases. The Northwest Territories is conducting a multilevel telehealth system pilot project (Baffin Health Net) which links the Pond Inlet and Kimmirut Community Health Centres to the Baffin Regional Hospital and Montreal Children's Hospital. The system provides a broad range of scheduled consultant and routine services in support of primary health care delivery. In New Brunswick, a

[27] Evidence-based decision making is seen as "… the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients …", "… integrating individual clinical expertise with the best available external clinical evidence from systematic research." By "best available external clinical evidence" is meant "clinically relevant research, often from the basic sciences of medicine, but especially from patient-centered clinical research …" See *Evidence-based medicine: How to practice and teach EBM*, by DL Sackett, WS Richardson, W Rosenberg, and RB Haynes, New York, Churchill Livingstone, 1997.

component of NBTel's 100 percent fiber-optic infrastructure links all hospitals. A provincial telemedicine strategy includes the New Brunswick Care Network, which aims to bring more health care services and health care consumer information on-line.

The provision of electronic health services is a new and largely unexplored area of health care. With the exception of privacy rules, there are few standards to govern its implementation and use in the Canadian health care environment.

3.1.9 Trends in Funding of Health Care

The federal government has responsibility of setting the broad national policy framework and standards for the health care system through the *Canada Health Act*. The Act out five core principles that all provinces must adhere to:

- **Universality**: all eligible residents of a province are entitled to coverage by public health insurance.
- **Accessibility**: insured health services must be reasonably accessible i.e., no financial or other impediments.
- **Comprehensiveness**: medically necessary hospital and physicians' services must be covered by public health insurance.
- **Portability**: the public insurance plan must cover eligible residents while they are temporarily absent from the province.
- **Public administration**: the public insurance plan must be operated on a non-profit basis and be accountable to the province.

The federal government provides to the provinces to support the health care system, and the provinces, in turn, have ultimate responsibility for administering the system. Traditional funding mechanisms for health care have changed, as the federal government has reduced direct health transfers to the provinces and has intermingled the remaining funding with education and social welfare transfers – i.e., the Canadian Health and Social Transfer, or CHST.

As the provinces have assumed an increased burden of meeting their own health care costs, they have also sought greater autonomy in insuring, funding and delivering the services. This shift in funding mechanisms has significant implications for the national health care system, including the extent to which national standards may be recognized by the provinces. To deal with this shift, federal bodies are recognizing the need to ensure that provincial representation is included in any national advisory groups on health, including the establishment of any new standards in health care.

3.1.10 Private Insurance Industry

Supplementary health insurance rates are growing as health care costs increase. Private health expenditures funded mostly by employers continue to expand at two to three times the rate of the growth in the economy. Supplementary health plans are generally provided to employees by their employers and cover the costs of drugs, dental care, vision care, and additional assistive medical devices. As federal and provincial funds diminish, provinces are de-listing previously provided health care services from their health insurance plans (e.g., electrolysis), this will create additional pressure on the private insurance industry to insure and provide these de-listed services.

As costs increase, employers and insurance companies are seeking new and cost effective ways to structure supplemental plans. Insurance companies increasingly require health care providers to submit medical evidence to support the diagnosis and the choice of treatment. Over and above the issues of the efficacy of the treatment, it is conceivable that standards for health care technologies would provide one source of criteria and evidence to support the choices of providers and consumers in selecting appropriate solutions.

3.1.11 Trends in Alternative Medicine

There is a growing private industry for health remedies that are outside of the traditional scope of academic, clinical medicine (for example, herbalism, acupuncture, massage therapy and reflexology). It is estimated that the total Canadian market for herbal remedies alone was $175 million in 1996 (a 17 percent growth over the previous year).[28]

There is a growing recognition that some alternative therapies can be appropriate as a complement to, or as a substitute for, traditional clinical medicine, and this industry is becoming more formalized in Canada. In May 1997, the Minister of Health Canada, Minister Dingwall, established the Advisory Panel on Herbal Remedies to provide advice to Health Canada on the safety and effectiveness of specific herbal remedies. The Advisory Panel consulted extensively with the public and with specific stakeholders and submitted their report to the Minister in May 1998.[29]

There may be an opportunity to develop national standards on the provision of alternate therapies and medicines. These standards can provide criteria and information to providers, consumers, and regulators.

3.1.12 Regulatory Reform in Health Care

In Canada, the regulation of medical devices is the responsibility of Health Canada. The new Canadian *Medical Devices Regulations*, which came into effect on July 1, 1998[30], set out new requirements governing the sale, importation and advertisement of medical devices. The goal of the *Regulations* is to ensure that medical devices distributed in Canada are both safe and effective.

Emphasis is placed on developing standards and regulatory requirements which are harmonized with those of Canada's international trading partners and eliminating, to "the greatest extent possible", requirements unique to Canada. Harmonization allows meaningful negotiations towards Mutual Recognition Agreements (MRA) to occur, thereby eliminating barriers to trade. MRAs, once operational, will allow devices to be assessed in one country and placed on the market in another without further assessment. Health Canada's Bureau of Medical Devices is committed to and supported by industry in achieving this goal.

The *Medical Devices Regulations* provide a good example of the type of reform occurring in regulation relating to health care issues. Governments are introducing balance between direct regulation and the use of third parties to carry out standards development and enforcement activities.

[28] Health Care Information Resources Website – Alternative Medicine (www.hsl.mcmaster.ca/tomflem/altmed.html).
[29] *Regulatory Framework for Natural Health Products*, Final Report of the Advisory Panel on Natural Health Products, Government of Canada, May 13, 1998.
[30] *Medical Devices Regulations*, Health Canada, Ottawa, 1998.

3.2 Health Care Technology Industry and Market

The health care industry can be grouped into at least three major components, all of which require some kind of standards development. These components are medical devices, pharmaceuticals and medical procedures for delivering health care and for technology manufacturing. Medical devices are an important and pervasive part of the Canadian health care system. As new and existing technologies continue to be available in the Canadian marketplace, appropriate steps must be taken to ensure that they are safe, effective and achieve their intended purposes. The generation of standards for medical devices and other related health care fields (including pharmaceuticals and procedures) has an important role in ensuring the safety of patients and health care personnel, and in the effective use of new medical technologies.

The following provides an overview of the various components of the health care industry, and trends impacting each of them.

3.2.1 Global Industry Growth

The global market for health products and services has been estimated at over 2 trillion Canadian dollars annually.[31] A number of important factors (see previous discussion in Section 3.1) are shaping the development of this large industry on a global basis, including the following:

- Changing demographics (including an aging population in industrialized countries), an emerging middle class in newly industrialized countries, and large population increases in developing countries have resulted in new challenges and priorities for the health care industry.
- Cost containment initiatives in industrialized countries such as Canada have prompted the need for new systems and methods to deliver health care. This has resulted in an increased emphasis on preventative medicine and community or home based care, and on improving the general quality of life.
- Negative environmental impacts, longer life spans and the presence of new drug resistant diseases are altering disease patterns.
- New and evolving communications and information technologies are increasingly relevant for health care services.

The global medical devices industry is dominated by emerging and start-up companies, and the above-mentioned factors have resulted in rapid growth of the medical devices industry. The global market for this part of the overall health care sector was estimated at US$137 billion in 1997. According to the Health Industry Manufacturers Association (HIMA), the United States constitutes 42 percent of the market, the European Union 28 percent, Japan 15 percent and the rest of the world 15 percent.[32] This sector is forecasted to grow by seven percent overall during the next three years.

The global pharmaceutical industry has experienced a tremendous increase in demand in non-traditional markets. As with medical devices, the same changes in demographics, health care delivery, disease patterns and research and development have resulted in the growth of pharmaceutical sales. This part of the overall health sector constituted a global market of

[31] *Canada's International Business Strategy for Health Industries, 1998-1999*; industry sector report by Industry Canada, Ottawa, 1998.
[32] *1997 Global Medical Technology Update: The Challenges Facing U.S. Industry and Policy Makers*; foreign market figures from Health Industry Manufacturers Association (HIMA), Washington, D.C.

US$256 billion in 1994. Since 1990 growth rates have approximated 10 percent per year. North America, Western Europe and Japan account for 80 percent of the world market. American and European brands dominate the market.[33] Canada accounts for 2 percent of the market.[34]

3.2.2 The Canadian Medical Devices Industry

The Canadian medical devices industry is made up of firms that provide a wide range of products used for diagnosis and treatment of ailments, including: medical, surgical, and dental equipment; furniture, supplies and consumables; orthopedic appliances; prosthetics; electromedical equipment; as well as diagnostic kits and other equipment.

The Canadian industry can be characterized as follows:[35]

- 800 manufacturing firms which employ over 17,000 people
- small firms (75 percent have less than 50 people)
- Canadian owned firms (approximately 90 percent).

In 1997, production in this industry accounted for an estimated $3.0 billion, which constitutes 1.6 percent of the global market. Consumption, in this same year, was estimated at $4.5 billion.

3.2.3 The Canadian Pharmaceutical Industry

The pharmaceutical industry can be divided into brand drug manufacturers, generic drug manufacturers, firms developing innovative biopharmaceutical products, nonprescription drug manufacturers, firms undertaking research on a contract basis, distributors and drug information processing/informatics companies. (Please note that these categorizations are arbitrary and may not be mutually exclusive.) Canadian academic centres and universities also constitute a major contributor to this sector.

The pharmaceutical sector in Canada can be characterized as follows:[36]

- 119 establishments producing or distributing a full range of pharmaceutical products
- employs approximately 19,300 (1994)
- factory sales equal to $7 billion in 1997[37]
- over 40 percent of firms have less than $2 million in sales
- 10 companies, including 8 multinational enterprises, have over $100 million in sales
- the two largest Canadian owned companies (Apotex and Novopharm), both generic producers, are among the top 10 in Canada, and export up to 40 percent of their production.

[33] *Ibid.*
[34] *Tenth Annual Report*, Patented Medicine Prices Review Board, December 31, 1997, p.12.
[35] *International Standardization: Strategic Issues for Canada*, Nordicity Group Ltd., report prepared for Industry Canada, Ottawa, May 7, 1997, p.199.
[36] *Canada's International Business Strategy for Health Industries, 1998-1999*, op. cit.
[37] *Tenth Annual Report*, op.cit., p.13.

3.2.4 The Canadian Health Care Services Industry

The Canadian health care services industry is composed mainly of small and medium sized enterprises, with some large organizations that provide services on a commercial basis in Canada and abroad. There are some 2,500 firms involved in health care in Canada, providing services related to design, establishment, operation, maintenance and improvement of health care systems and institutions, on a commercial basis.[38] Health services fall into eight general categories: clinical services; health administration and consultants; institutions and facilities management (including hospital care); contract research organizations (CROs); continuing medical, nursing and allied health education and training; architectural and design services; telehealth (health telematics and informatics); and health insurance.

An important trend in Canadian health care services is a growing emphasis on improving delivery, which is being shaped by managers of health services working hard to make their delivery systems more effective, less costly, less institutional and more community based.

3.2.5 Canadian Strategic Interests: Global Position in Health Care Sector

3.2.5.1 Health Care Technology

Access to world markets is critical for the development of the Canadian medical devices and pharmaceutical sectors. Tariffs are no longer a major issue as a result of the implementation of the North American Free Trade Agreement (NAFTA) and agreements under the World Trade Organization (WTO). Non-tariff barriers (NTBs), such as regulatory review processes, remain a stumbling block for market access.

Canadian-based health companies bring specific comparative advantages and strategic competitive values to the global health care market. Canadian strengths in the medical services sector include:[39]

- cardiovascular equipment: e.g. heart valves, pacemakers, catheters, electronic cardiography
- in-vitro diagnostics: e.g., for cancer/hepatitis/sexually transmitted diseases
- radiation therapy and therapy planning software
- medical imaging: e.g., 3-D imaging, image-archiving systems, ultrasound scanners
- dental materials: e.g., high-speed steam sterilizers, dental implants, sundries
- assistive devices/home health care: e.g., mobility aids, peritoneal dialysis
- orthopedics/prosthetics/orthotics: e.g., myoelectric limbs.

In terms of international performance, in the medical devices sector Canadian imports equaled $2.6 billion and exports equaled $1.1 billion in 1997. Canadian exports were up 17 percent from 1996. The key markets for exports are the United States, Europe and Japan. However, increasingly Canadian exports are going to other parts of Asia, South America and Mexico.

In the pharmaceutical sector, Canada has a number of advantages, including:

- internationally recognized universities and an excellent scientific/ research community
- strong research lead in specialized areas such as Alzheimer's, cardiovascular, central nervous system, and gene based diseases

[38] *International Standardization: Strategic Issues for Canada*, op.cit.
[39] *Ibid.*

- tax legislation that attracts companies to leverage R&D in Canada
- Mutual Recognition Agreement (MRA) negotiations under way with EU and the United States
- quality manufacturing and processing capabilities.

Canadian pharmaceutical imports in 1994 totaled $1.78 billion. The ratio of pharmaceutical imports to exports has remained relatively consistent over the past 15 years, at about $3 in imports to $1 in exports.

Canadian health services firms employ about 150,000 people and have about $3 billion in annual sales. Recognized strengths of health services firms include:

- hospital management skills
- operation of long-term care facilities and home-care organizations
- good public health and primary health care system
- architecture, construction and consulting engineering related to health-care facilities
- education and training
- health informatics and information systems
- medical laboratories.

3.2.5.2 Standards Strategic Initiative

The Standards Council of Canada has laid out its objectives for the next three years, into the millenium, in its recently released *Standards Council of Canada Strategic Plan, 1998-2001*.[40] Changes taking place in the world economy are shaping international relationships and mutual collaboration towards developing national and international standards infrastructures in all industry sectors. This includes modernization of standards and conformance institutions and development of human resources, to address the needs and challenges of the global economy.

Health care and health care technology, as discussed in the previous sections, represent a large component of the global economy, and constitute a major policy issue among the governments of developed and developing economies alike. The challenges for all countries, respectively, and Canada included, is how best to mobilize standardization stakeholders in this industry sector to work towards common objectives.

It is for this reasons that the SCC is preparing a *Canadian Standardization Strategy* (CSS) document. This document is intended to serve as a guiding document for all stakeholders. The SCC is providing the leadership to develop this document. The SCC is currently working with a 17-member Stakeholders Advisory Council (SAC) to develop and produce the CSS by means of a thorough consultation, review and consensus building process. The first national meeting of the SAC is to take place on August 31, 1998, to discuss the initiative towards a national standardization strategy.

Clearly, health care and health care technology interests should be represented in the SCC process. A Canada-wide consultation process is expected to contribute to the development of the *Canadian Standardization Strategy*. The issues and relevant factors discussed in the previous sections of this report are relevant to the context of developing a standardization strategy for health care.

[40] *Standards Council of Canada Strategic Plan, 1998-2001*, Standards Council of Canada, Ottawa, 1998.

The finalized CSS document of SCC is intended to be presented to the federal Minister of Industry, to provincial and territorial governments, and to other standardization stakeholders as a document that is intended to guide policy and to provide direction for mobilizing stakeholders around strategic objectives that address national interests.

3.3 Implications for Standards

The issues identified in the preceding discussion of health care trends, technologies, and strategic interests, indicates several potential standards-related implications for health care.

3.3.1 Health Care Trends and Technology

- The Canadian health care system is undergoing tremendous change. As pressures to reduce costs yet maintain quality increase, administrators, health care providers, policy makers, and consumers are searching for new, innovative, and cost effective ways to deliver health care.

- The need for evidence on the efficacy of these innovations and the need to provide information to assist consumers in making informed choices suggest that there will be a continuing and/or increasing need for standards well into the 21st Century.

- Standards can provide the information and the criteria for informed decision making by providers, consumers, policy makers, funding agencies, and regulators.

- In Canada, health cost containment initiatives have resulted in the need for new systems and methods to deliver health care. This has resulted in an increasing emphasis on preventative medicine and community or home based care, and generally improving the quality of life. This also implies new opportunities for developing community or home based health care standards.

- Standards can contribute to the information needs of the new "consumerism" in health care.

- Reform and down-sizing within the health care system will put more pressure on SDOs to address gaps in expertise and develop standards which facilitate the activities of health care institutions.

- Vertical integration within the health care system is consistent with a broad-based, multi-disciplinary approach to standards development

- The revised Canadian *Medical Devices Regulations* place a greater reliance on standards in order to satisfy the safety and effectiveness requirements for certain devices.

- When appropriate, both provincial and federal regulators are moving towards "regulating where necessary, but not necessarily regulating." Standards provide an important compromise to the choice between full versus no regulation; and provide the added flexibility needed in a field such as health care, where change and development occurs on an almost daily basis.

- The rapid and varied expansion of communications and information technology in the health care field suggests the need for the development of standards by a wide variety of

organizations, addressing issues ranging from privacy to image quality (for example, diagnostic uses of telemedicine) to infrastructure requirements.

- There is an increasing demand from health professionals, consumers and payers alike for clear evidence of the benefits, costs and outcomes of health care technologies.

- New approaches to standards development need to be evaluated to address the needs of the health care system in the context of evidence-based decision making

- The shift of health care services to the community is introducing new and previously institutionally-based technologies into the home environment. Standards need to be developed and/or revised to take into consideration the surrounding environment, socioeconomic circumstances and education/training needs of this new group of health care technology "users."

- Standards for medical procedures are becoming increasingly necessary.

- Methods for evaluating the effectiveness of standards will need to be developed and refined.

3.3.2 Strategic Interests and Scope of the CSA HCT Program

- Changes in the relative proportions of federal, provincial, private and out-of-pocket health care funding make it imperative that standards development activities include the full range of stakeholders impacted by a given issue.

- Canada needs to balance efforts between the pursuit of new fast-growing markets, and maintaining presence in mature markets. Canadian companies need knowledge and expertise in standards developments worldwide, and regulatory requirements, such as European Union directives. Canadian firms involved in health care technology need access to standards intelligence and standards development activities. The Canadian National Standards System, through programs such as the CSA HCT program, provide suitable venues for this.

- Clearly, from the broad scope of health care interests in Canada, the social and economic trends surrounding health care, and the new and rapidly evolving health care technologies being developed, the CSA HCT program is only one, though significant, part of the overall health care standardization context.

- In this context, the options of scoping the Program within this broad context is open to the CCOHTA board, the CSA itself, and the federal and provincial government authorities who are currently reviewing Canada's national standardization strategies through the Standards Council of Canada's *Canadian Standardization Strategy* initiative.

IV. ANALYSIS OF THE CSA HCT PROGRAM RESULTS

This section of the report provides an analysis of the CSA HCT program rationale, activities, and results. The implications of this analysis for the program workplan and suggested improvements are addressed in the subsequent sections of this report.

4.1 Rationale and Planning Process of the Program

As part of any program evaluation, an appropriate first step is to go back to the roots of the program, and to identify the original rationale, and then to examine whether the program is still timely. The role of the CSA Health Care Technology Program over the years has been fairly simple and consistent. "It is to help develop standards in the health care technology field and to help put those standards into effect."[41]

In discussions with CSA program representatives, interviews with stakeholders familiar with the program, and a review of file documents and past workplans – the evaluation team has identified the following original dimensions of the CSA HCT program.

CSA itself, as an SDO, has been in the health care field for about 40 years. An example of a standard developed during the earlier part of CSA's health care involvement, and modified in one edition or another, over the years, was the *Code for Prevention of Explosions or Electric Shock in Hospital Operating Rooms (Z32.1standard)*. In about 1973, as a result of the increase in technology, in the health care field, in hospitals, and as a result of a study that was conducted jointly by CSA and the then federal Ministry of Health and Welfare,[42] it became evident that more work was necessary in the health care field. It was rationalized that CSA needed to expand its activities to meet the needs of health care standards requirements. As a result, the Standards Steering Committee on Health Care Technology was established to consider what fields within Health Care were in need of standardization.[43] This Steering Committee included 13 technical committees in the following fields:

1. Diagnostic, therapeutic and electronic data processing equipment.
2. General hospital equipment.
3. Laboratory instrumentation, products and supplies.
4. Implants, prosthetics and sensory aids.
5. Surgical supplies, sterile and disposable devices.
6. Ionizing and non-ionizing, radiation-emitting, therapeutic equipment and diagnostic apparatus.
7. Metrication.

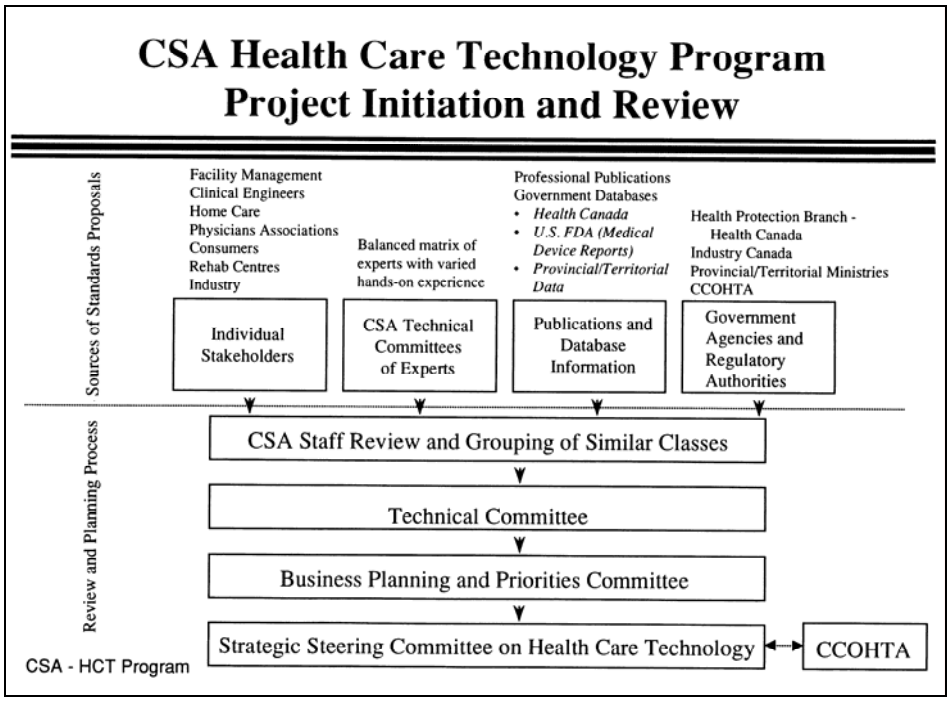
Over the years since its establishment, the Standards Steering Committee on Health Care Technology, has undertaken reviews of the needs for standardization in health care. The review and planning process of the CSA HCT program, as it has evolved to the present day, is shown in Exhibit 4.1.

In summary, this process is inclusive of individual stakeholders (including users of standards, health care providers, consumers, manufacturers, and other groups. Government agencies and regulatory authorities are also participants in the process, both in standards project initiation and in the review of project requirements.

[41] *CSA and the Health Care Technology Program*, by A.M.Dolan, CSA, October 12, 1978, p. 5.
[42] Ibid.
[43] Ibid., p. 4.

Exhibit 4.1 demonstrates that the process aims at achieving appropriate representation through a balanced matrix of experts with varied hands-on experience. These experts contribute to the process as members on Technical Committees (TCs) that contribute to the project initiation stages of the Program and to the review and planning stages. The actual representation on these TCs is examined further in a subsequent part of this section.

Exhibit 4.1



The review and planning process involves several filters, starting from CSA staff reviews and analysis of standards requirements as they relate to specific areas of standardization activities. Appropriate Technical Committees are identified to develop or update the required standards. Plans are also reviewed by the Business Planning and Priorities Committee of CSA and by the Strategic Committee on Health Care Technology.

Annual workplans of the CSA HCT program, resulting from this process, are submitted for review, amendment, and approval by CCOHTA. Opportunity for health care stakeholders (including provincial government representatives, federal regulators, industry manufacturers, health care providers, etc.) to contribute to the process of identifying priorities and needs for health care technology standardization, is provided at different stages of the project initiation and review process.

The current areas of activity of the Program include the following committees:

- Anaesthetic Equipment & Respiratory Technology
- Laboratory Medicine
- Child Resistant Packaging
- Dentistry
- Health Care Facility Engineering and Physical Plant
- Extracorporeal Circulation Technology

- Medical Gas Systems
- Sterilization
- Drug Related Standards
- Laser Safety
- Quality Management - HC Products
- Application of Electricity in Health Care
- Implantable Medical Devices
- Biological Evaluation of Medical Devices
- Assistive Technologies for Persons with Disabilities

Some of the specific technologies in these areas relate to the trends and directions in health care discussed previously in Section 3. However, there are many other areas of health care technology development that are not covered by the CSA HCT program. While the program is still very relevant – even more so in the current era of rapid technology change, and global economics – its activities do not embrace all the health care considerations for standards requirements in Canada. This is no fault of the program itself, but simply a question of addressing the needs of requesters of standards as they are expressed to CSA. The standards development process of the Canadian National Standards System, including CSA, as shown in Exhibit 2.5, responds to the needs expressed by stakeholders and interest groups. Section 5 provides some suggestions as to how to broaden the scope of the program to include standards requirements that reflect other, new and evolving needs for health care technology.

However, the consultation process undertaken for this study suggests some agreement around the following points:

- The objective of the program should be to develop standards which provide guidance to minimize the risk and maximize the safety of health care technologies, so as to ensure the "appropriateness" of health care technology products and to assess their quality.
- CSA standards should relate to "mechanical" health care technologies (e.g., gas systems, lifts, equipment, tools, construction) that support health care.
- CSA standards should not delve into the areas of professional practice standards or clinical practice guidelines.
- The program should develop standards which provide information regarding health care technology products which facilitates decision making regarding their appropriateness for a given health care facility.

4.2 Program Funding

As with any program, scope and activity is broadened or limited by the amount of funding available. Funding for the CSA HCT program over the years has come from the provincial government authorities. There is currently no direct funding to the program from the federal government. As shown in Exhibit 4.2, the annual funding provided to the HCT program by provincial Ministries of Health has been highly variable between 1993/94 and 1998/99. Funding for the program declined by 8.5 percent from 1993/94 to 1994/95, and then fell dramatically to 23 percent of 1993/94 levels in 1995/96. Funding was restored to 11 percent above 1993/94 levels for two subsequent years 1996/97 and 1997/98. The amount of funding requested by CSA for the HCT program during this period increased from $385,000 in 1993/94 to $697,975 in 1997/98. Funding requested for the HCT program was $945,575 in the *1998/99*

Workplan Submission but, on the recommendation of the CCOHTA Board of Directors, provincial government funding for 1998/99 was suspended subject to an external evaluation of the HCT program.

Exhibit 4.2: Funding of CSA Health Care Technology Program from 1993/94 to 1998/99

Fiscal Year	Amount Requested	Amount Awarded	Award as % of Request
1993/94	$ 385,000	$ 365,000	95%
1994/95	$ 405,000	$ 334,500	83%
1995/96	$ 575,000	$ 85,400	15%
1996/97	$ 659,275	$ 405,916	62%
1997/98	$ 697,975	$ 405,916	58%
1998/99	$ 945,575	$ 0	--
Total	$3,667,825	$1,596,732	43.5%

According to CSA's *1998 Annual Report* the revenue earned by CSA in 1997/98 as reported in the Consolidated Statement of Earnings was $134,733,000. Funding from provincial Ministries of Health for the CSA HCT program in that year was $405,916. Thus, funding for the HCT program represented about 0.3 percent of CSA's total revenue for 1997/98.

Between 1993/94 and 1997/98, provincial ministries of health funding to the HCT program totaled $1,596,732. During this period, the CSA HCT program developed or revised at least 145 standards. The average provincial contribution (total for all provinces) per CSA health care standard developed is therefore approximately $11,000 per standard. This is perceived as a small cost to pay for the anticipated benefits of developing standards.

Funding sources are not directly involved in the direction of the program, but CSA has a HCT strategic steering committee which guides the program, and all provinces are invited to actively participate on this committee, and to provide guidance and direction to the program (see Exhibit 4.1).

4.3 Achievement of Program Objectives

An inventory of standards developed by the program during the 1990s was developed as part of this program evaluation study. The inventory is contained in Annex E.

Exhibit 4.3 shows the number of health care standards developed by the CSA HCT program and each of the CSA health care technical committees between 1993 and 1998. At least 107 new health care standards were published and 38 revisions of existing standards were written during this period.

Exhibit 4.3: Number of Standards Published by Technical Committees of the CSA Health Care Technology Program from 1993 to 1998

Committee	Title	New Standards Published 1993 to 1998	Standards Revised 1993 to 1998	Standards Proposed for 1998/99
TC Z250	Health Care Technology			
TC Z251	Anaesthetic Equipment & Respiratory Technology	16	2	4
TC Z252	Laboratory Medicine	4	0	1
TC Z253	Child Resistant Packaging	0	1	1
TC Z254	Dentistry	24	0	1
TC Z257	Health Care Facility Engineering and Physical Plant	10	2	2
TC Z259	Extracorporeal Circulation Technology	4	0	2
TC Z261	Medical Gas Systems	0	4	1
TC Z262	Sterilization	3	5	4
TC Z264	Drug Related Standards	0	0	2
TC Z267	Laser Safety	0	0	1
TC Z289	Quality Management - HC Products	2	0	2
TC Z290	Application of Electricity in Health Care	23	20	2
TC Z291	Implantable Medical Devices	4	0	1
TC Z292	Biological Evaluation of Medical Devices	10	0	1
TC Z301	Assistive Technologies for Persons with Disabilities	7	4	0
	Total	**107**	**38**	**25**

The usefulness of health care technology standards developed by CSA through the HCT program can be shown by a number of significant contexts in which these standards are referenced within the Canadian health care system. For example, the Canadian Anaesthetists' Society references 42 CSA standards in its *Guidelines to the Practice of Anaesthesia*. The section of these Guidelines on *Anaesthetic Equipment and Anaesthetising Location* states that "The Canadian Standards Association has provided publications pertaining to anaesthetic facilities and to the selection, installation and maintenance of most anaesthetic and ancillary equipment. When purchasing new equipment or designing new installations, these standards, as well as specific recommendations arising from provincial legislation, shall be obtained and followed."[44]

Practically all of the 42 CSA standards referenced in the Appendix of these Guidelines have been developed or updated within the last five years by CSA under the HCT program. The development or revision of four additional standards pertaining to anaesthetic equipment were proposed in the 1998/99 Workplan.

Another example of the importance of CSA standards to health care is in the area of accreditation of health care organizations. Approximately 1,350 health care organizations participate in the accreditation programs of the Canadian Council on Health Services Assessment (CCHSA) which includes specific accreditation programs for acute care facilities, community health, cancer treatment centres, long term/continuing care, rehabilitation, mental health and home care. Compliance with CSA standards is a basic part of the evaluation and accreditation of these organizations and facilities in all provinces.

CSA HCT program standards are referenced in numerous provincial and federal regulations. The number of health care technology standards referenced in regulations is also growing, as

[44] *Guidelines to the Practice of Anaesthesia (Anaesthetic Equipment and Anaesthetising Location),* The Canadian Anaesthetists' Society, from their website, October 6, 1997.

governments seek more flexible and efficient alternatives to traditional legislative solution to social and economic issues. A partial list of CSA and other voluntary consensus standards cited in federal regulations, demonstrates an extensive use of referencing as a regulatory tool.[45]

The results of the consultation process for this study provide the following observations about satisfaction with program results.

- Overall, CSA has been effective in developing standards in the area of health care technology (but there is always work that has yet to be done!).
- The standards that have been developed to date are well used and well recognized.
- Concerns were raised regarding the timeliness of the standards development process, timeliness being an issue which was felt to be related to both funding constraints/ freezes as well as being a function of the standards development process itself.
- Many comments related to the need for better dissemination and marketing of standards, particularly to health care facilities outside major urban centres (related to the need for CSA to "reach out" to its constituents).
- The Canadian approach/process to developing consensus standards is a model for the world.

One of the stated objectives of the CSA HCT program is "to coordinate and manage a consensus standards development process". To this end, the following observations about CSA addressing this objective can be made:

- The consensus process is an integral part of the National Standards System of Canada under the guidance of the Standards Council of Canada (SCC). CSA is accredited by the SCC as one of five accredited Canadian standards development organizations (SDOs). In discharging its national responsibilities as an accredited SDO, CSA undertakes to coordinate and manage consensus standards in the health care area through the CSA HCT program.
- Consensus is the nationally and internationally recognized method for developing voluntary standards. For example, ISO and IEC standards are developed by consensus. Similarly, as examples at the national level, BSI in the United Kingdom, ANSI in the United States, AFNOR in France and DIN in Germany all develop health care related, technology standards by consensus, as is the case with CSA.
- Standards developed by CSA are developed by technical committees of experts. The HCT program has 16 such technical committees developing standards in health care. Under the HCT program CSA undertakes to coordinate and manage the process committee structures.

Another stated objective of the CSA HCT program is "to enable users to understand particular standards by providing standards-related information and interpretations". To this end, CSA undertakes the following activities:

[45] *Review of Standardization Activities and Opportunities*, report by Nordicity Group Ltd., for Standards Council of Canada, Ottawa, July 14, 1997.

- CSA maintains a website of standards information which includes a catalogue of up-to-date standards for health care and related fields (e.g. life sciences, environment, quality management).
- Currently improving its communications capability through technology solutions using electronic media – for example, a number of pilot studies are underway to develop solutions for wider participation by stakeholders in the standards development process.
- CSA technical committees provide standards information and form networking links to their constituencies. Canadian advisory committees, organized and coordinated by CSA, undertake research for representation of national interests in international standards fora.
- Publication of drafts and final standards are disseminated widely to health care interests and stakeholders by CSA.
- Participation in international committees and fora are spearheaded by CSA.
- CSA organizes ongoing conferences to address standards issues.
- CSA provides technical support services to its TC members.

Another objective of the CSA HCT program is "to encourage and assist stakeholders in identifying issues where CSA's standards development capability can offer effective consensus solutions". To this end CSA undertakes the following:

- management of national and international secretariats – in the CSA HCT program, of 15 TCs, 7 have the dual responsibility of being Canadian Advisory Committees for ISO and IEC representation;
- information products which may or may not be developed using consensus, e.g., *ISO 9000 Essentials* handbook, including one for implementing the ISO 9000 and related 13485 (ISO/TC210) documents for medical device manufacturers;
- electronic products standards information products;
- courses and seminars based on CSA products and services;
- focus groups and workshops as was recently done to assess the need for standards for an aging society;
- standards feasibility studies and assessments;
- other background research and publications on standards issues.

CSA also provides the following ongoing services to its health care standards clients, to encourage and support the development of standards solutions to technology problems:

- providing standards-related information and interpretations to users regarding existing and pending documents;
- supporting the business planning/project identification and prioritization process and TC work program coordination activities.

4.4 Benefits of the Program and the Approach to Assessing Priorities and Value

4.4.1 Benefits

There is general agreement among respondents to the telephone survey conducted for this study of the benefits of voluntary consensus standards for health care. The benefits identified range from achieving technical compatibility, to achieving consumer safety, to economic benefits and reduction of regulatory burden.

In general, the following observations provide the major benefits cited for the health care field as achieved by voluntary consensus standards:

- Health care technology standards save significant amounts of time and money within the health care system; and contribute to the safe and effective treatment of patients within health care institutions.

- The emphasis on a consensus approach was cited by many users as the key to CSA's success in terms of being able to develop standards which are practical/usable, engender compliance on the part of industry, and have "clout" and "buy-in" due to the multi-disciplinary nature of their development.

- Overall, the standards development process is more efficient and more flexible than a regulatory approach, particularly with regards to a sector that experiences such rapid technological change.

- Standards contribute to due diligence, such that facilities comply with best practices and are not negligent.

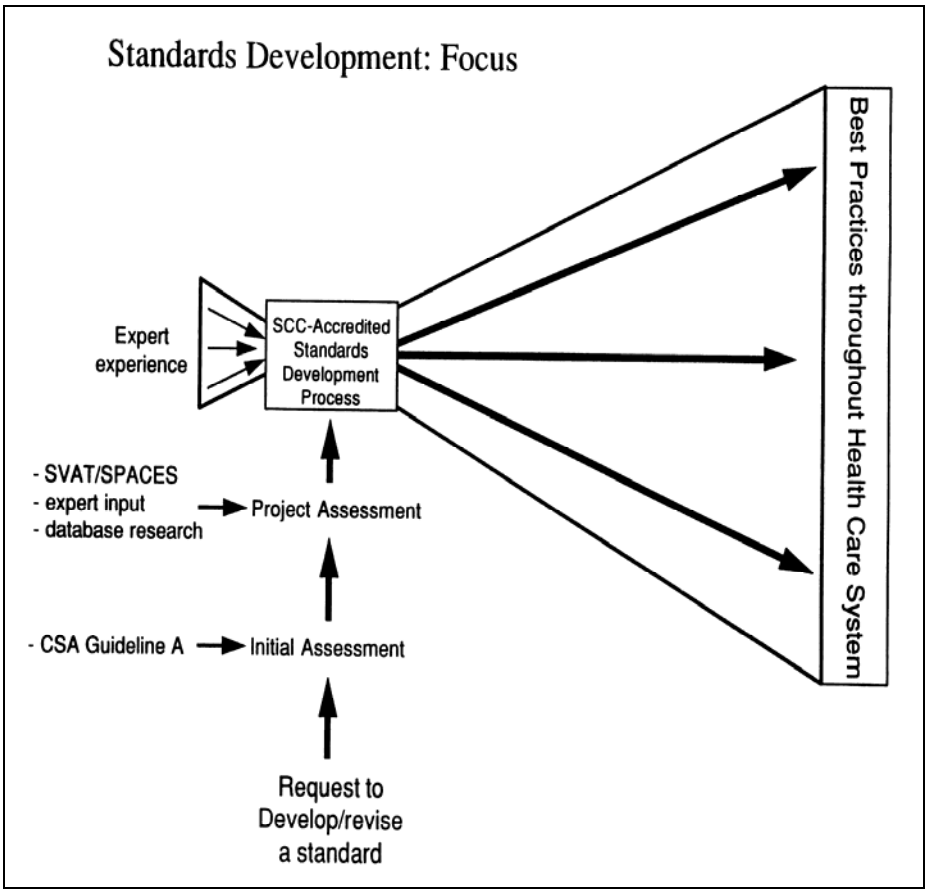
- The greatest single contribution of standards has been in the area of patient safety and anaesthetic gases (Canada is the only country in the world to have complete standardization in this area, with the result that Canada is the only country in the world that has not had a death related to anaesthetic gas systems for the last 20 years).

Program benefits of the CSA HCT program are primarily attributable to the infrastructure and process of standards development that the program brings to the health care field. Exhibit 4.4 illustrates this process which is intended to lead to the ultimate benefit of implementing best practices throughout the health care system.

A request for developing or revising a standard initiates the process. These requests typically come from health care providers, government regulators, manufacturers, or other interest groups. An initial assessment of the request is made, to determine feasibility, costs and appropriate scheduling of the standard required.

Project prioritization is then assessed using the SPACES approach of CSA – Standard Proposal Assessment Criteria Expert System. SPACES is a decision support system which assigns a score to a proposal based upon the criteria of feasibility, consequences, equity, and risk. The role of CSA staff is to assist the members of the TCs to obtain sufficient information

Exhibit 4.4: The CSA HCT Program Standards Development Process



to help them answer the questions posed by the SPACES system. The SPACES system is designed to assist TC members in the evaluation of proposals by providing a consistent framework. The system prompts the user with each question on the evaluation questionnaire and supplies a multiple-choice answer set.

Within the SPACES system, the potential consequences of developing and implementing a standard have been subdivided into five categories of concern. These categories include: health consequences; occupational and environmental consequences; social consequences; technological consequences; and, economic consequences.

The SPACES evaluation questionnaire includes 36 questions that essentially function as a standard checklist of critical items to consider in assessing priorities. The following considerations highlight some of the important factors considered by CSA, the CSA Strategic Steering Committee on HCT, and health care TCs, in determining priorities through the SPACES approach:

- ✓ strong evidence of a problem that requires a standard solution
- ✓ cost of developing the standard
- ✓ likelihood of the implementation of the standard
- ✓ stakeholder endorsement of the development of the standard
- ✓ safety and health implications for consumers and health care providers of implementing the standard

- ✓ likely harmonization of the standard with international standards
- ✓ contribution of the standard to advancement of technology solutions to health care problems
- ✓ impacts of the standard on the manufacturers of health care products.

Clearly, these considerations are critical elements for prioritizing standards activities. They were developed through a process of consultation with experts and users of standards. The whole SPACES system provides a consistent method by which evaluators can apply objective criteria in their assessment of priorities and achieve synergy through group decisions.

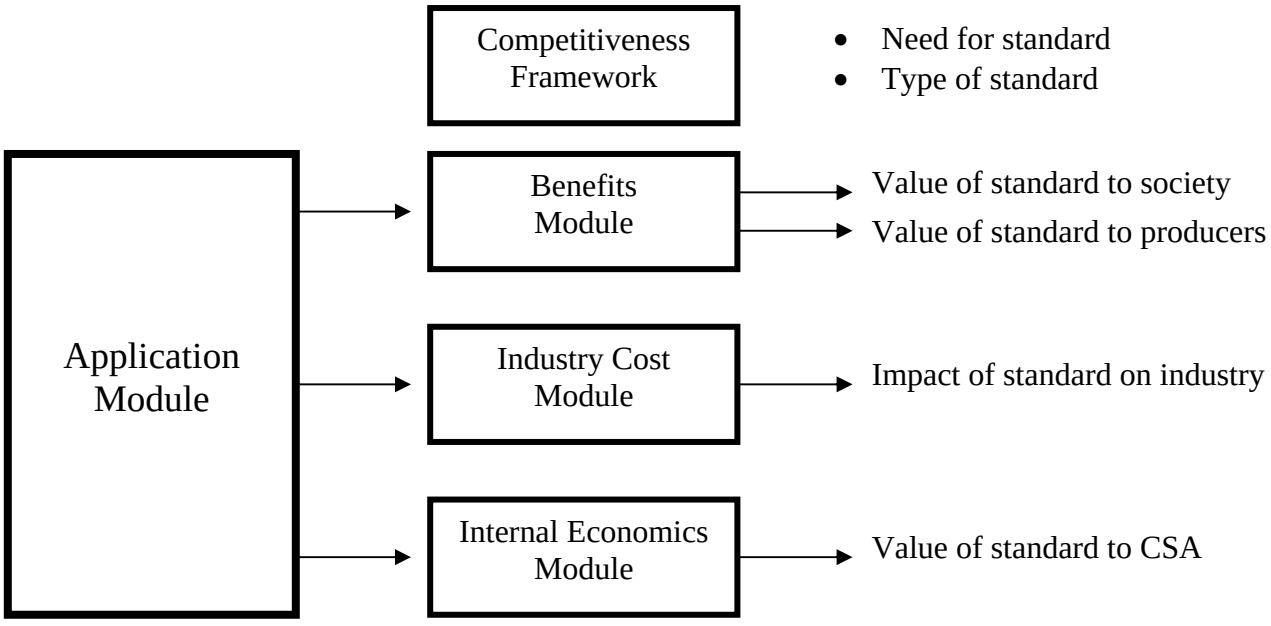
What the SPACES system does not do, however, is bring new proposals/requests for standards to the table for consideration of new standards solutions to health care problems. SPACES is applied to prioritize proposals that come to the table from outside sources (interest groups such as regulators, health care providers, manufacturers of health care products). It is merely a decision tool that helps standards developers assess existing proposals/requests for standards, but does not identify a specific need for new proposals.

4.4.2 Assessment of Value

The second component of the CSA approach to determining benefits of a standard is the SVAT, or the Standards Value Assessment Tool. The purpose of this tool is to determine the value of standards to stakeholders and society in general, and to express that value as a dollar figure. A lot of information goes into the SVAT approach to assessing the value of standards.

SVAT is again a decision tool that helps standards developers determine the likely benefits of a standard to be developed. Exhibit 4.5 provides the overall framework of the SVAT. The

Exhibit 4.5: Standards Value Assessment Tool -- Framework



aimed for benefits of SVAT are as follows:

- provides a consistent and quantitative approach to planning and analysis
- uses current, detailed information to review value
- is based on comprehensive stakeholder input
- is able to rank projects based on dollar values
- is complementary to the SPACES prioritization tool.

This SVAT framework as shown in Exhibit 4.5 provides the highlights of the system. The value of the standard to society, producers, and to CSA are assessed. The need for the standards and the specific type of standard are also assessed by SVAT. By applying the various analytical modules of SVAT, the value of a specific standards application can be determined.

CSA implemented the use of the new CSA SVAT for the first time to prepare the 1998/99 Workplan submission. The tool itself was designed as a decision support tool and not as a decision making tool. In its first year of use, the TCs have found that it is very useful for determining if a project has value. However, because SVAT depends on health care data for its results, and because consistent data is not always available, the use of SVAT across all fields of health care is not guaranteed to be reliable. The results of the SVAT analysis is only as good as the data it uses.

4.5 Participation of Stakeholders

One of the strengths of Canada's consensus-based voluntary standards development process is the level of representation and participation achieved for all relevant stakeholders. Broad-based participation contributes to stakeholder "buy-in" for the resulting standard and ensures that groups most affected by the standard can contribute to its development.

Exhibit 4.6 shows the percentage representation of each stakeholder group on Technical Committees of the CSA HCT program. Overall, stakeholder representation for each of the four groups is: 21 percent government; 25 percent industry; 28 percent health care providers (users); and 26 percent "other", which includes independent experts and consumer, non-profit and other interests.

This tabulation of stakeholder participation indicates an appropriately balanced representation overall in the technical committees. What this table does not indicate, however, is the level of *active* participation and the *quality* of this participation.

An analysis of TC government members shows that the proportion of provincial officials is almost 70 percent of government representation on these committees. In discussion with the Standards Council of Canada, they indicated that, in general, approximately 16 percent of representatives at international standards development meetings were from the federal/provincial governments. The SCC database is being improved and it is expected that in the next year it will be possible to obtain more specific data with regard to a particular industry sectors.

Exhibit 4.6: Stakeholder Representation on Technical Committees of the CSA Health Care Technology Program

Committee	Title	Gov't %	Industry %	Users %	Other %	Total %	Total Persons
TC Z250	Health Care Technology	36	17	30	17	100	**30**
TC Z251	Anaesthetic Equipment & Respiratory Technology	**	36	36	28	100	**14**
TC Z252	Laboratory Medicine	30	26	26	18	100	**23**
TC Z253	Child Resistant Packaging	20	33	27	20	100	**15**
TC Z254	Dentistry	7	21	21	21	100	**14**
TC Z257	Health Care Facility Engineering and Physical Plant	20	14	33	33	100	**15**
TC Z259	Extracorporeal Circulation Technology	15	31	31	23	100	**13**
TC Z261	Medical Gas Systems	17	26	9	48	100	**23**
TC Z262	Sterilization	17	21	41	21	100	**24**
TC Z264	Drug Related Standards	27	20	33	20	100	**15**
TC Z267	Laser Safety	19	19	19	43	100	**16**
TC Z289	Quality Management - HC Products	29	36	14	21	100	**14**
TC Z290	Application of Electricity in Health Care	25	25	25	25	100	**12**
TC Z291	Implantable Medical Devices	15	31	23	31	100	**13**
TC Z292	Biological Evaluation of Medical Devices	13	31	31	25	100	**16**
TC Z301	Assistive Technologies for Persons with Disabilities	29	21	21	29	100	**14**
	Total	**21**	**25**	**28**	**26**	**100**	**271**

Source: Canadian Standards Association: Technical Committees Database.
** Data not available for this item.

Stakeholder consultations undertaken for this study indicates that there is some level of dissatisfaction with the active participation levels of provincial government officials, and others, in the standards development process. The following observations can be made from the consultation process:

- Stakeholders from all sectors need to be knowledgeable; and need to come to the table prepared to participate fully in the standards development process, without bias and with honesty and integrity.
- Stakeholders from all sectors need to make a concerted effort to provide liaison back to their own constituencies, so as to bring the broader input of that sector back to the table to feed into the process.
- Government departments/agencies could/should: provide greater input in helping the standards development process mesh more effectively with regulatory needs; and provide more support to the process in terms of financial resources and manpower (i.e. send representatives that are interested in seeing the standards development process "work").
- The current level of participation by health care manufacturing industry representatives is appropriate (i.e. it should not increase further, as it may compromise the public's perception of the credibility of the standard), and provides useful expertise and input into the standards development process.
- For the most part, health care providers (i.e. end users) are under-represented at the standards development table (mainly due to funding constraints), when they should, in fact, be taking ownership of the process; and perhaps more emphasis on approaching professional associations can help circumvent the funding issue which seems to be the main limiting factor to the full participation of this group.

- While it was generally agreed that consumers were important participants in and provided valuable insights to the standards development process, many questioned whether it was appropriate, from both an expertise and an interest perspective, to have consumer representatives on every standards development committee. Their role, however, is likely to become more important as more health technologies move into the community/home.

4.6 Participation in International Standards Fora and Harmonization

The fourth stated objective of the CSA HCT program is "to respond to the needs of health care providers and Canadian manufacturers in developing standards which are specific to Canadian needs, yet harmonized wherever possible with international standards".

The 1998/99 CSA HCT Workplan proposed to achieve international harmonization for 50 percent of standards in the Workplan. Generally, 58 percent of the published standards within the program are harmonized with international standards.

In addition to harmonization, the following observations about Canadian participation in international fora for health care standards.

- Canada holds participant status in the majority of ISO and IEC committees related to medical and health-care products, and holds the secretariat for one sub-committee in this sector (ISO TC106 SCI, Filling and Restorative Materials for Dentistry). This participation is most likely at a suitable level given the relatively smaller size of this Canadian industry in relation to the economy as a whole. Related health care technical committees in which Canada holds participant status include:
    - ✓ ISO TC106 (Dentistry)
    - ✓ ISO TC121 (Anaesthetic and Respiratory Equipment)
    - ✓ ISO TC194 (Biological Evaluation of Medical Devices)
    - ✓ ISO TC198 (Sterilization of Health Care Products)
    - ✓ ISO TC210 (Quality Management and Corresponding General Aspects for Medical Devices)
    - ✓ ISO TC212 (Clinical Laboratory Testing and In Vitro Diagnostic Test Systems)
    - ✓ IEC TC62 (Electrical Equipment in Medical Practice).

- Canada also holds observer status in three committees (ISO TC84, Medical Devices for Injections); ISO TC172, Optics and Optical Equipment; and IEC TC76, Optical Radiation Safety and Laser Equipment).

- Other international fora that are important to this sector include:
    - ✓ International Federation of Clinical Chemistry (IFCC)
    - ✓ International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
    - ✓ Pharmaceutical International Convention (PIC)
    - ✓ International Committee on Harmonization (ICH)

- U.S. standards development fora that are related to this sector include:
    - ✓ American Association of Clinical Chemists (AACC);
    - ✓ Association for the Advancement of Medical Instrumentation (AAMI)
    - ✓ American Pharmaceutical Association (APA)
    - ✓ Biological Stain Commission (BSC)
    - ✓ Health Industries Manufacturers Association (HIMA)
    - ✓ Instrument Society of America (ISA)
    - ✓ Pharmaceutical Manufacturers Association (PMA)
    - ✓ Radiological Society of North America (RSNA)
    - ✓ United States Pharmacopeial Convention (USPC)

Harmonization of standards is becoming increasingly critical in the health care sector, due mainly to the internationalization of technologies developed and sold globally. Canada is often caught between harmonizing with the U.S. and harmonizing with Europe. As much as possible, the strategy in this sector should be to encourage Canadian interests in health care technologies and to participate in relevant fora and standards organizations, as those indicated above. The CSA and the National Standards System of Canada provide a conduit, an opportunity, for Canadian health care interests to participate in these organizations.

Foremost among the international organization that are relevant for health care technology standards are the ISO and the IEC. The *International Organisation for Standardization (ISO)* develops international standards over almost the entire range of technology. Its membership comprises the national standards institutes of some 130 countries. ISO is a non-governmental organization and the standards it develops are voluntary and based on consensus. Many of the ISO standards – including many of those concerned with health, safety or environmental aspects – have been adopted in member countries as part of their regulatory framework.

ISO standards are market-driven. They are developed by international consensus among experts drawn from the industrial, technical or business sectors that have expressed the need for a particular standard. These may be joined by experts from government, regulatory authorities, testing bodies, academia, consumer groups or other organizations with relevant knowledge, or which have expressed a direct interest in the standard under development. Although ISO standards are voluntary, the fact that they are developed in response to market demand, and are based on consensus among the interested parties, ensures widespread use of the standards.

The International Electrotechnical Commission (IEC) is the world organization that prepares and publishes international standards for all electrical, electronic and related technologies. The IEC membership consists of more than 50 participant countries, including all of the world's major trading nations and a growing number of industrializing countries. The same consensus-based, voluntary standardization process, as that of ISO, is practiced by the IEC and its members.

4.7 Alternatives

The only internationally recognized alternative to national consensus standards is regulation. All modern industrialized countries in the world either impose a "command and control" system of regulations or a system of voluntary consensus standards. In most cases, as in Canada, these two systems complement each other – to provide the required compliance to health care technology needs.

Alternatives, however, do exist in the methodologies and balance between regulations and national consensus standards. Built-in efficiencies and procedures can be achieved, to create more effective implementation of standards systems. In the U.S., the voluntary consensus system is very much based on market forces, with as little government intervention as needed. The reliance on market driven checks and balances is higher in the U.S. probably than anywhere else in the world. The Canadian system, in contrast, provides a structured relationship between the private standards and government regulatory systems.

Specific comparisons of alternative implementation mechanisms need to consider the following components of the two systems:

- source of financing
- elements of cost
- efficiencies.

Exhibit 4.7 provides a breakdown of these components for the two systems.

Exhibit 4.7 Comparative Components for Alternative Implementations

COMPONENT	REGULATIONS *(Regulatory System)*	CONSENSUS-BASED STANDARDS *(National Standards System)*
SOURCE OF FINANCING	Federal and provincial goverrnment departments: • operating budgets • contract funding	Private sector: • sales of services and published standards • contracts with clients Government: • Standards Council of Canada: gov. appropriations • Funding programs (e.g., CCOHTA)
ELEMENTS OF COST *(selection of key elements involved in process)*	• Management of resources • Consultation with stakeholders • Contracts administration • Impacts analysis • Training • Equipment and lab resources • Publication and dissemination • Legal requirements and liabilities • Maintenance and enforcement of regulations • Interface with regional and international organizations • Intergovernmental interfaces	• Management of resources • Coordination and administration of consensus process and standards committees • Feasibility analysis & review of requirements • Recruiting and training staff • Equipment and lab resources • Publication and marketing standards • Accreditation and certification (facilities, products and processes) • Interface with regional and international organizations
EFFICIENCIES	• Regulatory review • Program evaluation • Management review and audit • Public officials and funds • RIAS	• Management systems • Contractual obligations • Market and competitive process • Voluntary participation • Standards value assessment (SVAT)

The following observations were made by stakeholders consulted in this study, regarding achieving efficiencies in the implementation of alternatives by CSA.

- CSA health care standards are generally recognized as being very important in the delivery of health care in Canada. By implication, CCOHTA's funding of the HCT program is very important and should be maintained.

- Mandatory standards (regulations) are seen as the preferred alternative method of control for drugs and, to some extent, for medical procedures; but consensus standards are better for devices, quality management systems and medical facilities design and construction.

- The benefits of the consensus process as an alternative lie in its flexibility and the potential or realized involvement of all interested parties in the committee matrix.

- Most respondents thought that governments (particularly the federal) should continue to provide funding for, as well as participating in, health care standards development. The manufacturing industry, health care providers (especially), and consumers, all have special expertise to bring to the process. Alternative mechanisms for encouraging effective participation by these groups need to be devised. The volunteer system is currently the only (and most cost-effective) approach available for consensus standards. A recent survey by the Standards Council of Canada, showed that volunteers participate in the standards development process mostly to network with professionals in similar fields, to be recognized by their peers, and for personal enrichment and career development. Replacing the volunteer system will be very costly as an alternative. Estimates by CSA indicate that the total in-kind contribution within Canada by volunteers is approximately $2.5 million annually for the CSA HCT related technical committees (see Section 4.4 above).

- CSA is generally regarded as being very effective in health care standards development, particularly in view of resource restraints. There were some criticisms regarding the slow speed of production and poor administration, and in this respect alternative management procedures and program implementation methods are being considered and implemented by CSA.

- Priorities for health care standards are addressed by CSA, but the telephone survey provided many suggestions for future standards needs that are not being addressed. Alternatives for assessing needs could be considered by the program, however this is largely a program scoping issue (see Section V), to be addressed by participants in the program (i.e., CCOHTA, CSA, and related committees).

- International harmonization is seen by most respondents to be somewhere between important and absolutely critical. As an alternative to CSA-led standards development initiatives, respondents use health care standards from many other sources, particularly international standards and others originating in U.S. and European standards organizations, including the FDA in the U.S., and others such as DIN in Germany, BSI in Britain, and CEN/CENELEC from the European Union..

- The lack of funding at CSA was frequently blamed for any inadequacies in the standards development process, and some respondents recommended an expansion of funding for the CSA HCT program in order to address issues related to alternative approaches for implementation efficiencies, and development of value assessment mechanisms.

- There is a need to develop alternative approaches to evaluating the implementation of standards. Clearly, two critical questions that need to be answered on an ongoing basis for purposes of accountability to the CSA HCT program are:
  - ✓ To what degree are the standards being used?
  - ✓ What is their impact?

  The first question is quantifiable (for example by sales figures of the standards). The second question is more difficult to answer, but CSA is one of the first SDOs in the world to develop an assessment tool (SVAT) to examine this question.

- There is a need to look at alternative (additional) funding sources for the program.
  - ✓ For example, many of the respondents to the telephone survey indicated that funding should come from federal government sources for the CSA HCT program (particularly, Industry Canada, Foreign Affairs and International Trade, Health Canada) – especially given the contribution that the standards development process makes to federal regulatory authorities, international trade and economic development.

- Finally, CSA should look at alternative marketing and communications strategies, to promote its role in the health care standards area, and to encourage wider participation by expert stakeholders by adopting innovative approaches used by American standards organizations. A benchmarking study on marketing and communications strategies could possibly contribute to this process.

V. EVALUATION OF THE 1998-99 WORKPLAN

The Workplan evaluation section of this report which follows is not intended to be a "financial audit", nor an audit of management practices as they relate to the CSA HCT program. The following evaluation focuses on providing a critique and suggestions for improvement of the program's planning process as evidenced in the 1998/99 Workplan.

5.1 Elements of the 1998-99 Workplan

The CSA's *Health Care Technology Program--Workplan Submission Fiscal Year 1998/99* submitted to CCHOTA in October 1997 consists of a five-page text and three attachments (including a prioritized list and summary descriptions of projects, a reference spreadsheet, and a list of standards completed in 1996/97).[46]

The prioritized list of projects (Attachment 1) employs the CSA methodologies for prioritizing projects for standards development (i.e. SPACES) and assessing the value of proposed or existing standards (i.e. SVAT). Each proposed project is evaluated in terms of its scope, current status, likely benefits and potential impact if the standard is not developed.

The 'bottom-up' business planning process first introduced in the 1996/97 Workplan, in which the business plans of individual Technical Committees are used to develop a single comprehensive business plan for the CSA HCT program, was again used in the 1998/99 Workplan.

5.2 Review by CCOHTA Board of Directors

The review by the CCOHTA Board of Directors that was sent to CSA in response to the 1998/99 Workplan, outlines several suggestions made by the Board. These suggestions can be summarized as follows:[47]

(a) prioritization of projects: make transparent the presentation of the process for identifying "value for money", selection of projects, and prioritization of projects; and relate development of standards to quantifiable outcomes;

(b) fixed costs: explain the $100,000 "fixed cost" of the Z250 Strategic Steering Committee (SSC);

(c) economies of scale: explain why variable costs are cumulative – i.e. no economies of scale;

(d) proposal for a contractor: give terms of reference for $65,000 contractor review of methods.

[46] *CSA Health Care Technology Program – Workplan Submission, Fiscal Year 1998/99,* Canadian Standards Association submission to CCOHTA, October 1, 1997.

[47] See letter of October 28, 1997 from John Dicaire, Chairman of the Board of Director (CCOHTA) to Mr. Gerd Galler, Manager, Canadian Standards Association.

This section of the report provides evaluative comments related to these suggestions by the CCOHTA Board of Directors, but first a discussion of a fundamental requirement to improve the planning process for the CSA HCT program follows.

5.3 Evaluation of the Workplan

5.3.1 Need a Program "Charter"

A first rule of program evaluation is to examine whether the participants and contributors, to the program being evaluated, all agree on the objectives and scope of the program. In the case of the CSA HCT program, from the interviews of stakeholders and review of program documents, there does appear to be a need for re-examining the consistency in expectations of this program.

The CSA HCT Workplan appears to have been developed annually for many years without the benefit of a program "charter" which demonstrates such a consistency in expectations, and which defines the program's objectives and scope from within a broad stakeholders' perspective. It is true that individual program projects and activities are rationalized each within their technological domain, and related stakeholder needs, but it is also true that a broader scoping of the program is required.

Program participants and contributors should focus on developing a program "charter", to arrive at an agreed set of objectives and to scope the program. The primary participants in this process should be the CCOHTA Board of Directors, CSA, and the CSA Strategic Steering Committee on Health Care Technology.

Developing such a program "charter" would accomplish the following:

- Define (or re-define) the scope of the CSA HCT program in such a way that it meets the requirements of health care stakeholders, participants in the program, and the financial contributors to the program. From the evaluation findings, especially as indicated in Section 3 of this report, there is a need to re-examine the scope of the CSA HCT program, in light of the many health care standardization opportunities that are emerging due to significant changes in this field, and the technological infrastructure which supports it. This does not necessarily mean dropping current work items or projects, but rather determining what other areas are important, and identifying what the relative long term health care standards priorities should be for the program that are in the national interest of Canada.

- Such a program charter should also provide a clear definition of the program in terms of its participants, contributors, reporting relationships and authorities, and the expected deliverables.

5.3.2 Workshop and Outline of a Program "Charter"

It is a good idea to develop such a charter with the assistance of a third-party facilitator, experienced in conducting workshops which could bring the various players in the program together, to design an appropriate program definition and scope. At the end of this process the outcome should be a stable program charter which provides the following:

- **Objectives:** These have to be defined within the framework of health care technology needs as agreed upon by the financial contributors to the program. The objectives

need to be defined from a longer term perspective, over a three to five year period to reflect the life-cycle of standards development activities.

- **A detailed "in/out of scope" statement:** This has to define the program within realistic parameters of what is achievable, given the expertise and particular institutional basis of the program, and given an appropriate context of health care needs as identified through a recognized consultation and research approach.

- **Strategic milestones:** Strategic goals of the program should be defined in medium to long terms, so that the program is not "re-invented" each year. It should be noted that the business of developing standards for many technologies often last longer than one-year, in many cases up to five years. Strategic milestones that reflect this aspect of standards development should be indicated in the program charter.

- **Workplan (activities/projects):** Clear expectations of what contents, and levels of detail need to be included in annual workplans, should be identified in the charter.

- **Deliverables:** This will define the deliverables of the program "in principle" – i.e., identify what are the expected outcomes of the program (namely, standards for health care technologies, and other potential developmental activities and projects such as improvement of "value-for-money" approaches and evidence-based standards development). Individual annual workplans would define specific deliverables, within the context of annual goals that address the strategic directions defined in the program charter.

- **Resources:** Parameters for a program administrative and operating budget (not including project funding) should be identified in the program charter. This should be consistent with the objectives and scope of the program. Annual workplans would identify separately the needs as they relate to specific project activities, and related overhead.

- **Reporting Relationships and Authorities:** Finally, reporting relationships and authorities should be identified in the program charter as well. It would be useful to include a CSA HCT organization chart to graphically describe how all the committees that are referred to in the 1998/99 Workplan interact with each other (e.g., Exhibit 4.1 in Section 4 of this evaluation report). There used to be direct links between CCOHTA and the CSA HCT program (i.e., Mr. Dev Menon of the CCOHTA Board of Directors used to sit on the Strategic Steering Committee). This would be an appropriate approach to re-instate, which will provide for a more active participation by CCOHTA in determining workplan items and priorities (but, naturally, CCOHTA would need to have sufficient funding to support this). Furthermore, the CSA HCT Strategic Steering Committee should have the opportunity to address CCOHTA Board members' questions directly at their fall meeting to answer questions about the annual workplan submissions.

The program charter itself would not address year to year goals and specific annual resources for projects and work items. However, a broad basis of the context and rationale for the program should be identified in the program charter, and approved by the CCOHTA Board of Directors, so that the terms of reference for annual expenditures and related Workplan items are clear to all parties involved.

An absence of agreement on program scope is detrimental to the future of the program, especially within the current climate of broad and significant health care technology standardization needs, as discussed in Section 3 of this report. The program need not accomplish all that is required for health care standards (indeed Exhibit 2.2 shows that the world of standards and regulations development is very complex with many major players other than CSA). However, those areas of health care technology that the program does target should be clearly defined within a broad and strategic context.

5.3.3 Specific Workplan Evaluation Comments and Suggestions for Improvement

Seen within the context of the recommendation provided in the preceding discussion, for developing a program charter, the following additional evaluation comments are provided regarding the Workplan presentation and content. These comments flow from the evaluation analysis and consultations undertaken in this study.

Addressing Accountability Concerns

- A retrospective statement on completed projects, and work in progress, should be given a separate treatment within the body of the Workplan, with highlights and individual project achievements. A list of standards developed is not sufficient as an accountability item in the Workplan.
- Each project proposed should indicate whether this is a new activity or an ongoing work in progress. For ongoing activities, a brief narrative description of what had been achieved in the past year (at what cost) and what is proposed for the upcoming year (with separate cost estimates), is needed.

Standards Value Assessment

- The approach for estimating the "values" of standards is not sufficiently explained. The approach need not be explained within the workplan itself, but the CCOHTA Board of Directors deciding on funding and priorities need to be provided with a convincing explanation of the SVAT methodology, recognizing that this methodology is a work in progress and that this tool may be breaking new grounds as a value assessment methodology (see discussion of SVAT in Section 4). CSA is working on this tool and trying to improve their process for assessing priorities and standards values, but if this methodology is to be used for achieving appropriations of public funds, it should be validated.
- At the same time, the members of the CCOHTA Board of Directors should recognize that the SVAT tool was designed as a decision support tool, and not as a decision making tool itself.
- The SVAT tool is only as good as the information it uses. Because SVAT depends on health care data for its results, and because consistent data is currently not available across all of the fields covered by the workplan, the use of this tool to assign value estimates to CSA's prioritization process is somewhat presumptive at this point. Nonetheless, CCOHTA could help CSA develop some of their information sources and needs. CCOHTA doesn't get paid by the provinces to do this, so it will require increased funding to undertake such support.

Content

- As part of the program charter (see above), CSA and CCOHTA should decide jointly on an approved format (table of contents) for annual workplans, that includes all the

necessary items for decision making by the CCOHTA Board of Directors, and for accountability purposes. A model workplan can be discussed during a joint workshop, and finalized through the process suggested in Section 5.3.2 above.

Budget

- Within the budget, it needs to be clarified whether CSA provides any funding for volunteer members (i.e., travel, etc.); if not, it would be useful for them to include in their budget an assessment of such "in kind" support. Estimates of "in kind" and other CSA contributions were discussed previously in Section 4.
- Terms of reference for new developmental assignments that are not directly related to standards writing activities should be provided in the workplan. The value assessment contractor proposed in the 1998/99 Workplan, for example, should be presented with a job description or a terms of reference, so that CCOHTA Board of Directors can review the details for approval of the budget for this proposal.
- Operating expenses for the Program should be itemized in more detail by project activities. Budgetary elements of standards development that qualify as operating costs and that could be itemized for the annual workplan, include the following:
  - ✓ Travel: the standards development process includes subsidizing travel costs of some members (often consumers) in order to maintain the balance of the committee. Costs of travel and accommodation for SDO staff is also required, if meetings are held outside the home base of the SDO (for CSA this is Toronto).
  - ✓ Expenses of visiting experts, if necessary, should also be accounted for.
  - ✓ Administration costs (indirect): This includes a share of SDO facilities costs and management expenses, and a proportion of each Technical Committee's secretarial salaries.
  - ✓ Administration (direct): This includes preparation and distribution of documents (e.g. workplans, reports, minutes, draft standards, balloting, and final standard). Committee meeting arrangements expenses involving room rentals, refreshments, etc.), and possible arrangement of workshops to exchange ideas with a wider audience, could also be included in direct administrative costs.
  - ✓ Translation into French (if the standard is to become a National Standard of Canada).
  - ✓ Research: Background searches for related standards and other information are additional expense items (if the documents can be obtained through the SCC this is relatively easy, but, frequently, searches on the Internet and/or requests to other bodies are necessary, which can be very time-consuming and, therefore, expensive). The costs of analyzing these documents for their relevance and inclusion in the standards development process is also an item to consider.

"In/Out of Scope" Statement

- The annual workplan, and projects included in the workplan, should be rationalized with an "in/out of scope" statement. For example, such a statement should provide references to appropriate segments of the program charter, and the long term strategic framework provided by the program charter.
- In addition, such a statement of scope, as it relates to projects, needs to make note of where the request for a standard came from, especially in the case of new standards (perhaps categorized along the following lines: regulator--provincial vs. federal,

international harmonization initiative, professional association, consumer association, patient advocacy group, health care institution, etc.).

Benefits

- The benefits that are listed in the project statements within the 1998/99 Workplan, for the CSA HCT program, seem reasonable, and intuitively convincing. However, the manner in which these benefits are presented create some difficulty in deciphering them (e.g., from the small print in the workplan attachment across the many project proposals). We suggest that a summary table which separates benefits into categories (by project), and filled in as applicable to the issue (standard) at hand, and as discovered through the CSA analysis of benefits. Categories of benefits could include the following:
    - ✓ direct economic benefits (or cost savings)
    - ✓ indirect economic benefits (or cost savings)
    - ✓ health status/clinical outcome benefits
    - ✓ quality of life/quality of care benefits
    - ✓ regulatory benefits
    - ✓ industry benefits
    - ✓ other benefits (tangible/intangible).

See discussion on benefits of standards in Section 4 of this report.

Prioritization

- Priority projects listed in the 1998/99 Workplan do not reflect the broader changes in the scope and location of health care provision in today's health care system as discussed in Section 3 of this report (e.g., community-based versus institutional health care needs). However, CSA responds to specific requests for standards from clients in the public sector, industry, and health care providers. To a great extent, these clients set the agenda for CSA standards development activities. In this respect, CCOHTA and CSA could improve their communications with each other by undertaking the following:
    - ✓ communicate on an ongoing basis, regarding program activities, including proactive involvement by CCOHTA members in the early stages of developing the annual workplan submission;
    - ✓ CCOHTA act as a conduit to facilitate information dissemination to the provinces and territories about the Program, new initiatives, published standards, etc., and facilitate information input into the Program and exchange of information regarding needs that the provinces and territories have identified;
    - ✓ have CSA and the CSA HCT program mentioned on the CCOHTA website, in CCOHTA publications, etc., to identify and emphasize a cooperative link between CCOHTA and the CSA HCT program.
- As mentioned in the “in/out of scope” segment above, the workplan priorities should be linked to where the request for a standard came from, especially in the case of new standards (regulators, industry associations, etc.).

VI. CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

- The Canadian health care system is undergoing tremendous change. As pressures to reduce costs yet maintain quality increase, administrators, health care providers, policy makers, and consumers are searching for new, innovative, and cost effective ways to deliver health care.

- The need for voluntary consensus standards in health care is increasing and will continue to do so for the foreseeable future. The CSA HCT program is capable of fulfilling only a small part of this need, but there was overwhelming support for its continuation.

- CSA is a facilitating standards development organization and its expertise is in organizing committees for standards development and in providing an infrastructure for conformity assessment to standards.

- International liaison and harmonization of standards is essential, bearing in mind Canada's dependence on imported health care products and the support required for the domestic manufacturing industry.

- People in the manufacturing industry, governments, and health care institutions who were contacted expressed enthusiasm for the CSA HCT program and for CSA. There were many suggestions for future standards and recognition that CSA needs more resources.

- The arrangements for determining priorities for the program need clarification. Clearly there are misunderstandings on both sides of the roles of the CSA and CCOHTA. Improved communications between the organizations is essential.

- Voluntary consensus standards may not be appropriate for all areas of health care at the present time. For example, standards for drugs and pharmaceutical products, which require extensive trials and tests, would be difficult to incorporate in the current process.

- The shift of health care services to the community is introducing new and previously institutionally-based technologies into the home environment. Standards need to be developed and/or revised to take into consideration the surrounding environment, socioeconomic circumstances and education/training needs of this new group of health care technology users.

- Funding sources for the CSA HCT program are not directly involved in the direction of the program, but CSA has a HCT strategic steering committee which guides the program, and all provinces are invited to actively participate on this committee, and to provide guidance and direction to the program.

- The standards that have been developed to date by the CSA HCT program are well used and well recognized.

- Many comments in the survey of stakeholders related to the need for better dissemination and marketing of standards, particularly to health care facilities outside major urban centres.

- The emphasis on a consensus approach for the National Standards System of Canada was cited by many users as the key to CSA's success in terms of being able to develop standards which are practical/usable, engender compliance on the part of industry, and have "clout" and "buy-in" due to the multi-disciplinary nature of their development.

- There is a need to develop alternative approaches to evaluating the implementation of standards. Clearly, two critical questions that need to be answered on an ongoing basis for purposes of accountability to the CSA HCT program are:
  - ✓ To what degree are the standards being used?
  - ✓ What is their impact?

  The first question is quantifiable (for example by sales figures of the standards). The second question is more difficult to answer, but CSA is one of the first SDOs in the world to develop an assessment tool (SVAT) to examine this question.

6.2 Recommendations

- The program should recognize the need for more international liaison and harmonization of health care standards and increase its support for international standardization efforts.

- There is a need to re-examine the scope of the CSA HCT program, in light of the many health care standardization opportunities that are emerging due to significant changes in this field, and the technological infrastructure that supports it.

- Program participants and contributors should focus on developing a program "charter", to arrive at an agreed set of objectives and to scope the program. The primary participants in this process should be the CCOHTA Board of Directors, CSA, and the CSA Strategic Steering Committee on Health Care Technology.

- The program charter should define the program objectives within the framework of health care technology needs as agreed upon by the financial contributors to the program. The objectives need to be defined from a long-term perspective, over a three to five year period to reflect the life-cycle of standards development activities. Strategic goals of the program should be defined in these terms, so that the program is not "re-invented" each year. It should be noted that the business of developing standards for many technologies often last longer than one year, in many cases up to five years. Strategic milestones that reflect this aspect of standards development should be indicated in the program charter.

- It is a good idea to develop such a program "charter" with the assistance of a third-party facilitator, experienced in conducting workshops which could bring the various players in the program together, to design an appropriate program definition and scope. At the end of this process the outcome should be a stable program charter which delineates the following: objectives, a detailed "in/out of scope" statement, strategic milestones, and reporting relationships and authorities.

- The program charter itself should not address year to year goals and specific annual resources for projects and work items. However, a broad basis of the context and rationale for the program should be identified in the program charter, and approved by the CCOHTA Board of Directors, so that the terms of reference for annual expenditures and related Workplan items are clear to all parties involved. An absence of agreement on

program scope is detrimental to the future of the program, especially within the current climate of broad and significant health care technology standardization needs.

- A retrospective statement on completed projects, and work in progress, should be given a separate treatment within the body of the Workplan, with highlights and individual project achievements. A list of standards developed is not sufficient as an accountability item in the Workplan.

- The approach for estimating the "values" of standards is not sufficiently explained in the Workplan. The approach need not be explained within the Workplan itself, but the CCOHTA Board of Directors deciding on funding and priorities need to be provided with a convincing explanation of the SVAT methodology, recognizing that this methodology is a work in progress and that this tool may be breaking new grounds as a value assessment methodology. CSA is working on this tool and trying to improve their process for assessing priorities and standards values, but if this methodology is to be used for achieving appropriations of public funds, it should be validated.

- The SVAT tool is only as good as the information it uses. Because SVAT depends on health care data for its results, and because consistent data is currently not available across all of the fields covered by the Workplan, the use of this tool to assign value estimates to CSA's prioritization process is somewhat presumptive at this point. Nonetheless, CCOHTA could help CSA develop some of their information sources and needs. CCOHTA doesn't get paid by the provinces to do this, so it will require increased funding to undertake such support.

- As part of the program charter (see above), CSA and CCOHTA should decide jointly on an approved format (table of contents) for annual workplans, that includes all the necessary items for decision making by the CCOHTA Board of Directors, and for accountability purposes. A model workplan can be discussed during a joint workshop, and finalized through a process involving program participants and funders.

- The benefits that are listed in the project statements within the 1998/99 Workplan, for the CSA HCT program, seem reasonable, and intuitively convincing. However, the manner in which these benefits are presented create some difficulty in deciphering them (e.g., from the small print in the workplan attachment across the many project proposals). We suggest that a summary table which separates benefits into categories (by project), and filled in as applicable to the issue (standard) at hand, and as discovered through the CSA analysis of benefits. Categories of benefits could include the following:
    - ✓ direct economic benefits (or cost savings)
    - ✓ indirect economic benefits (or cost savings)
    - ✓ health status/clinical outcome benefits
    - ✓ quality of life/quality of care benefits
    - ✓ regulatory benefits
    - ✓ industry benefits
    - ✓ other benefits (tangible/intangible).

- Priority projects listed in the 1998/99 Workplan do not reflect the broader changes in the scope and location of health care provision in today's health care system as discussed in this report (e.g., community-based versus institutional health care needs). However, CSA responds to specific requests for standards from clients in the public sector, industry, and health care providers. To a great extent, these clients set the agenda for CSA standards

development activities. In this respect, CCOHTA and CSA could improve their communications with each other by undertaking the following:

- ✓ communicate on an ongoing basis, regarding program activities, including proactive involvement by CCOHTA members in the early stages of developing the annual workplan submission;
- ✓ CCOHTA act as a conduit to facilitate information dissemination to the provinces and territories about the Program, new initiatives, published standards, etc., and facilitate information input into the Program and exchange of information regarding needs that the provinces and territories have identified;
- ✓ have CSA and the CSA HCT program mentioned on the CCOHTA website, in CCOHTA publications, etc., to identify and emphasize a cooperative link between CCOHTA and the CSA HCT program.

ANNEX A: PROGRAM EVALUATION QUESTIONS[48]

Background and Rationale of Program:

1. What was the original rationale for introducing the CSA Health Care Technology Program? Has the rationale for this Program changed?
2. What are the current objectives of this Program and are these objectives still relevant?
3. How has the Program been funded in the past and in what amounts?
4. How is the Program currently funded? To what extent are funding sources involved in the direction of the Program? Are stakeholders and funding sources satisfied with their levels of involvement/participation in the Program process?
5. What other Programs and organizations in Canada are involved in standards development activities for health care technologies (including medical devices, drugs, procedures)?
6. Is there a duplication of effort taking place between these Programs and organizations and the CSA Health Care Technology Program?
7. What is an appropriate allocation of responsibilities for standards development in health care technologies (i.e., for medical devices, drugs, and procedures)?

Program Results:

1. What standards have been developed under this Program since 1973 – and in what specific areas of health care technologies?
2. Who are the users of these standards (hospitals, clinics, manufacturing industry, regulators/government departments, doctors, research and development institutions, etc.)? To what extent are these users involved in the standards development process?
3. Have or will these standards be harmonized with corresponding international standards?
4. Have these standards been developed in accordance to an appropriate workplan, which establishes priorities that respond to standards development requirements identified by the health care industry?
5. To what extent does the Program assist stakeholders in identifying gaps in the health care industry, which currently require standards development?
6. Have the standards developed under this Program been developed in an efficient manner providing value for money – i.e., does the program provide efficient use of resources to develop or update standards and to prioritize the response to standards development requirements?

[48] These program evaluation questions are based on the Statement of Work provided in the *Request for Proposals* for this study, CCOHTA.

7. What has been the impact of the Program in fulfilling requirements for health care technology standards in Canada? What are the benefits of the standards developed from this Program, and how do these benefits compare to costs of developing the standards?

Alternatives:

1. How effective is CSA in undertaking the role of standards development in health care technologies?
2. Are there other effective ways/programs for achieving the same results? Do other organizations effectively develop standards for health care (in the same/different areas of health care)?
3. How have other Western industrialized countries addressed the same issues that are addressed by this Program (particularly emphasizing selection, prioritization and achieving value for money for review and development of standards)?
4. What role should the health care manufacturing industry play in standards development and in this Program?
5. What related opportunities for international collaboration and harmonization have resulted through the CSA and this Program?
6. What standards have resulted from this collaboration and harmonization?

Evaluation of Workplan and Recommendations:

1. In light of the evaluation findings, what recommendations can be made regarding the proposed 1998-99 CSA Health Care Technology Program Workplan and Budget?
2. How can the CSA Health Care Technology Program be improved?
3. What is the appropriate role and directions for this Program in the future?

ANNEX B: LIST OF INTERVIEWEES

1. CCOHTA Board Members

Dr. Renaldo BATTISTA (CCOHTA Board)
Président, Conseil D'Evaluation des Technologies de la Santé, Montréal, Quebec

John DICAIRE (CCOHTA Board)
Assistant Deputy Minister, Public Health & Medical Services, Department of Health & Community Services, Fredericton, New Brunswick

Lauren DONNELLY (CCOHTA Board)
Director, Acute and Emergency Services Branch, Saskatchewan Health, Regina, Saskatchewan

Don JUZWISHIN (CCOHTA Board – left in June 1998)
Former Director, Accountability, Standards and Policy, British Columbia Ministry of Health and Ministry Responsible for Seniors, Victoria, British Columbia

Dr. Devidas MENON (CCOHTA Board)
President & CEO, Institute of Pharmaco-Economics, Edmonton, Alberta

Ed NORWICH (CCOHTA Board)
Manager, Planning, Evaluation, Research and Information Services, NWT Department of Health and Social Services, Yellowknife, Northwest Territories

Pat STUCKLESS (CCOHTA Board)
Manager Provincial Planning, Information, Planning and Evaluation Branch, Ontario Ministry of Health, Toronto, Ontario

Dr. Ian WILKINSON (CCOHTA Board)
Head, Metabolic Diseases and Clinical Chemistry, Manitoba Health, Winnipeg, Manitoba

2. Health Care Providers

Stephan BAUER
Manager, Medical Engineering, Hospital for Sick Children, Toronto, Ontario

Bob BELANGER
Director of Engineering, Grey Bruce Regional Health Centre, Owen Sound, Ontario

Cheryl BISHOP
Director of Pharmacy, CHARA Health Care Society, St. Vincent's Hospital, Vancouver, British Columbia

Janet COOPER
Pharmacist, Canadian Pharmacists Association, Ottawa, Ontario

Dr. Ken CORBET
Clinician/Physician, Foothills Provincial General Hospital & University of Calgary Occupational Health Clinic, Calgary, Alberta

R.C. DAWE
Acting Director, Facility Planning Division, Department of Health, Government of Newfoundland and Labrador, St. John's, Newfoundland

Alfred DOLAN (CHA representative to CSA Board of Directors)
Graduate Coordinator, Institute for Biomedical Engineering, University of Toronto, Toronto, Ontario

Myrna DOLOVICH
Associate Professor of Clinical Medicine, Faculty of Health Sciences, McMaster University, Hamilton, Ontario

Kelly GRIMES
Manager, Research and Development, Canadian Council on Health Services Accreditation, Ottawa, Ontario

Susan HADFIELD
Director, Central Processing, Health Sciences Centre, Winnipeg, Manitoba

Jean JONES
Chair, Health Committee, Consumers Association of Canada, Dundas, Ontario

Olaf KOESTER
Director of Pharmacy, Portage District General Hospital, Manitoba

Peter LANGELLE
Chief Executive Officer, Crossroads Regional Health Authority No. 9, Wetaskiwin, Alberta

Bill LESLIE
Executive Director, Canadian Society of Hospital Pharmacists, Ottawa, Ontario

Guy MARTEL
Senior Development Officer, Research Institute, Royal Ottawa Regional Rehabilitation Centre, Ottawa, Ontario

Dr. Tofy MUSSIVAND
Director, Cardiovascular Device Division, University of Ottawa Heart Institute, Ottawa, Ontario

Dr. John SMITH
Director, Technology Planning, Hospital for Sick Children, Toronto, Ontario

Flora THOMPSON
Occupational Therapist/Educator; Consumer Representative, Canadian Association of Occupational Therapists, Vancouver, British Columbia

Dianne TRUDEAU
Corporate Director, Sterile Supply Department, Vancouver Hospital and Health Sciences Centre, Vancouver, British Columbia

Barbara WELLS
Executive Director, National Association of Pharmacy Regulatory Authorities, Ottawa, Ontario

Bill WILSON
Director of Pharmacy, Mount Sinai Hospital, Toronto, Ontario

Mike WOJCIK
Regional Director, Building Services, Crossroads Regional Health Authority, Wetaskewin District Hospital Resource Centre, Wetaskewin, Alberta

3. Provincial and Federal Government Representatives

Dale BERRY
Planning and Construction Division, Manitoba Health, Winnipeg, Manitoba

Pavel DVORAK
Head, X-Ray Section, Health Canada, Ottawa, Ontario

Bill HENDES (for Barbara Hall)
Regional Director, Nova Scotia Department of Health, Halifax, Nova Scotia

Alex HOWSE
Director, Group Purchasing, Newfoundland & Labrador Health Care Association, St. John's. Newfoundland

Derek KIRBY
Manager, Medical Gas Inspections, New Brunswick Research and Productivity Council, Fredericton, New Brunswick

Pierre LANDRY
Head, Quality Management, Medical Devices Bureau, Health Canada, Ottawa, Ontario

Andre LAPRAIRIE (for Denis Brodie)
Policy Analyst, Health Canada, Policy and Coordination Bureau, Ottawa, Ontario

Anna LEHN
Program Officer, Canadian General Standards Board, Ottawa, Ontario

Bev LEVER
Health Economic Development, Ontario Ministry of Health, Toronto, Ontario

Dr. George MICHALISZYN
Director, Health Products Directorate, Industry Canada, Ottawa, Ontario

Craig MOOLENBEEK
Head, Health Facilities Planning, Surgeon-General's Office, National Defence, Ottawa, Ontario

Dr. Philip NEUFELD
Head, Standards and Testing, Medical Devices Bureau, Health Canada, Ottawa, Ontario

Shirley PATON
Chief, Noscomial and Occupational Infections, Laboratory Centre for Disease Control, Health; Protection Branch, Health Canada, Ottawa, Ontario

Gloria RACHAMIN
Toxicologist, Occupational Health and Safety, Ontario Ministry of Labour, Toronto, Ontario

Jean-Louis ROBERT
Chief Electrical Examiner, Regie du batiment du Quebec, Quebec, Quebec

Denis ROY
Standards Officer, Medical Devices Bureau, Health Canada, Ottawa, Ontario

Catherine SAAR-PARADIS
Specifications Manager (Health Facilities), Alberta Public Works and Supply, Edmonton, Alberta

Gwen SCHMIDT
Health Devices Manager, Workers Health and Safety Centre, Don Mills, Ontario

Dr. Alex SINCLAIR
Research & Sandards Division, Health Protection Bureau, Health Canada, Ottawa, Ontario

Al SULEIMAN
Fire Protection Engineer, Office of the Fire Marshal, Govt. of Ontario, Toronto, Ontario

4. Manufacturers of Health Care Products

Dr. Francois AUGER
President, Altertek-Bio Inc. Sillery, Quebec

Joe BEYGER
Director Regulatory Affairs, NuPharm Incorporation, Richmond Hill, Ontario

Len BRAUTIGAM
Territory Manager, Nellcor Puritan Canada Ltd., Pickering, Ontario

Betty-Anne BUTCHER
Quality Auditor, Allied Signal Aerospace Canada Inc. Etobicoke, Ontario

William CARSON
Project Manager Commissioning, Steen Contractors Ltd., Toronto, Ontario

Rod CHU
Senior Physicist Specialist, MDS Nordion Inc., Kanata, Ontario

Betsy CLIFFE
Regulatory Affairs, Novamann (Ontario) Inc., Mississauga, Ontario

Frank DEPAEPE
Doerkson Medical Gas Systems Limited, Mississauga, Ontario

Wes J. DRODGE
CEO, Peninsulas Health Care Corp, Clarenville, Newfoundland

Pauline FOLLIS
Consultant, Infection Control Central Services, NOSOL H.C. Inc., Richmond Hill, Ontario

Fred FIKSEL
President, HTC Associated Healthcare Technology Consultant, Ottawa, Ontario

Mr. D. FRASER
Manager Quality Control, Vas Cath of Canada, Mississauga, Ontario

John GAMS
Director Technical Centre, Metronic of Canada Ltd., Mississauga, Ontario

Becky GEESON
Manager, K-Bro Operating Room Services, Edmonton, Alberta

William GOODWIN (President, Association of Ontario Medical Manufacturers)
Manager Research & Development, Dumox Medical, Scarborough, Ontario

Vija HAY
Operating Room Nurses Association of Canada (ORNAC), Gloucester, Ontario

Barry HUNT
President, Class I Inc., Kitchener, Ontario

Dr. Asoka JAYAWARDENE
Director, Quality Assurance and Regulatory Affairs, CIBA Vision, Mississauga, Ontario

Jane JONES (Regulatory Steering Committee Chair, Medical Devices Canada)
Manager, Regulatory Affairs, Alcon Canada Inc., Streetsville, Ontario

Nathan LEIPCIGER
Leipciger, Kaminker, Mitelman & Partners Inc., Don Mills, Ontario

Mr. H. MARCUS
Environmental and Regulatory, MDS Laboratories, Etobicoke, Ontario

Lee MCDONALD
President, South Medic Inc., Barrie, Ontario

David J. MCLAUGHLIN
Partner & Ex VP, Veritas Communications Inc., Toronto, Ontario

Dr. Jolyon MITCHELL
Laboratory Director, Trudell Medical International, London, Ontario

Phillipa MURPHY
VP Regulatory Affairs, Astra Pharma Inc., Mississauga, Ontario

Kevin MURRAY
Director Regulatory Affairs & Communications, Medical Devices Canada, Etobicoke, Ontario

Michael O'REILLY
Principal, Workers Health and Safety Centre, St. John's, Newfoundland

John PARKS (V.P. Regulatory Affairs & Quality Assurance, MEDEC)
Baxter Corporation, Mississauga, Ontario

Brent RUSK
Calgary Association of Medical Products, Calgary, Alberta

Brian SKUHAC
Air Liquid Canada Inc., Winnipeg, Manitoba

Jeff SMITH
Territory Manager, Essex Medical Products, Edmonton, Alberta

Julian STEDMAN
Care Technology, Spruce Grove, Alberta

Rodney SYKES
National Service Manager, Picker International Canada Inc., Brampton, Ontario

Dr. Jonathan TYLER
Tyler Research Corp., Edmonton, Alberta

Hans VAANDERING
Manager Equipment Services of Quality Assurance, Praxair Canada Inc., Mississauga, Ontario

Bill WHITTINGTON
President, Walsh Medical Devices Inc., Oakville, Ontario

Tom WOOLHOUSE
Partner, Wilson Engineering, Markham, Ontario

ANNEX C: SURVEY QUESTIONS

Contact information

Please provide the following contact information for each interviewee:

Name of Interviewee: _____
Title: _____
Organization: _____
Date: _____
Name of Interviewer: _____

Introduction

I am calling on behalf of Coopers & Lybrand in Ottawa. We are presently undertaking an evaluation of the Canadian Standards Association (CSA) Health Care Technology Program. We are doing this study for the Canadian Coordinating Office for Health Technology Assessment (CCOHTA). We would like to ask you some questions about standards and standards development for health care.

Thank you.

Familiarity with CSA standards

1. The CSA Health Care Technology Program provides funds to CSA for the purpose of developing health care standards. Are you familiar with this Program? (yes/no)

2. Are you familiar with any CSA standards for health care technologies? If so, can you name any?

Involvement in standards activities

3. Are you presently (or have you ever been) on any of the CSA health technology standards committees? If so, in what capacity?

4. Are any other members of your organization (i.e. department, ministry, branch, company, institution) involved in standards committees of the Canadian Standards Association (CSA) or the Canadian General Standards Board (CGSB)? If so, could you give his/her name, contact number? If so, in what capacity?

Significance of standards

5. In your view, what is the significance of CSA standards for health care technologies as they pertain to your organization's mandate or responsibilities? Why are they relevant to you? What specific impacts have they had?

6. What would you say are the benefits, if any, of having national voluntary (non-mandatory) consensus standards for health technologies? Are there any problems with this approach?

Role of stakeholders

7. In your view, what role should federal and/or provincial departments, ministries or agencies play in developing non-manadatory standards for health care technologies? Are there additional roles that they should be playing? (e.g. funding, committee participation, setting priorities, etc.)

8. In your view, what role should the health care manufacturing industry play in developing non-manadatory standards for health care technologies? Are there additional roles that they should be playing? (e.g. funding, committee participation, setting priorities, etc.)

9. In your view, what role should health care providers play in developing non-manadatory standards for health care technologies? Are there additional roles that they should be playing? (e.g. funding, committee participation, setting priorities, etc.)

10. In your view, what role should consumers or other users of health care services play in developing non-manadatory standards for health care technologies? Are there additional roles that they should be playing? (e.g. funding, committee participation, setting priorities, etc.)

Scope of standards

11. To what extent are non-mandatory standards appropriate for each of these areas (respond for each area on a scale of 1 = very appropriate to 5 = not at all appropriate; n/a = no opinion). Please comment on your assessment of appropriateness for each.

Area	**1**	**2**	**3**	**4**	**5**	**n/a**
a) medical devices						
b) drugs						
c) medical procedures						
d) quality management systems						
e) medical facilities design & construction						

12. Who/what organizations should/could be allocated primary responsibility for developing standards on each of the five areas identified above.

13. Can you identify any duplication of effort within the standards development process with regard to the health care industry?

Effectiveness of CSA

14. In your view, how effective is the CSA in developing standards in your areas of health care activity? If not effective, why not?

15. Have the CSA health technology standards developed to date addressed priorities that you have identified within the health care sector? If not, what priorities are not being addressed?

16. Could you identify any gaps within any portion of the health care industry, which currently require some priority with respect to standards development? Has the CSA been effective in identifying such gaps and addressing them in the past?

Additional points that could be raised (depending on the knowledge/experience of interviewee)

17. How important to your organization is the harmonization of Canadian health care technology standards with international standards? Has there been sufficient harmonization to date? Give examples from harmonization efforts.

18. What impact (if any) will the recent revisions to Medical Devices Regulations have on the development of non-mandatory standards for these health care technologies in Canada?

19. Does your organization use non-mandatory health care technology standards from Canadian or international sources other than the CSA? If yes, what organizations and standards other than CSA's do you use?

20. Do you have any final comments or suggestions with regard to the CSA Health Care Technology Program or Canadian health technology standards?

Conclusion

This concludes the interview. Thank you for taking the time to participate in this evaluation process. If you have any questions regarding this interview, please contact Hussein Rostum at Coopers & Lybrand (613) 237-3702.

ANNEX D: LIST OF RELEVANT REPORTS AND PROGRAM AND POLICY DOCUMENTS REVIEWED

1997 Global Medical Technology Update: The Challenges Facing U.S. Industry and Policy Makers, foreign market figures from Health Industry Manufacturers Association (HIMA), Washington, D.C.

A New Perspective on the Health of Canadians—A Working Document, M. Lalonde ("the Lalonde report"), Government of Canada, Love Printing Service, Ottawa, 1974.

Achieving Health for All: A Framework for Health Promotion, Jake Epp ("the EPP document"), Ministry of Supply and Services, Ottawa. 1986.

Alternative Medicine and Seniors: An Emphasis on Collaboration, National Advisory Council on Aging.

Benefit/Cost Analysis Guide for Regulatory Programs, Treasury Board of Canada, August 1995.

Canada Health Action: Building on the Legacy, National Forum on Health, 1997.

Canada's International Business Strategy for Health Industries, 1998-1999, industry sector report by Industry Canada, Ottawa, 1998.

Canadian Medical Devices Industry, report by Department of Foreign Affairs and International Trade, Ottawa, December 1996.

Criteria and Procedures for the Preparation and Approval of National Standards of Canada, CAN-P-2E, Standards Council of Canada, January 1992.

CSA and the Health Care Technology Program, by A.M. Dolan, Manager, Health Care Technology Program, Canadian Standards Association, October 12, 1978.

CSA Health Care Technology Program Business Planning Process for Technical Committees and Strategic Steering Committee (DRAFT), Task Force on Business Planning, CSA, June 1995.

Evidence-based medicine: How to practice and teach EBM, by DL Sackett, WS Richardson, W Rosenberg, and RB Haynes, New York, Churchill Livingstone, 1997.

Facts at a Glance - Regulation of Herbal Medicines, Health Canada Fact Sheet, May 1997.

Federal Regulatory Process Management Standards, Regulatory Affairs, Treasury Board Secretariat, November 1996.

Frequently Asked Questions on Recognition of Consensus Standards, U.S. Department of Health and Human Services, February 19, 1998.

Guidance on the Recognition and Use of Consensus Standards, U.S. Department of Health and Human Services, Washington D.C., February 19, 1998.

Guidelines for the Prioritization of Standards Development Proposals and Preparation of the Annual Workplan, prepared for the Strategic Standard Steering Committee, Health Care Technology, CSA Subcommittee on the Workplan Guidelines, March 1995.

Guidelines Relating to the Application of the Spaces Program for the CSA Steering Committee Business Planning Process, Fred Fiksel, CSA, July 1995.

Health Care Technology Program – Workplan Submission, Fiscal Year 1998/99, submission to CCOHTA from CSA October 1, 1997.

Health Care Technology Program—Workplan, submissions to CCOHTA from CSA, various years since 1994-95.

Health Care Information Resources Web Site – Alternative Medicine (http://www-hsl.mcmaster. ca/tomflem/altmed.html).

Health Care Technology: a Quest for Safety and Quality, Standards Forum Update, Canadian Standards Association, Winter 1983.

Health Costs and Private Sector Competitiveness, Conference Board of Canada, 1995.

"Health Minister announces membership of the Advisory Panel on herbal remedies", Health Canada, May 22, 1997.

Health Reform Update 1996-97, Canadian College of Health Service Executives, 1997.

International Standardization: Strategic Issues for Canada, prepared for Industry Canada by Nordicity Group Ltd., Ottawa, May 7, 1997.

ISO 9000—A shot in the arm for medical devices, segment in *Consensus*, Standards Council of Canada, May 1998.

ISO Members 1996, Information Report by International Organization for Standardization, Geneva, 1996.

Medical engineering standards—past, present and future, by A.M. Dolan, in *Engineering Journal*, May/June 1977.

Medical Device Industry: Current Trends and Future Prospects, by Terri Cooper, Coopers & Lybrand, USA, January 1998.

Medical Devices Regulations, Health Canada, Ottawa, 1998.

National Conference on Home Care: March 8-10, 1998. Proceedings prepared by Helen Patriquin of the Nova Scotia Association of Health Organizations.

National Export Strategy, Trade Promotion Coordinating Committee, Fourth Annual Report to the United Sates Congress, Washington, D.C., October 1996.

Procedures for Processing a Request to Prepare a National Standard of Canada , CAN-P-1015A, Standards Council of Canada, September 1991.

Program Management and Beyond: Management Innovations in Ontario Hospitals, by Leatt, P., Lemieux-Charles, L., & Aird, C., 1994.

Regulatory Framework for Natural Health Products, Final Report of the Advisory Panel on Natural Health Products, Government of Canada, May 13, 1998.

Regulatory Impact Analysis Statement, Medical Devices Regulations, Health Canada, Ottawa, 1997.

Request for Proposals (RFP) for an Independent Evaluation of the Canadian Standards Association Health Care Technology Program, Canadian Coordinating Office for Health Technology Assessment, Ottawa, February 4, 1998.

Review of Standardization Activities and Opportunities, prepared for Standards Council of Canada by Nordicity Group Ltd., Ottawa, July 14, 1997.

Speaking Notes for A Federal Perspective on Health Care Reform. Pulse '9, by Alan Nymark, Associate Deputy Minister of Health Canada, Toronto, Ontario, May 1998.

Speaking Notes for 130th Annual Meeting of the Canadian Medical Association, by Allan Rock, Minister of Health Canada, Victoria, B.C., August 1997.

Speaking Notes for National Home Care Conference, by Allan Rock, Minister of Health Canada, Halifax, Nova Scotia, March 9, 1998.

Speech to the Canadian Medical Association Conference on Regionalization and Decentralization in Health Care, by Marie Fortier, National Forum on Health, June 15, 1995

Standardization is Good Business, by R.P. Preston, Standards Council of Canada, June 1978.

Standards Conformity Assessment and Trade into the 21st Century, National Research Council, Washington D.C., 1995.

Standards Council of Canada Act, House of Commons, Ottawa, 1997.

Standards Council of Canada Strategic Plan, 1998-2001, Standards Council of Canada, Ottawa, 1998.

Standards Value Assessment (SVA) Special Requirements for HVAC Systems in Health Care Facilities, Canadian Standards Association: Making Standards Work for People and Business, August 25, 1997.

Tenth Annual Report, Patented Medicine Prices Review Board, December 31, 1997.

The World Health Report 1998. Life in the 21st Century - A Vision for All, World Health Organization., 1998.

Who Should Profit from Sales of Industry Standards, by Stacey Bell, Medical Device Link, website article (www.devicelink.com), 1998.

ANNEX E: INVENTORY OF HCT PROGRAM STANDARDS (1993-94 TO 1998-99)

ANNEX F: CRITERIA FOR A NATIONAL STANDARD OF CANADA

Standards submitted for approval as National Standards of Canada normally are required to comply with all the criteria listed hereunder. These criteria are listed in *Criteria and Procedures for the Preparation and Approval of National Standards of Canada,* (CAN-P-2E, Standards Council of Canada, January 1992).

Criterion 1. The significance, timeliness and suitability of a standard as a National Standard of Canada shall be determined on the basis of a reasonable agreement among the views of a number of capable individuals whose collective interests provide a balance of representation of producers, consumers and others with relevant interests, as may be appropriate to the subject in hand.

Criterion 2. Standards designated as National Standards of Canada may deal with any subject appropriate for standards in common use, as well as other subjects for which standards needs may develop, provided that they meet the established criteria.

Criterion 3. All National Standards of Canada shall carry statements identifying the intended coverage of the subject and use of the standard, the interests represented in the preparation or review for adoption of the standard, and the responsibility of standards users to judge the suitability of the standard for their purposes.

Criterion 4. Limitations in the breadth or depth of the coverage of the subject as such shall not be cause for rejection of a standard for designation as a National Standard of Canada provided that such limitations are indicated in the standard for the guidance of the user.

Criterion 5. All National Standards of Canada shall be based on requirements which are stated as far as possible in measurable terms, the basis for such measurements and the criteria against which they will be judged being set out or identified in the standard in terms which will permit one skilled in the art to determine conformance.

Criterion 6. Requirements in standards, regardless of the breadth of coverage such as safety and quality, or other combinations, are desirably formulated in terms of performance in order to avoid inhibition of design or innovation and at the same time to facilitate objective measurement of conformance. There are a number of cases, however, where this may not be feasible or even desirable and no constraint on eligibility as a National Standard of Canada should be imposed on this account.

Criterion 7. National Standards of Canada should not be framed with intent to act as a restraint on trade, nor to limit unduly innovation or freedom in design to meet the essential requirements of the standards; they should not unnecessarily limit the properties of the product, or service required, by the inclusion of parameters or property requirements which go beyond the national interest.

Criterion 8. National Standards of Canada should be consistent with or should incorporate appropriate international standards as well as pertinent national standards, except that it must recognize that the standard with the greater coverage (i.e., national as compared to local, or international as compared to national, or generic product coverage as compared to a specific product) will in general, be forced to make concessions in the elimination of specific or detailed requirements in the interest of broader coverage.

Criterion 9. National Standards of Canada shall be prepared and reviewed and revised when necessary by standards-writing organizations accredited by the Standards Council of Canada. Standards prepared initially by other than an accreditated organization, but later proposed for consideration as National Standards of Canada, shall normally be asssigned to one of the accredited agencies for review and revision as necessary to meet the established criteria as required.

Criterion 10. There shall not be more than one National Standard of Canada dealing with substantially the same subject, unless in the judgement of the Standards Council it is in the national interest to provide a choice in respect of the differences between them.

Criterion 11. The format of National Standards of Canada shall be in accord with good standards-writing practice, and may vary as appropriate, depending on the source, purpose, and subject of the standards.

Criterion 12. A standard shall be maintained as a National Standard of Canada only so long as it continues to meet the established criteria; National Standards of Canada shall be reviewed every five years, or at shorter intervals as may be justified.

Criterion 13. National Standards of Canada shall be made available in both French and English.

Criterion 14. Quantities and dimensions shall be expressed in National Standards of Canada in SI or yard/pound units with preference given to the former. Should it be desirable for both yard/pound and SI units to be used to express a particular quantity or dimension, one of the systems shall be designated as the official one for purposes of the standard, and the other identified as a conversion. In such cases, the purpose of the conversion, including limitations of application, shall be stated and the precision determined accordingly.

Criterion 15. During its preparation a National Standard of Canada shall be offered for public review.

Criterion 16. References of certification or administrative requirements shall not be included in the body of a National Standard of Canada.