Canadian Council on Animal Care
Conseil canadien de protection des animaux

Good Animal Practice in Science
Bonnes pratiques animales en science

Canadian Council on Animal Care

Five-Year Plan
2009–2014

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Preamble

The Canadian Council on Animal Care (CCAC) is the peer-based organization created in 1968 to oversee the care and ethical use of animals in research, teaching and testing throughout Canada as "an outside advisory body established to ensure uniform application of guidelines principles at the national level and to assist local animal care committees." As described in its mission statement, the CCAC acts *"... in the interests of the people of Canada to ensure through programs of education, assessment and persuasion that the use of animals, where necessary, for research, teaching and testing employs optimal physical and psychological care according to acceptable scientific standards, and to promote an increased level of knowledge, awareness and sensitivity to relevant ethical principles*."

The CCAC's first integrated strategic planning process began with consultation of its constituents through the March 1998 *CCAC Forum – Charting the Future*. The five standing committees of the CCAC Council (Assessment; Guidelines; Education, Training and Communications; Planning and Priorities; and Finance) developed action plans based on suggestions made at the Forum, with the CCAC Board of Directors prioritizing any identified projects. This process resulted in a five-year vision, *Good Animal Practice: an Ethical Partnership for Quality Science*, which led to improved accountability and transparency through the merging of planning and reporting frameworks into performance reports that are released to the public every six months. In addition to client's satisfaction, this vision included a multifaceted strategy towards the universal implementation of the CCAC programs that resulted in the formal recognition of CCAC guidelines and policies by funding and regulatory organizations at the national and international levels. While CCAC guidelines and policies are now referenced in regulations to provincial legislations, they remain guidelines and policies developed, reviewed and assessed for their implementation by animal care committees (ACCs) through an entirely peer-based, voluntary oversight system operating independently from regulatory systems, and comprising 2,000 volunteer scientists, veterinarians, animal care personnel, and representatives of the public and of the animal welfare movement.

The CCAC currently delivers its mandate through five mutually supportive business lines: Assessment; Guidelines; Three Rs (Reduction, Replacement and Refinement Alternatives); Education, Training and Communications; and Planning and Finance. The present *CCAC Five-Year Plan 2009-2014* describes the perceived needs, requirements and expected outcomes for each business line. These have been identified by the standing committees on Council and the respective program staff, based on the *CCAC Five-Year Plan 2004-2009*, the grant submission and granting Agencies' response for the 2008-2011 funding cycle, and the outcome of the *CCAC Forum 2008 – Building on Strength*.

Over the next five years, a significant increase can be expected in activity and complexity of research in the life and biomedical sciences, including those disciplines reliant on animal subjects, and in public debate over the ethical aspects of this work and its applications. This expectation is based on:

- growing public recognition of the urgency of addressing pressing and complex health issues (such as the role of environmental factors, including climate change) in the etiology and spread of diseases;
- increased awareness of the links between the economy and research progress in health-related areas;
- increased expectations for better preparation against pandemics and threats from biological agents;
- demand for better protection against health risks from new products and treatments;
- the rapidly changing nature of science and the publicity surrounding it, focusing attention on the ethical implications of new approaches and discoveries, such as those related to genetic modifications and genetic screening; and
- new challenges for the harmonization of ethical practices and approval processes created by the greater internationalization of science and technology, driven in part by recognition of the need for global approaches to emerging health problems, escalating costs of research in some areas requiring that unique facilities be shared, and improved opportunities for international collaboration.

To address these many challenges, the CCAC will need to review its governance structure to ensure continuing coherent decision-making in fulfilment of its mandate. Seamless communications between the sectors of the Secretariat, that support the work of the five standing committees, and between the standing committees is also essential to the functioning of the inter-related programs. Finally, integrated communications are also needed between the CCAC and its constituents and other key players, such as the granting Agencies and regulatory departments and agencies, to pro-actively continue to achieve the universal and sustainable implementation of GAP- Good Animal Practice® in science in Canada.

Executive Summary of Plans and Priorities

Assessments (Section 1)

The CCAC is carrying out increasing numbers of assessment/special/initial/orientation visits every year, as more institutions join the CCAC Program. In order to meet this continuing challenge, the Assessment Committee will be restructured/expanded to be able to oversee and participate in all of the Assessment Program's work; special/initial/orientation visits will be performed as planned and assessment reports for these visits will be produced within the 10-week deadline; and the 8-week timeframe for following up on institutional implementation reports and on issues being faced by institutions will be met. Ongoing work on the *Animal Care and Use Program Review Form* will be continued to make it more relevant and user-friendly to all CCAC constituents and assessment panel members. In the same way, work with the Guidelines Program will be pursued to provide information obtained during the analysis of recommendations from assessment reports, as well as feedback on existing guidelines and input for new guidelines.

The Assessment Program also needs to actively provide feedback and input to other CCAC programs, share relevant information gathered from selected assessment databases, and make use of input from other programs for its own work.

Work with federal granting and regulatory Agencies will be sustained to ensure successful understanding and avoid working at cross-purposes.

The Assessment Program will also continue the production of annual animal use statistics, the creation and revision of policy statements and information/interpretation bulletins.

Guidelines (Section 2)

Guidelines will continue to be developed and revised according to the prioritization criteria established by the Guidelines Committee. The engagement of expert subcommittee members and representatives of stakeholders groups will be key to developing guidelines that are tailored to the Canadian situation. The Guidelines Program also needs to actively provide feedback and input to other CCAC programs, give them access to relevant information gathered from the guidelines development process, and make use of input from other programs for its own work.

Guidelines implementation requires the development of a variety of implementation tools to support the introduction of each new guidelines document. In the coming five years, an impact analysis will be carried out prior to development of a new guidelines document, to determine upfront the support that might be required to implement new requirements.

Interdisciplinary collaborations are essential in the development, implementation and acceptance of CCAC guidelines, and will continue to be an important element of the Guidelines Program, as well as providing feedback and input to other CCAC programs.

The use of guidelines from other jurisdictions and international guidelines increases the efficiency of guidelines development. Collaboration with the international focus group that is collating recently developed guidelines will continue, as well as collaboration with the International Council for Laboratory

Animal Science (ICLAS) to develop internationally agreed principles for the care and use of animals in science, and participation by CCAC personnel at relevant international meetings.

Three Rs (Section 3)

Building the Three Rs Program will require keen attention to the fundamental basis for the CCAC as a whole, involving close links with each of the other programs: Assessments; Education, Training and Communications; and Guidelines. In this respect, development of the Theoretical Basis of the Three Rs Program will be important, as will the Promotion of the Three Rs within the CCAC's constituency. Information documents posted on the CCAC website will be required, which outline the basis of the CCAC Three Rs Program and the definition of related concepts and terms used by the CCAC.

Keeping the Three Rs microsite up-to-date with periodic addition of new tools and information will ensure that the microsite is a valuable resource for members of Canadian institutions. Use of the information provided should assist investigators in implementing best practices, which will ultimately benefit both the quality of science and the welfare of animals used in science.

The CCAC already has standing as Canada's Centre for the Three Rs within the international community. It will be key to the success of the Program to continue to work collaboratively with international colleagues while building the credibility of the Program through collaborations with Canadian institutions.

Prioritization of the Three Rs Program Projects is critical to implementation of the Three Rs, providing an appropriate balance to the various uses of animals in science: research; teaching and testing. Access to a database of recommendations made in assessment reports is required to provide objective information concerning challenges faced by institutions. In addition, the continued gathering and analysis of animal use data, which will be completed in partnership with the Assessment Program, is required to identify animal welfare and ethical issues.

Education, Training and Communications (Section 4)

The development of targeted educational opportunities and resources for animal users, veterinarians, members of institutional Animal Care Committees (ACCs), and the scientific community, including new training modules for the National Institutional Animal User Training (NIAUT) Program, workshops and training sessions will be continued.

Long-distance education tools will be used to reach, communicate with and more efficiently educate animal users, veterinarians, members of institutional ACCs, and the scientific community.

Enhanced, optimized communication services, methods, and tools (including a well-organized, user-friendly website and a consistent and efficient publication procedure), tailored to targeted audiences will be provided as part of an integrated communications strategy involving CCAC stakeholders and its institutional and individual constituents.

The ETC Program will actively provide feedback and input to other CCAC programs, give them access to relevant information, and make use of input from other programs for its work with all CCAC constituents.

Planning and Finance (Section 5)

Planning (Section 5.1)

Given the rapidly changing nature of science and related ethical considerations of new approaches and discoveries, future forums and accompanying comprehensive consultation processes will be held every five years and synchronized with every second triennial grant submission to the CIHR and NSERC.

The multifaceted strategy to achieve national and international recognition of CCAC standard will be sustained with a special focus on all funders of direct and indirect costs of scientific activities involving

the use of animals, and the continuation of discussions towards memoranda of understanding (MOUs) between the CCAC and federal science-based departments and agencies (SBDAs).

The CCAC management, in collaboration with relevant Secretariat sectors will enhance communications with the granting and regulatory agencies through the development of fora that will facilitate regular interface with key players and prevent the organizations from working at cross-purposes.

The CCAC Board of Directors will define a process to prioritize decisions relating to the activities of the standing committees requiring in depth discussion and prior approval, to ensure an efficient use of resources, an effective knowledge transfer between programs, and the optimal functioning of CCAC's governance in support of a coherent oversight system.

The identification of an appropriate mechanism to include research trainees (students) within the CCAC's formally recognized constituency will facilitate greater exchange of information with future scientists.

The development of a database of volunteers involved with all CCAC programs and the elaboration and implementation of procedures to recognize their contributions will strengthen the relationship between the CCAC and the many volunteers on which its programs depend.

Finance (Section 5.2)

The financial aspects of the programs will continue to be given efficient scrutiny by the new Planning and Finance Committee. The financial reporting process implemented since 1999 will be continued, to ensure accountability to CCAC stakeholders and the general public.

The implementation of recommendations contained in the Business Model, and discussions with the Canada Foundation for Innovation and Genome Canada regarding complementary funding will be pursued to ensure the long-term financial viability of the CCAC.

1.   Assessments

Since the creation of the CCAC in 1968, the CCAC Assessment Program has been responsible for determining whether the animal care and use programs of participants in the CCAC Program meet Canadian guidelines and policies for animal care and use in science. As of 1994, the Assessment Committee has been responsible for the oversight of the Assessment Program, and has been working closely with the members of the Assessment Sector to ensure that all participants in the CCAC Program receive appropriate, complete, fair and timely services.

1.1   Delivery of Assessment Services to Participants

1.1.1   Restructuring of the Assessment Committee

1.1.1.1 Background

The CCAC has struggled to provide timely assessment services in the past because of a lack of resources. As of 2008, sufficient resources have been secured to provide the Assessment Program with four assessment directors (the fourth director joined at the end of 2008), one manager of assessment communications, three scientific writers (the third writer will be hired during the first half of 2009) and one administrative assistant. Excellent progress has been made towards having a sufficiently large, skilled and fully functional team in place for 2009-2014, with assessment reports produced in a timely fashion and other parts of the program managed to provide sound results.

However, this substantial workload is putting excessive pressure on the members of the Assessment Committee, who review hundreds of assessment reports and institutional implementation reports annually. These volunteers have the major responsibility of certifying institutional programs by assigning a status to each participant in the CCAC Program, following review of the relevant implementation report(s) and associated documents.

1.1.1.2 Perceived Needs

This situation is untenable with the current structure and composition of the Assessment Committee, and will need to be corrected by an increase in the number of persons reviewing reports and proposed statuses. An appropriate structure, consistent with the essential CCAC responsibility of certifying institutional animal care and use programs, will need to be found and implemented in 2009.

1.1.1.3 Requirements

For the entire process to remain consistent, solid and credible, additional peers from the community will need to become involved in the review of assessment documents. These people will need to:

- have experience and expertise in institutional animal care and use programs and in the CCAC assessment process;
- between them, cover work in English and in French, with sufficient numbers available to review French work;
- provide a balance of scientists, veterinarians and community representatives;
- provide a balance of different types of institutions and representation from different parts of the country; and
- participate in regular meetings/updates with the other members of the Assessment Committee.

1.1.1.4 Outcomes

Implementation of a flexible structure able to accommodate an increasing number of reports to review and institutions to certify, will sustain the delivery of quality assessment and certification services delivered in a timely way, using appropriate expertise.

1.1.2 Constituent Concerns

Voicing strong support for the objectives of the CCAC and an excellent working relationship with the CCAC, participants in the CCAC Forum 2008 presented suggestions on how to better work together. These are reviewed in the following sections.

1.1.2.1 Financial and Administrative Burden

1.1.2.1.1 Perceived Needs

Participants in the Forum noted that the CCAC needs to apply guidelines with a sensitivity to institutional size, scope, fiscal constraints and past performance, while reducing documentation and administrative burden.

1.1.2.1.2 Requirements

Consistent efforts are required in the production of new and revised policies to keep the requirements as practical and reasonable as possible. New draft policies and related documents that are directed towards participants in the CCAC Program need to be disseminated for widespread review, in addition to more focused reviews with those most directly affected.

Outdated requirements should continue to be eliminated (e.g., the removal of the requirement to include the names of animal users in the Animal Use Data Form in 2008).

New requirements should be avoided unless demonstrated to be essential to the quality of animal care and use programs. For example, two recently implemented requirements in CCAC policies, the designation of an animal care committee (ACC) coordinator and the development of institutional post-approval monitoring programs, have proven to be invaluable to the quality of institutional programs, resulting in a network of ACC coordinators who exchange good practices and engage in other forms of assistance across the country, and problems in programs being effectively identified and corrected.

Pre-assessment documentation requirements should be reduced for institutions that have received two consecutive statuses of Compliance. In addition, interim visits of shorter duration, alternating with full assessment visits every three years, should be implemented for these institutions.

1.1.2.1.3 Outcomes

Measures to implement new policies will likely reduce the bureaucratic and financial burden imposed on participants in the Assessment Program.

1.1.2.2 Prescriptiveness

1.1.2.2.1 Perceived Needs

Participants in the Forum recommended that the CCAC strive for consultation in verifying site visit information with more than one institutional source before, during and after the site visit timeframe, and avoid tendencies to view and apply guidelines prescriptively.

1.1.2.2.2 Requirements

Only the most essential, general considerations should be captured in CCAC policies and associated documents with scope to apply these with discernment to different types of institutional programs, given the peer review, flexible nature of the CCAC Program and the wide variety of institutional programs covered.

Careful and continuing attention should be given to this perception through widespread and more focused reviews of CCAC policies and associated documents.

1.1.2.2.3 Outcomes

Sustainable and constructive participation of assessed institutions in the CCAC Program through their engagement in relevant guidelines and policy development at an early stage will result in a shared understanding of the use to be made by the CCAC of these guidelines and policies as assessment tools.

1.1.2.3 Consistency

1.1.2.3.1 Perceived Needs

Participants in the Forum noted the need to ensure consistency in application of CCAC guidelines documents and policies from one assessment panel to the next.

1.1.2.3.2 Requirements

The following tools must be refined and new ones developed to facilitate greater consistency:

- an Animal Care and Use Program Review Form (PRF) tailored to a variety of types of institutional programs, while keeping the same general principles and standards for all programs, that is used by all assessment panels;
- regular, normally weekly assessment director and Assessment Sector meetings;
- more focused meetings between the four assessment directors and other members of the Assessment Sector as needed, designed to ensure that each component of animal care and use programs is being assessed in a consistent way; and
- focused efforts to ensure active interactions are maintained with the Guidelines Program with respect to the prioritization, production and implementation of new and revised guidelines.

1.1.2.3.3 Outcomes

Better alignment of the assessment process with institutional size, scope, fiscal constraints and past performance will improve consistency in the delivery of services.

1.1.3 Scope of the CCAC Certificate of GAP – Good Animal Practice®

1.1.3.1 Background

Since 1998, the CCAC, through its Assessment Program, has provided a tangible symbol identifying satisfactory animal care and use programs: the CCAC Certificate of GAP – Good Animal Practice®, transforming the Assessment Program into a certification program.

The CCAC certificate is now used by participants in the CCAC Program to demonstrate that they meet Canadian guidelines and policies for animal care and use in science, and by provincial, national and international regulatory authorities and scientific bodies as a tool for ensuring that the institutions they fund, oversee or work with meet Canadian guidelines and policies. The joint work of the programs, committees, Board of Directors and Council of the CCAC has led to the CCAC Program becoming more universal than it has ever been.

1.1.3.2 Perceived Needs

It would seem that there are relatively few groups using animals for scientific purposes in Canada that are not already part of the CCAC Program. These groups may use animals in a limited or sporadic way, or for purposes that are at the margins of what the CCAC defines as being "scientific purposes" (research, teaching, testing and production of animals or biologics for scientific purposes).

The Assessment Program needs to continue to work closely with the other CCAC programs, and in collaboration with the Planning and Finance Committee, to effectively build towards full universality of the CCAC Program.

1.1.3.3   Requirements

The CCAC's continuing progress towards the universal implementation of its Program requires the active participation of the Assessment Program in:

- defining exact obligations already in place with respect to an organization having to be CCAC-certified to obtain funding or meet a regulatory or scientific requirement;
- identifying groups that are using animals for scientific purposes in Canada without being either CCAC-certified or in the process of becoming so;
- defining more exactly the limits of what constitutes animal use for "scientific purposes" or to meet the requirement of scientific or regulatory bodies; and
- considering whether the CCAC certificate should be subdivided into more limited certificates that would allow smaller organizations to undertake only specific types of animal-based work.

1.1.3.4   Outcomes

A realistic plan for structured progress towards full universality of the CCAC Program will be developed with: (i) a detailed definition of exactly what this work entails, both for participants in the CCAC Program and for the CCAC itself; (ii) appropriate resources to carry out this work for both participants and the CCAC; and (iii) a timeframe within which the work towards universality will be carried out.

1.2   Assessment Visits and Reports

1.2.1   Background

The CCAC is carrying out increasing numbers of assessment/special/initial/orientation visits every year, as more institutions join the CCAC Program. These include academic, private and governmental groups seeking a CCAC certificate for the reasons outlined in section 1.1.3.1 of this document.

Despite this increasing workload, the Assessment Sector has consistently been meeting its goal of assessing participants in the CCAC Program every three years, and has carried out assessment visits on time, as scheduled between 2004 and 2009. The Assessment Sector has been able to meet or improve on the 10-week deadline for submission of reports to institutions visited since 2004, except in a few cases of mostly very large or complex programs.

The use of the current assessment report format (introduced in 2002 and refined periodically since then) has been well received by institutions and allows the CCAC to record complete assessment information for each institutional program. Further refinements will be pursued to ensure that the structure of the assessment report is clear, facilitates the work of CCAC assessment panels to complete consistent and thorough assessments, corresponds well to the PRF as filled out by the institution, and is user-friendly for both institutions and the CCAC (assessment panels and the Assessment Committee).

1.2.2   Perceived Needs

Visits and the production of reports within the 10-week deadline will continue to be the very highest priorities of the Assessment Program for 2009-2014.

Further refinements are needed for the assessment report format.

1.2.3   Requirements

The current, full complement of Assessment Sector members needs to be maintained, with regular reviews to adjust staffing to the size and nature of the workload.

Restructuring of the Assessment Committee is needed to add enough qualified persons for timely review of all assessment reports.

1.2.4   Outcomes

Better structured reports, a fully functional Assessment Sector and restructuring of the Assessment Committee will ensure assessment visits are carried out on schedule, and reports are produced and reviewed within 10 weeks.

1.3   Implementation Reports

1.3.1   Background

The timely follow-up of assessment visits (processing implementation reports, addressing institutional issues and concerns, and issuing statuses and certificates of GAP–Good Animal Practice®) remains the second highest priority for the Assessment Program.

Considerable progress has been made on this front with the hiring of a manager of assessment communications in 2006, and the implementation of structured CCAC responses to implementation reports (specific updates before/after CCAC certificates are issued, use of special visits/teleconferences) and of structured tracking of all exchanges. The four assessment directors and a manager of assessment communications, along with continued improvements in databases/IT tools and record keeping, will allow the Assessment Program to consolidate this progress into permanent improvements in service to institutions.

1.3.2   Perceived Needs

Responses to all institutional communications about implementation of CCAC recommendations need to be provided within eight weeks of receipt of the communication.

1.3.3   Requirements

The current, full complement of Assessment Sector staff should be maintained, with regular reviews to make adjustments related to the size and nature of the workload.

The Assessment Committee should be restructured to add enough qualified persons to review all implementation reports and assign statuses/certify institutions in a timely way.

Ongoing work with IT personnel on database and project tracking software is needed for more efficient follow-up of visits and concerns.

1.3.4   Outcomes

Changes to the Assessment Committee and improvements in IT will ensure implementation reports are processed within the eight-week timeframe.

1.4   Program Review Form

1.4.1   Background

The 2007-2008 revision of the PRF allowed for a complete updating of all sections and questions, along with a "modular" approach to make the form more relevant to different types of institutions (smaller institutions and institutions using farm animals, fish or wildlife).

1.4.2   Perceived Needs

The Assessment Sector and IT personnel need to work together to develop a database for the management of all matters relating to the certification of institutions.

There is a need to improve the PRF to make it more relevant to institutions that undertake animal-based teaching but not research; are involved in production only; and have received two consecutive statuses of Compliance, to request less information for interim visits of these institutions.

The PRF needs to be revised periodically to remain up–to-date and tailored to the needs of different types of institutions, and to facilitate the analysis and use of the information by members of assessment panels and the Assessment Sector.

1.4.3   Requirements

Continuing feedback from constituents and joint work on the PRF by the Assessment Sector and IT personnel will continue to be required.

1.4.4   Outcomes

PRFs will be user-friendly and more relevant for various types of institutions, as well as for the CCAC and its assessment panels.

1.5   Work with the Guidelines, Three Rs and Education, Training and Communications Programs

1.5.1   Guidelines Program

1.5.1.1   Background

New and revised guidelines create apprehension in some quarters, and this can largely be alleviated through good exchanges with constituents, as well as clear explanations of how the guidelines are to be implemented and how they will be applied during assessments.

1.5.1.2   Perceived Needs

There is a need for the Assessment Sector to provide the Guidelines Program with feedback on each of the existing guidelines and additional topics of concern that arise during assessment visits.

In addition to providing feedback in anticipation of new and revised guidelines documents, it will also be very important for the Assessment and Guidelines Programs to continue to work closely together as new or revised guidelines documents are being completed.

1.5.1.3   Requirements

As assessment reports are written and implementation reports and other work processed, the assessment directors, the director of assessment communications and scientific writers will record their comments and observations, regarding the practical application of guidelines and the need for other guidance, in these files. These comments, along with information obtained during the analysis of recommendations contained in assessment reports, will be provided to the Guidelines Program for the revision of existing guidelines documents or the development of new ones.

It will be essential for the Assessment and Guidelines Programs to continue to consult as guidelines documents are being completed to ensure that they fit well with existing CCAC requirements (policies, other guidelines documents and associated documents) and that they can be well implemented in practice by the various categories of institutions. Continued close work on implementation documents and Frequently Asked Questions sections will also be very important.

1.5.1.4   Outcomes

The development of mechanisms to ensure timely linkages between the Assessment and the Guidelines Programs is necessary to ensure an optimal fit between new guidelines and existing CCAC requirements,

so that they can be well implemented in practice by the various categories of institutions participating in the CCAC Program.

1.5.2   Three Rs Program

1.5.2.1   Background

This newly created program is of great value to constituents, who have always sought replacement, reduction and refinement alternatives but have not always had access to user-friendly resources to do so. The Three Rs microsite provides user-friendly access to many resources for a wide variety of types of animal-based work.

1.5.2.2   Perceived Needs

The Assessment Program needs to inform constituents about the Three Rs microsite and other Three Rs Program initiatives, and to provide feedback about how they are working in practice and are helping to replace, reduce and refine animal use in Canada.

1.5.2.3   Requirements

Assessment directors will include information on the Three Rs microsite and other Three Rs implementation tools developed under the Three Rs Program in their communications to individual institutions assessed.

Structured feedback on the use of the Three Rs implementation tools needs to be provided to the Three Rs Program on a regular basis.

1.5.2.4   Outcomes

Greater visibility given to Three Rs implementation tools will result from their contextualized exposure to institutional users as part of the assessment process.

The timely collation and transfer of practical information on the engagement of users with specific implementation tools will allow the evaluation of their impact on the practices of animal users and inform changes to those Three Rs implementation tools.

1.5.3   Education, Training and Communications Program

1.5.3.1   Background

The Assessment Program and the other sectors of the CCAC have contributed extensively to the Education, Training and Communications (ETC) Program. The ETC Program is now actively working on improving the CCAC website and workshops, and exploring new tools and ways of expanding the information and resources made available to constituents.

1.5.3.2   Perceived Needs

The Assessment Program needs to continue to work closely with all other CCAC programs to provide assistance with respect to the content of various ETC initiatives in order to serve CCAC constituents well.

1.5.3.3   Requirements

The Assessment Program needs to actively provide feedback and input to all programs, give them access to relevant information gathered from assessment databases, and make use of input from other programs for its own work.

1.5.3.4   Outcomes

Increased interaction with other programs will improve services to constituents.

1.6 Production of Annual Animal Use Statistics

1.6.1 Background

Production of annual animal use statistics is one of the two main ways in which the CCAC is accountable to the Canadian public (the other being the publication of the names of holders of the Certificate of GAP – Good Animal Practice® on the CCAC website). It is important for this data to be as complete and accurate as possible, given the fact that the CCAC cannot provide any information on individual institutional animal care and use programs to the public.

Institutions have, for the most part, been providing their animal use data more easily and promptly in recent years, following extensive efforts on the part of institutional members and CCAC scientific writers, and the publication of the *CCAC interpretation bulletin on the animal use data form* in 2006. Annual surveys of animal use in science in Canada are now published within one year of the calendar year for which the survey is being published, and measures are in place for this to continue.

1.6.2 Perceived Needs

Further work needs to be done, in collaboration with the Guidelines Program, to define and clearly explain which animals should, and which should not, be included in annual animal use data, with updates to the interpretation bulletin and other documents as necessary.

Further work is also needed to facilitate information transfer from institutions to the CCAC.

1.6.3 Requirements

The Assessment Sector needs to work closely with the Guidelines Sector on a clearer understanding of what animals to include, and with IT personnel to build a framework for institutions to enter their data online directly into the CCAC SharePoint portal.

1.6.4 Outcomes

Continued publication of accurate and complete national animal use data in a timely way and facilitation of the work of institutions and the CCAC in doing so, will provide the oversight system for accountability to the Canadian public.

1.7 Policy Statements

1.7.1 Background

CCAC assessment-related policy statements are of two types: external policies, meant to establish the ground rules and basic requirements for all animal care and use programs; and internal policies, guiding the operations of the Assessment Program itself. Between 2004 and 2009, two external policy statements were produced, as planned:

- the 2006 *CCAC policy statement on: terms of reference for animal care committees* (revision of the 2000 version); and
- the new, 2008 *CCAC policy statement for: senior administrators responsible for animal care and use programs*.

1.7.2 Perceived Needs

The Assessment Program needs to:

- pursue regular revisions of policy statements to keep them useful, relevant and up-to-date;
- ensure that a sound rationale is in place before any policy revision or new policy work is undertaken;

- limit the creation of any new requirements to those needed to meet serious concerns or significant emerging issues; and

- normally avoid revising policy statements more often than every six years (two full assessment cycles).

The following internal policies need updating for the stated reasons:

- update and consolidate the 2000 *CCAC policy statement on: compliance and non-compliance* with the 2000 *CIHR and NSERC Policy on Non-compliance* into the *CCAC policy statement on: certification of animal care and use programs* to reflect the CCAC certification program and the ways in which the CCAC certificate is given and used;

- update the 2000 *CCAC policy statement on: definitions of recommendations in CCAC reports* to better summarize and reflect current CCAC practices in defining and expressing recommendations, and obtaining institutional answers to them (a companion interpretation bulletin is also needed);

- update the 1999 *CCAC policy statement on: confidentiality of assessment information* to reflect recent CCAC policy and procedure adjustments;

- updating the 2000 *CCAC policy statement on: independent peer review of the scientific merit of animal-based research projects* to reflect the more comprehensive information on scientific merit review defined in the *CCAC policy statement for: senior administrators responsible for animal care and use programs* (2008) and to take into account the full spectrum of peer review practices for the various types of animal-based research;

- updating the 2003 *CCAC policy statement on: animal-based projects involving two or more institutions* and producing a companion interpretation bulletin, given that CCAC constituents have extensive questions about the ethical (and scientific merit) review of collaborative projects, and that the original policy does not cover a variety of situations;

- updating the 1999 *CCAC policy statement on: assessment panels* to reflect current Assessment Program structure and practices; and

- updating the 1999 *CCAC policy statement on: the assessment program* to reflect current Assessment Program structure and practices, including emphasis on the CCAC certification program.

A CCAC policy statement on the pedagogical merit of animal-based teaching protocols, included in the *CCAC Five Year Plan 2004-2009*, was not produced, although some guidance on this is given in the 2006 CCAC *policy statement on: terms of reference for animal care committees*; further thought will be given to this in 2009-2014.

1.7.3   Requirements

The Assessment Sector and Assessment Committee need to work together with the Board of Directors to ensure that a sound rationale, including an impact analysis, is in place prior to the revision or development of any policy statement, and that the work takes place in a comprehensive, structured and timely way, once it has been approved by the Board of Directors.

1.7.4   Outcomes

Revision and development of policies within a structure that involves the Assessment Committee and the Board of Directors will ensure the implementation of appropriate policy statements that serve the needs of constituents and the CCAC.

1.8   Information/Interpretation Bulletins

1.8.1   Background

An interpretation bulletin was produced to accompany the Animal Use Data Form (2006), and work has begun on an interpretation bulletin for human resources within institutional animal care and use program

structures as a companion piece to the CCAC *policy statement for: senior administrators responsible for animal care and use programs* (2008).

1.8.2   Perceived Needs

There is a continuing need for the CCAC to develop new information/interpretation bulletins to assist institutions in following the various guidelines and policy statements produced by the CCAC.

New interpretation bulletins for policy statements need be developed, along with other information pieces, such as the revision of the document entitled *CCAC Assessment Panel Member – A Crucial Role* (2006), to assist panel members in carrying out their duties effectively.

1.8.3   Requirements

Collaboration between the Assessment Program and the Guidelines and ETC Programs is required to provide contents for specific documents where they have expertise, in order to facilitate the production of information/interpretation bulletins.

1.8.4   Outcomes

The production of information/interpretation bulletins as needed will assist constituents in implementing the requirements detailed in CCAC guidelines and policies.

1.9   Summary of Plans and Priorities

The CCAC is carrying out increasing numbers of assessment/special/initial/orientation visits every year, as more institutions join the CCAC Program.

In order to meet this continuing challenge, the Assessment Committee will be restructured/expanded to be able to oversee and participate in all of the Assessment Program's work; special/initial/orientation visits will be performed as planned and assessment reports for these visits will be produced within the 10-week deadline; and the 8-week timeframe for following up on institutional implementation reports and on issues being faced by institutions will be met.

Ongoing work on the *Animal Care and Use Program Review Form* will be continued to make it relevant and user-friendly to all CCAC constituents and assessment panel members.

Work with the Guidelines Program will be pursued to provide feedback on existing guidelines and input for new guidelines, including the use of a database of recommendations from assessment reports.

Work with federal granting and regulatory Agencies will be sustained to ensure successful understanding and avoid working at cross-purposes.

The Assessment Program will also continue the production of annual animal use statistics, the creation and revision of policy statements and information/interpretation bulletins in a timely manner.

2.   Guidelines

The CCAC Guidelines Program encompasses four main focuses:

- the development of high quality guidelines documents that provide a solid base for an effective Canadian system of oversight of animal care and use in science;
- the development of implementation tools that assist in the application of best practices for the care and use of animals in science;
- interdisciplinary collaborations (involving scientists, veterinarians, members of the animal welfare community, and laboratory animal care personnel) for the transfer of knowledge regarding best

practices between various disciplines and the CCAC, and for the purpose of achieving rapid buy-in for new guidelines documents; and

- international harmonization to contribute to, and benefit from, transfer of knowledge between jurisdictions, and a high international reputation for Canadian science and animal care.

2.1   Guidelines Development

2.1.1   Prioritization of Guidelines to be Developed

2.1.1.1   Background

The prioritization criteria used by the Guidelines Committee for initiating the development of new guidelines documents and the revision of published guidelines documents consider:

- ethical impact – numbers of animals affected, trends in animal use, and the potential for pain and distress; and
- demand – from the scientific community and the CCAC Assessment Program, and arising from advances in laboratory animal science.

Additional factors that are taken into consideration include:

- public perception;
- downloads of particular guidelines documents from the CCAC website;
- the publication date of existing CCAC guidelines documents; and
- the availability and publication date of appropriate guidance material from other jurisdictions.

Guidelines documents to be considered for development are mainly classified as procedures or care and maintenance, as the prioritization criteria can apply differently to the two categories (e.g., certain procedures are used on a variety of species, making ethical impact more difficult to assess). Additionally, it is important to ensure continued progress in each category in order to address issues associated with both the care and the ethical use of animals in science.

2.1.1.2   Perceived needs

Sufficient background information is needed for the Guidelines Committee to form a clear understanding of:

- the numbers of animals used in science, and trends in their use, for different species;
- current and emerging research where there are ethical or animal welfare issues;
- refinements in animal care and in animal use procedures; and
- the needs of the Assessment Program, ACC members (including community representatives) and scientists in relation to guidance on the care and use of animals in science.

2.1.1.3   Requirements

To effectively prioritize guidelines documents for development, the Guidelines Committee requires that the Guidelines Program staff provide the following:

- information from the Assessment Sector on the numbers of animals used in science in Canada;
- timely identification of new information on emerging issues involving the use of animals in science and advancements in animal care, through the regular review of scientific journals, including animal welfare/ethics and animal care journals;
- objective and specific information concerning challenges faced by research institutions and information gaps in current guidance materials, through access to a database of recommendations made in assessment reports;

- information from the Three Rs Program regarding advancements in relation to the Three Rs;
- identification of advancements in science and challenges faced by researchers through regular involvement with the scientific and animal welfare communities (See Section 2.3 Interdisciplinary Collaborations); and
- identification of challenges and best practices in animal care through structured communication with laboratory animal personnel (See Section 2.3 Interdisciplinary Collaborations).

2.1.1.4 Outcomes

The prioritization of guidelines documents will have a solid traceable basis that addresses animal welfare concerns, the needs of constituents and issues emerging in the conduct of research. The formal process for prioritization will provide accountability for decisions made pertaining to the development of guidelines documents, and quicker responses to current challenges faced by ACCs, the Assessment Program and the scientific community.

2.1.2 Guidelines Development Process

2.1.2.1 Background

In the recent past, the preliminary draft of a guidelines document has been produced in a number of ways:

- by volunteer members of an expert subcommittee set up to develop guidelines in a particular area;
- by a consultant;
- by the subcommittee chair and a CCAC director; and
- by a research fellow.

The preliminary draft is further revised by the subcommittee and Guidelines Program staff until such point that it is agreed upon by the subcommittee and Guidelines Committee that it is ready for peer review. The peer review process involves experts identified by the subcommittee, whose collective expertise covers the range of topics included in the guidelines documents and who represent the scientific, veterinary and animal welfare communities. Two additional review stages may be implemented, including a widespread review (which broadly invites participation through the CCAC website) and a final review (which involves all who commented during the previous reviews), if deemed necessary by the Guidelines Committee. Following each review, the subcommittee assesses the feedback received and the draft is modified accordingly.

2.1.2.2 Perceived needs

The Guidelines Program needs to undertake a comprehensive analysis of issues underpinning a proposed guidelines document at the onset to better define the scope of the document and inform the decision of whether or not to proceed with its development.

The timely development of a guidelines document throughout the process, requires the following:

- an efficient means of resolving areas of conflict;
- efficient access to reference materials to assist subcommittee members in making decisions and to substantiate statements made in the guidelines; and
- improved contact with the scientific community to ensure the involvement of scientists in reviews of draft guidelines, as per requests made at the CCAC Forum 2008.

2.1.2.3 Requirements

Background papers developed by research fellows or graduate students (through collaborations with their supervisors) prior to initiation of work by the subcommittee are needed as a basis for subcommittee

members to discuss issues to be covered in the guidelines documents, and for the Guidelines Committee and Board of Directors to decide to proceed with the development of the document.

Throughout the guidelines development process, targeted face-to-face consensus meetings of subcommittee members are required to resolve key issues that arise. Focused workshops may also be needed to engage CCAC constituents in a particular complex issue and help subcommittees understand how stakeholders are affected by an issue.

Timely access to references is needed to ensure steady progress on guidelines and verify the appropriateness of references that have been recommended during the reviews.

Means of increasing the involvement of scientists in guidelines development are required, such as through the distribution of drafts for review by institutional administration systems, and scheduling reviews in accordance with academic calendars, grant cycles and other factors that may impact the availability of reviewers.

2.1.2.4   Outcomes

A smooth process for the development of guidelines documents through the integration of the work of research fellows, consensus meetings and other volunteer contributions, and the resources of the CCAC Secretariat will ensure more efficient completion of guidelines documents. This will further enhance subcommittee involvement (See Section 2.1.3). Furthermore, ensuring all stakeholders are included in the review process will increase acceptance of the guidelines documents when published.

2.1.3   Subcommittee Involvement

2.1.3.1   Background

Guidelines development relies heavily on the expertise of volunteer subcommittee members; continued engagement of these volunteers is essential for the timely publication of high quality guidelines documents and ensuring a broad sense of ownership in the animal research and welfare communities, and in the Canadian public.

2.1.3.2   Perceived needs

Transparency in the process of subcommittee selection is needed to add credibility to the peer-based foundation of guidelines development, as per requests made during the CCAC Forum 2008.

Better engagement of subcommittee members in guidelines development is needed through:

*   clear identification of roles of subcommittee members to ensure their understanding of the commitment required;
*   regular communications;
*   incentives to remain engaged in the process; and
*   recognition of contributions.

2.1.3.3   Requirements

A more transparent process for subcommittee selection can be achieved through:

*   revision of *Terms of Reference for Subcommittee Members* (last updated by the Guidelines Committee in 2003); and
*   formalization of the subcommittee selection process, with a description of the process posted on the website.

Means of improving the level of engagement in guidelines development by subcommittee members include:

- enhanced use of the portal to manage subcommittee communications, with detailed plans for regular communication;
- quarterly work plans and detailed outcomes for subcommittee members, rather than the current annual work plans, to provide up-to-date information on the progress of the guidelines documents and the requirements for their participation;
- continued education (training) of Secretariat staff in group dynamics and facilitation to ensure face-to-face meetings achieve the desired outcomes in a minimum amount of time, and to ensure that all interests are heard;
- opportunities for input from graduate students supervised by subcommittee members (see Section 2.1.2.3); and
- recognition of contribution of subcommittee members, for example, through a letter from the CCAC to the institution of the volunteer, if desired, indicating the amount of time the volunteer has contributed and outlining the benefits of the work of the subcommittee to the institution.

2.1.3.4   Outcomes

The formation of subcommittees with balanced membership (scientists, veterinarians, community representation, etc., as appropriate), that have been formed through a transparent process, will contribute to better acceptance of published guidelines documents.

Improved interaction with subcommittee members should result in improved understanding of the process for guidelines development and willingness of members to commit time to review drafts and provide constructive input and advice in a timely manner. Greater commitment from the volunteers will assist in shortening the time frame for developing guidelines.

2.1.4   Guidelines Production

2.1.4.1   Background

In recent years, the Guidelines Program has undertaken the concurrent development of five guidelines documents, given the availability of staff within the Secretariat to support the work of the guidelines subcommittees. Recent changes to the Guidelines Program have added a full-time research assistant and seen re-alignment of the guidelines program director's work to support the new Three Rs Program.

Emphasis over the next five years will be on decreasing the time required to publish each guidelines document, while maintaining the same number of guidelines documents under development at one time. Efficiency will also be realized through the continued used of guidance materials from other jurisdictions as a basis for the development of guidelines documents, and the adoption of these materials where appropriate.

2.1.4.2   Perceived needs

Strong coordination and scheduling of work on guidelines documents under development, as well as other Sector projects, is needed to ensure Secretariat resources are applied effectively. In addition, increased Secretariat resources need to be dedicated to supporting the work of guidelines subcommittees (e.g., for reference searches).

2.1.4.3   Requirements

The Guidelines Program staff needs to develop dynamic work plans that are regularly reviewed to adjust staffing to the size and nature of the workload. These work plans should be communicated to all affected personnel on a monthly basis.

2.1.4.4 Outcomes

More efficient production of guidelines documents will provide a quicker response to evolving challenges faced by the Assessment Program, ACCs and the scientific community.

2.1.5 Publication of Guidelines

2.1.5.1 Background

When the CCAC recently moved to only publish guidelines documents in electronic format, it was noted that the 'saved' resources (i.e. printing costs) would be balanced by improved service to constituents. In this respect, the format change would allow for easier updating of website links within the documents, and would lead to easier access to information within large guidelines documents.

Additionally, participants of the CCAC Forum 2008 requested that executive summaries of guidelines documents be provided, along with clear statements to identify individual guidelines where there was little or no latitude for interpretation.

2.1.5.2 Perceived needs

The ability of users to access current and accurate information in published guidelines documents requires maintenance of up-to-date links within guidelines documents, clear summary statements, and electronic guidelines documents with enhanced ability for users to efficiently access and print relevant information.

2.1.5.3 Requirements

Providing guidelines documents with up-to-date information requires the dedication of resources to regularly check website links to ensure accuracy.

Executive summaries are required to provide more clarity. Further improvement to the presentation of information within guidelines documents will require collaboration with the ETC Sector and IT personnel to design a user-friendly format for online access to information in guidelines documents (e.g., replacement of the newspaper-column format used in print documents).

2.1.5.4 Outcomes

Greater ease in accessing information in guidelines documents will result in more successful transmission of information to constituents, and ultimately better welfare for animals used in science. Making CCAC literature more available via web methods recognizes a communications reality which affects science, business and everyday life in much of the world.

2.2 Guidelines Implementation

2.2.1 Implementation Tools

2.2.1.1 Background

Implementation tools are intended to assist the Assessment Program, ACCs, scientists and animal care personnel in the application of best practices identified in CCAC guidelines documents. These tools include overarching guidance on how to interpret concepts in CCAC guidelines documents, as well as best practice information that is particular to a species or situation.

2.2.1.2 Perceived needs

The smooth implementation of new guidelines documents following publication needs to be enhanced by providing:

- a common understanding among constituents of complex concepts used in CCAC guidelines documents, so that they are applied appropriately;

- an understanding among constituents on how guidelines apply to different situations (e.g., regulatory testing, institutions of different sizes); and
- additional resources to assist in implementing best practices outlined in the guidelines documents (e.g., species-specific recommendations and links to relevant papers).

2.2.1.3 Requirements

Through collaboration with the Three Rs Program and the Assessment Program, discussion papers should be developed on overarching topics in CCAC guidelines documents, such as the concept of best practice, environmental enrichment versus environmental improvement, etc.

Workshops following the publication of guidelines documents are required to provide participants with practical assistance in implementing the guidelines within their local animal care facilities. In addition, collaboration with the ETC Sector to explore the use of webinars to disseminate information on guidelines documents should assist in reaching a wider audience.

Additional materials should be developed by the Guidelines Program to supplement published guidelines documents, as needed. This will be done in collaboration with the Three Rs Program which will identify published scientific evidence to support best practice information.

2.2.1.4 Outcomes

Investigators, animal care staff, ACCs and the Assessment Sector will have a better understanding of how to implement CCAC guidelines, resulting in higher standards of care and use for the animals.

2.2.2 Impact Analysis

2.2.2.1 Background

To facilitate the implementation of guidelines, an assessment of any additional burden on institutions (financial or human resources) and/or investigators should be carried out when a guidelines document is proposed for development, by consulting those who will potentially be impacted by the guidelines. Some aspects of impact analysis are already performed in collecting data for the prioritization framework (e.g., an analysis is undertaken to estimate the numbers of animals likely to be impacted by the guidelines document, and the potential for reducing the level of pain and/or distress through implementation of these guidelines).

The likely impact on an institution and on its investigators, as well as the impact on the animals, can then be used to determine potential costs and benefits, and be included in the rationale for the development of the guidelines document. Such impact analysis has been recommended by participants in the CCAC Forum 2008. This information is also important for grant selection committees (e.g., the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Research Council (NSERC) were asked to inform their grant selection committees that implementation of the *CCAC guidelines on: antibody production* (2003) would involve increased costs for investigators to determine whether a monoclonal antibody could be raised in vitro, or to purchase a newer adjuvant eliciting a less aggressive reaction in the animal), in that these costs were eligible expenses to be claimed through Agencies' grants.

This impact analysis should be reviewed prior to publication of the guidelines to ensure it remains accurate and complete.

2.2.2.2 Perceived needs

An estimation of any additional costs (financial, human resources, etc.) that a proposed guidelines document will entail for institutions and/or investigators is required at the onset of its development. In addition, potential means of addressing any additional costs need to be determined.

2.2.2.3 Requirements

Estimating additional costs that a guidelines document will entail requires consultation with institutional representatives that are likely to experience additional client costs as a result of addressing issues identified in the scope of the guidelines document. As a follow-up, a review of the initial cost analysis (directed by the subcommittee) is required prior to publication of the guidelines document to determine any additional factors that have arisen through the guidelines development process.

To determine potential means of addressing additional costs that may result, a review of best practices internationally is needed to explore how other institutions are dealing with directly related funding issues. A means of communicating this impact analysis and suggestions to facilitate implementation of the guidelines with institutions, funding agencies, etc. is also required.

2.2.2.4 Outcomes

Identifying areas where institutions and/or investigators may experience financial or human resource impacts, and proposing solutions for dealing with these impacts, will assure institutions and investigators that the CCAC understands the constraints they are facing. This should promote greater cooperation among parties and help to facilitate the implementation of new guidelines documents.

2.3 Interdisciplinary Collaborations

2.3.1 Background

Maintaining strong communications between the Guidelines Program and members of the scientific, veterinary, animal welfare and laboratory animal care communities is essential to the development of high quality guidelines documents, and their acceptance by those involved in the care and use of animals in science.

2.3.2 Perceived needs

Active participation of representatives of the scientific, veterinary, animal welfare and animal care communities in guidelines development, and access to appropriate scientific expertise as required, is needed to produce quality guidelines documents and ensure acceptance of the guidelines documents once published.

Increased visibility of the CCAC in fora used by scientists is needed to communicate relevant information and build strong relationships. In addition, identification of information gaps where scientific evidence is needed for guidelines development, and communication of such research needs to granting Agencies and researchers will benefit both researchers and the CCAC.

2.3.3 Requirements

The Guidelines Program needs to maintain contact with appropriate representatives of scientific societies, Chairs of departments using animals, veterinarians, laboratory animal care groups and animal welfare organizations to ensure all stakeholders are invited to contribute to the review of draft guidelines documents in a timely manner. In addition, maintaining a strong network of contacts with expertise relevant to areas covered by CCAC guidelines documents assists in addressing new questions and issues that arise.

Participation by CCAC personnel at relevant scientific meetings, through presentations, posters, workshops or CCAC update sessions, and publication of papers authored by CCAC personnel in peer-review journals and other appropriate media, increases awareness of the role of the CCAC and contributes to the advancement of science and animal welfare. Placement of CCAC fellows within academic and other relevant departments and institutions involved in the use of animals provides additional opportunity for interaction between the CCAC and research scientists and laboratory animal care personnel.

Surveying guidelines subcommittees on an annual basis is needed to determine areas where scientific evidence for guidelines' formulation is lacking. Forwarding this information to granting Agencies and scientists through letters and newsletter articles may lead to more research in these areas.

2.3.4   Outcomes

Involvement of the scientific community, veterinarians, laboratory animal care personnel and animal welfare specialists results in CCAC guidelines documents that meet high ethical standards and are well grounded in scientific evidence. Their collective input in developing and reviewing draft guidelines documents balances the welfare of animals used in science with scientific goals and requirements. Inputs from the scientific community provide the necessary evidence on which to base recommendations for improvements in the care and use of animals, while knowledge from experts in animal welfare and veterinary science contributes greatly to understanding factors that may impact research results.

Interdisciplinary collaborations result in guidelines documents that have buy-in from the various stakeholders. These interactions also lead to improved understanding of the CCAC by all stakeholders, including an understanding of the distinction between the role of the local animal care committees and the CCAC itself.

Interaction between the CCAC and the scientific community can potentially promote increased availability of information on the scientific basis for refinements, as the CCAC will provide feedback to funding agencies regarding critical areas where research is needed in support of the welfare of animals used in scientific procedures and resulting quality science.

2.4   International Harmonization

2.4.1   Background

The international harmonization of guidelines documents is a priority for the CCAC Guidelines Program due to the broad implications for international scientific collaboration, global acceptance of research data, and international trade. Strategic involvement with relevant international organizations is necessary for both efficient development of CCAC guidelines documents, and the integration of the work of the CCAC with the international community.

2.4.2   Perceived needs

The CCAC needs to contribute to the development of international guiding principles and participate in relevant international fora, both to increase the CCAC's awareness of guidelines development in other jurisdictions and how it can feed into the CCAC guidelines development process, and to facilitate international recognition of the CCAC and its guidelines documents.

2.4.3   Requirements

Guidelines Program staff requires knowledge of key international organizations with expertise in the area of guidelines documents under consideration by the CCAC to identify existing guidelines for adoption or incorporation into CCAC guidelines documents, and for inclusion of organizations and/or their membership in the review stages of CCAC guidelines documents.

The CCAC needs to both contribute to the development of international guidelines documents and gain recognition of CCAC guidelines documents through:

- continued collaboration with the international focus group that is collating recently developed guidelines on housing and husbandry, and additional relevant science-based evidence, as the basis for a set of international guidelines for animal housing and husbandry;

- continued collaboration with the International Council for Laboratory Animal Science (ICLAS) to develop internationally agreed principles for the care and use of animals in science, and to promote international recognition of CCAC guidelines documents; and

- participation by CCAC personnel at relevant international meetings, through presentations, posters or workshops, to contribute to the advancement of science and animal welfare at the international level.

2.4.4   Outcomes

The use of guidelines documents from other jurisdictions and/or international guiding principles as a foundation for developing CCAC guidelines documents will increase the efficiency of their development.

Contributing to the work of the international focus group and ICLAS has the potential to improve the welfare of animals in science by establishing common guiding principles for international animal-based collaborations. Ultimately, this will improve the welfare of animals used in science irrespective of where the studies are performed, and will increase accountability to the public and the quality of science. For Canadian scientists, this means guiding principles that are similar internationally and that are based on sound scientific evidence.

The increasing globalization of science presents a challenge to ensure that studies are conducted according to high scientific and ethical standards. To be competitive internationally, Canadian science must be well-regarded. Canadian science benefits from the CCAC's work to transfer knowledge generated in Canada to the international community. The recognition of CCAC guidelines documents by ICLAS initiatives provides increased international credibility for the CCAC and recognition of Canadian guidelines documents.

Sharing of information in areas of research where there is considerable international collaboration, such as for genetically-engineered animals, will facilitate the transfer of valuable data, resulting in improvement in the care of the animals and more efficient use of resources, with increased validity of scientific data.

2.5   Summary of Plans and Priorities

Guidelines documents will continue to be developed and revised according to the prioritization criteria established by the Guidelines Committee. The engagement of expert subcommittee members and representatives of stakeholders groups will be key to developing guidelines documents that are tailored to the Canadian situation. The Guidelines Program also needs to actively provide feedback and input to other CCAC programs, give them access to relevant information gathered from the guidelines development process, and make use of input from other programs for its own work.

Guidelines implementation requires the development of a variety of implementation tools to support the introduction of each new guidelines document. In the coming five years, an impact analysis will be carried out prior to development of a new guidelines document, to determine upfront the support that might be required to implement new requirements.

Interdisciplinary collaborations are essential in the development, implementation and acceptance of CCAC guidelines documents, and will continue to be an important element of the Guidelines Program.

International harmonization provides benefits to the CCAC in the transfer of knowledge generated in Canada to the international community, directly addressing the increasing globalization of science. In addition, the use of guidelines documents from other jurisdictions and international guiding principles increases the efficiency of guidelines development. Collaboration with the international focus group that is collating recently developed guidelines documents will continue, as well as collaboration with ICLAS to develop internationally agreed guiding principles for the care and use of animals in science, and participation by CCAC personnel at relevant international meetings.

3. Three Rs

The year 2009 marks the 50th anniversary of the publication of Russell & Burch's book, *Principles of Humane Experimental Technique* [1], which first described the Three Rs. It is fitting that the CCAC has formally launched its Three Rs Program, providing an opportunity to outline and substantiate the role of the CCAC in the promotion and implementation of the Three Rs in Canada.

As the Three Rs Program is new, in the next five years it will need to establish a theoretical basis for its work and prioritize its activities as detailed in Sections 3.1 and 3.2. There are two primary focuses for the Three Rs Program, described in Sections 3.3 and 3.4, namely:

- promoting the Three Rs through communication of the CCAC's ethics of animal experimentation, the maintenance of an up-to-date Three Rs microsite, and the consolidation of CCAC's role as Canada's national centre for the Three Rs; and
- supporting the implementation of the Three Rs in all areas relating to the use of animals in science covered by the CCAC Program.

At the Secretariat, the work of the Three Rs Program is carried out by staff in the Guidelines and Three Rs Sector, as detailed in Section 3.5. This arrangement operationalizes the connections between the Guidelines Program and the Three Rs Program.

3.1 Development of the Theoretical Basis of the Three Rs Program

3.1.1 Background

The *CCAC policy statement on: the ethics of animal investigation* (1989), which defines the Three Rs for the CCAC, provides the fundamental basis for the CCAC Program as a whole, and is the starting point for all CCAC guidelines documents. The CCAC's adherence to these principles is directly in line with the fundamental basis for both international and national bodies responsible for overseeing animal use in science[2].

It is important for the CCAC to have a scholarly basis for its work, to lend credibility to the CCAC as a nationally and internationally recognized organization and as the centre for the Three Rs in Canada.

3.1.2 Perceived needs

The Three Rs Program will need to adopt a science-based approach for its work, both to build the credibility of the program and to align with the fundamental basis for the other CCAC programs. In this regard, there is a need to develop an understanding of the process involved in the translation of science into policy. Development of an understanding of legislative and non-legislative drivers for the implementation of the Three Rs in other jurisdictions, e.g., CIOMS *Principles on Biomedical Research*, U.S. Government *Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, *EU Directive 86/609*, and European REACH legislation, is needed to further define the theoretical basis of the CCAC Program.

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1   Russell WMS & Burch R (1959) *Principles of Humane Experimental Technique.*238pp. Potters Bar, Herts UK: UFAW.

2   For example: Council for International Organizations of Medical Sciences (CIOMS) (1985) *International Guiding Principles for Biomedical Research Involving Animals* http://www.cioms.ch/frame_1985_texts_of_guidelines.htm; *The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf; and Council Directive of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC) http://ec.europa.eu/food/fs/aw/aw_legislation/scientific/86-609-eec_en.pdf

In addition, definitions of concepts and terminology frequently used by the CCAC, and the application of these concepts in the implementation of CCAC guidelines documents, along with the dissemination of this knowledge to constituents is needed to foster a better understanding of the CCAC Program.

3.1.3   Requirements

Research to better understand the translation of science into policy is required, e.g., through the involvement of the research fellows in the Department of Public Policy at the University of Ottawa. It will also be necessary to keep up-to-date with international legislative and regulatory changes relating to the Three Rs through regular interactions with international colleagues.

Setting the parameters for an understanding of the theoretical basis of the implementation of the Three Rs in different areas will require peer reviewed publications co-authored by members of the CCAC Secretariat and collaborators on the implementation of the Three Rs for particular types of research (e.g., *Incorporation of the Three Rs in Wildlife Research*[3]), as well as discussion papers researched and co-authored by members of the CCAC Secretariat and collaborators on relevant matters such as categories of invasiveness, the term 'humane', definition of pain etc.

To assist in understanding the basis for CCAC terminology, information documents posted on the CCAC website will be required, which outline the basis of the CCAC Three Rs Program and the definition of related concepts and terms used by the CCAC.

Reinforcement of the basis and implementation of the Three Rs will require presentations at the CCAC national workshop, regional workshops and scientific meetings.

3.1.4   Outcomes

With the provision of the fundamental information described above, those involved in the care and use of animals in science will have a greater understanding and appreciation of the CCAC's science-based approach to policy/guidelines development. They will have detailed information on how to apply the Three Rs in special categories of scientific animal use, and will have opportunities to be involved in associated policy development at an earlier stage than occurs presently. These factors will provide animal users with a stronger basis for the interpretation of CCAC guidelines documents and policies and a greater understanding of the governance of animal use in science.

3.2   Prioritization of Three Rs Program Projects

3.2.1   Background

The potential impact of a proposed activity in terms of replacement, reduction or refinement of animal use is the main criterion being used by the Three Rs Committee to determine the activities to be undertaken.

3.2.2   Perceived needs

In order to prioritize Three Rs Program projects, each project will require sufficient background information for the Three Rs Committee to form a clear understanding of:

- the needs of the Assessment Program, ACC members (including community representatives) and investigators in relation to Three Rs information and advice;
- the types and prevalence of animal use in research and the most pressing ethical or animal welfare issues;
- the impact of the use of animals on student learning and/or on competence of trainees;
- scientific and policy trends affecting regulatory testing; and

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[3]   Griffin G. & Gauthier C. (2004) Incorporation of the principles of the Three Rs in wildlife research. *ATLA* 32 (Suppl. 1):215-219

- the impact of any proposed activity on constituents involved in the use of animals in science.

3.2.3 Requirements

The regular review of scientific journals, including animal welfare/ethics and animal care journals is required, to ensure that the most current information available on emerging issues involving the use of animals in science and advancements in animal care is identified. Involvement with the scientific and animal welfare communities is required to identify advancements in science and challenges faced by investigators and regulators. Access to a database of recommendations made in assessment reports is required to provide objective information concerning challenges faced by institutions. In addition, the continued gathering and analysis of animal use data, which will be completed in partnership with the Assessment Program, is required to identify animal welfare and ethical issues.

In order to process the above inputs, an objective framework for prioritization requires developing. Once in place, appropriate "project management" tools are required to ensure oversight of workflow with measurable outcomes.

3.2.4 Outcomes

Prioritization of Three Rs activities will provide a solid basis that addresses animal welfare concerns, the needs of constituents, and issues emerging in the conduct of research or the interface with regulators concerning animal policy matters. The formal process for prioritization will provide accountability for decisions made regarding which activities are pursued, and allow a quicker response to current Three Rs related challenges faced by ACCs, the Assessment Program and the scientific community. As recommended by participants in the CCAC Forum 2008, an impact assessment prior to the implementation of any proposed activity will identify costs and concerns of constituents, and assist in prioritization of effort.

3.3 Promotion of the Three Rs

The Three Rs Program was initiated to promote awareness, knowledge and sensitivity to the ethics of animal use in science, in line with the following request from the granting Agencies:

> "...continued attention needs to be given to exploring and promoting the fundamental principles of the "3Rs"... we believe that the concept of "Replacement" of animals with appropriate non-animal systems or with species lower on the phylogenetic scale should receive equal emphasis..."

> NSERC/CIHR Evaluation Committee Report 2002

3.3.1 CCAC Three Rs microsite

3.3.1.1 Background

Before establishing the Three Rs Program, a consultant developed a Three Rs microsite for the CCAC. It is anticipated that by March 2009, the four main elements of the microsite will be online: Three Rs Alternatives; Special Topics and Additional Resources; Three Rs Search Guide; and a Table of Alternatives Methods: Regulatory and Validation Status.

3.3.1.2 Perceived needs

An up-to-date Three Rs microsite, tailored to Canadian investigators, ACC members and animal care personnel, that provides sufficient general information for interested lay readers, is needed. Rather than consider the Three Rs in abstract terms, communication of "success stories" is needed (e.g., descriptions of studies which have added value through the implementation of the Three Rs; best practice information; and the current status of alternative methods). The communication of best practices and new Three Rs

information that is progressive is needed, with a means to signal that this may go beyond what is currently required by CCAC guidelines documents.

3.3.1.3   Requirements

A regular review of the microsite is required to add new relevant information, maintain the Alternative Methods Table up-to-date, feed the Reference Databank with new references, and maintain functional links. Collaboration with Canadian scientists is needed to identify stories of successful implementation of the Three Rs. In addition, the identification of unique resources that are required by Canadian investigators, ACC members and animal care personnel will assist in directing the efforts in developing new areas of the microsite. This may require:

- commissioned articles on key topics;
- workshops to explain the functioning of the Three Rs microsite and seek feedback; and
- timely response to constituent feedback about the microsite.

3.3.1.4   Outcomes

Keeping the Three Rs microsite up-to-date with periodic addition of new tools and information will ensure that the microsite is a valuable resource for members of Canadian institutions. Use of the information provided should assist investigators in implementing best practices, which will ultimately benefit both the quality of science and the welfare of animals used in science.

3.3.2   CCAC as Canada's Three Rs Centre

3.3.2.1   Background

Many countries have national centres on the Three Rs. These centres provide advice and guidance on reduction, refinement and replacement alternatives. The CCAC is already recognized internationally as the official Three Rs Centre in Canada, as evidenced through invitations to the Secretariat to participate in international meetings of the Three Rs centres (November 2006 in Baltimore, and August 2007 in Tokyo, Japan) and the CCAC's membership on the international project team for Altweb[4], a comprehensive web-based resource for the Three Rs. The CCAC has also been invited to host the 8th World Congress on Alternatives & Animal Use in the Life Sciences (WC8) in Montréal in 2011, in recognition of the important contributions made by the CCAC and Canadian investigators and veterinarians in the area of the Refinement alternatives.

3.3.2.2   Perceived needs

At present, the CCAC is recognized abroad as Canada's Three Rs Centre. There is a need to consolidate this role nationally for the CCAC to be effective as a National Three Rs Centre. The organization of a successful WC8 in Montréal in 2011 is needed in fulfillment of this objective.

3.3.2.3   Requirements

Enhanced interaction and resource sharing between international Three Rs centres will be required to identify the important elements of a centre that should be mirrored in Canada. To support a successful WC8, identification of national and international partners, investigators, and animal care personnel will be required to develop the scientific program and other activities for WC8.

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4   http://altweb.jhsph.edu/

3.3.2.4   Outcomes

Further interaction with international partners on Three Rs initiatives will result in the CCAC continuing to be seen and used as the Centre for the Three Rs in Canada. Timely sharing of new information between centres will solidify the CCAC's standing nationally as well as internationally.

The identification of key players in Canada and internationally who can contribute scientific excellence related to the Three Rs, or demonstrate successful involvement of community representatives in the ethical use of animals, will result in a sound scientific program for WC8. While it is a privilege for the CCAC to host this world congress, a successful WC8 will also result in an enhanced international profile for the CCAC.

3.4   Supporting the Implementation of the Three Rs

To maintain good public accountability and international credibility for the oversight of Canadian science, previous CIHR/NSERC committees evaluating the CCAC Program recommended an increased Three Rs mandate:

> "...additional activities which could contribute to ensuring a credible national program are... ensuring a solid scientific basis for standards and practices by promoting research in support of replacing animal use, refining the procedures involved to minimize pain and distress, and reducing the number of animals used to the justifiable minimum."

CIHR/NSERC Evaluation Committee Report 2005

The activities detailed below are aimed at encouraging the effective implementation of the Three Rs in each of the main areas of science overseen by the CCAC.

3.4.1   Implementation of the Three Rs in Research

There is a wide range of opinions concerning the acceptability of research involving animals. However, the Three Rs has provided an approach to the use of animals in research that is supported by a broad cross-section of opinion.

While this can be conceptually muddling, the term "alternatives" was defined by Smyth (1979)[5], with the intent of providing focus on areas where there is the greatest potential for pain and distress, that is not only by replacing animals (Replacement) but also by reducing the numbers used (Reduction) or by causing less animal suffering (Refinement). This is the approach in use by the CCAC.

According to the *CCAC policy statement on: the ethics of animal investigation* (1989)*,* animals can only be used for research if there is no other way of obtaining the information. However, meeting this requirement can be challenging, requiring the development of new alternative methods, commitment to improved searching strategies and the use of alternatives already in existence.

3.4.1.1   Research Proposal Review

3.4.1.1.1   Background

A recent study from Radboud University, The Netherlands[6], showed that providing assistance to investigators in consideration of the Three Rs prior to review by local ACCs improved scientific excellence by ensuring appropriate experimental design (reduction), appropriate methods of statistical analysis (reduction), selection of appropriate animal (or non-animal) models (replacement and reduction),

[5]   Smyth, D. (1978). *Alternatives to Animal Experiments.* 218pp. London, UK: Scolar Press (David Smyth a UK physiologist was President of the UK Research Defence Society when he developed the Three Rs definition of alternatives)

[6]   Savenije B., van der Vaart L. & Ritskes-Hoitinga M. (*2007*) Searching for Alternatives : A Service by the 3Rs Research Centre. Presented at the 7th World Congress on Alternatives and Animal Use in the Life Sciences. Tokyo.

and improvement in methodology (refinement). This type of support was requested by CCAC constituents during the CCAC Forum 2008.

3.4.1.1.2 Perceived needs

Enhanced access for investigators to information on appropriate experimental design, methods of statistical analysis, selection of models, and methodology is needed. In particular, pre-protocol evaluation of animal-based research studies is needed, including identifying questions on whether the proposed animal species is the most appropriate for the study, and any Three Rs alternatives if applicable.

3.4.1.1.3 Requirements

Implementation of the online Three Rs Search Guide is required for investigators to have easy access to Three Rs resources.

Formal discussion with representatives from the CIHR and NSERC is required to determine how pre-protocol evaluation might be accomplished within the framework of the current grant review process. Even if this is possible, a review of staff resources will be necessary to permit the Guidelines and Three Rs Program Director to coordinate pre-protocol reviews with CCAC experts, the granting Agencies and external experts from the national and international scientific community.

Presentations (e.g., symposium, webinars, etc.) in association with CCAC national workshops or as stand-alone sessions, and at scientific meetings are required to engage mainstream scientists in implementation of Three Rs alternatives.

3.4.1.1.4 Outcomes

The Three Rs microsite will provide tools tailored to meet the needs of Canadian investigators and thereby assist in a Three Rs analysis before submission of a protocol for review by an ACC. The Three Rs review of funded grants should improve scientific excellence by ensuring appropriate experimental design, appropriate methods of statistical analysis, and selection of appropriate animal (or non-animal) models. Benchmarking this initiative against similar reviews carried out by the UK National Centre for the Three Rs (NC3Rs)[7] and the Radboud University, including the use of similar outcome measures, will highlight areas where additional work is required to provide added value for research studies. Symposia or webinars that engage mainstream scientists should result in effective implementation of the Three Rs.

3.4.1.2 Promoting Research in Support of the Three Rs

3.4.1.2.1 Background

Two previous granting Agencies' evaluation committees asked the CCAC to increase its efforts in promoting research in support of the Three Rs, including method development for product safety testing. A discussion was held with representatives from the granting Agencies to explore the possibility of "top up" funding for investigators that have already been awarded a grant to carry out additional studies, mainly in the area of refinement alternatives (e.g., improved endpoints, use of analgesics and development of in vitro approaches to monoclonal antibody production).

3.4.1.2.2 Perceived needs

There is a need for targeted funding for research in the area of the Three Rs to bring Canada in line with other nations where funding for Three Rs alternatives is provided separately. There is also a need for funding for research gaps identified during guidelines development exercises.

Fostering of communication with established systems biology and bioinformatics research centres is needed to identify places where Three Rs alternatives are being developed, or where this might be stimulated.

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[7] http://www.nc3rs.org.uk/

3.4.1.2.3 Requirements

Lobbying all pertinent granting Agencies and other funders of animal-based scientific activities is a requirement to provide top-ups, identify mechanisms for funding for research (possibly through the creation of a "virtual" Three Rs Research Institute), or provide a specific funding envelope for grants in the area of the Three Rs.

Analysis of advances in systems biology and bioinformatics is required as these might have relevance as replacement alternatives.

3.4.1.2.4 Outcomes

Three Rs funding through the granting Agencies and other funders, and identification of research that is funded to develop Three Rs alternatives and posting it on the Three Rs microsite would encourage more research on Three Rs alternatives.

3.4.2 Implementation of the Three Rs in Teaching/Training

3.4.2.1 Background

Animals used for educational purposes are not being used to discover, prove or develop new ideas or techniques, but rather to demonstrate principles which are already well-known or to learn manual skills and techniques. This places a greater level of responsibility to ensure that animals are used only when the knowledge to be gained from the use of an animal exceeds that which might be gained from the use of a replacement alternative. The new CCAC Three Rs microsite provides a section on teaching and the Three Rs, and offers resources which can be used to find suitable replacement alternatives.

3.4.2.2 Perceived needs

There is a need for access to up-to-date resources for use by those responsible for teaching and/or training in Canada. Even if those resources are made available, there is a need to develop criteria that can be used to evaluate the pedagogical merit of non-animal and animal teaching and training methods. As some of the difficulties in implementing the Three Rs relate to the cost of changing, there is a need to develop a strategy for dealing with outlay costs for institutions wanting to move to the use of non-animal teaching methods.

3.4.2.3 Requirements

Regular updates to the CCAC Three Rs microsite are required to ensure that the information is current and suitable for use by Canadian educators and trainers. This includes posting information about teaching/training methods that implement the Three Rs and that are in use in Canadian educational institutions. In addition, workshops on the implementation of Three Rs alternatives in teaching are required to further support the move away from traditional animal labs. These workshops could be explored as a means to address the cost of changing to non-animal labs.

The establishment of a working group is required to prepare a report on how to evaluate the pedagogical merit of a teaching/training method.

3.4.2.4 Outcomes

Providing access to replacement alternatives and a means of assessing the pedagogical merit of the resources will give the necessary tools to educators and trainers to include the most relevant non-animal methods within their teaching/training labs. ACCs will also have the tools to be able to evaluate that this is occurring satisfactorily within their institutions.

3.4.3   Implementation of the Three Rs in Testing

3.4.3.1   Background

Implementation of the Three Rs for regulatory testing is particularly challenging due to a number of factors, including:

- a legal obligation to use animals in testing to ensure that products are safe – this requires adherence to regulatory guidelines and may restrict how test procedures can be modified by ACCs in response to Three Rs-related concerns;

- an experimental goal of producing a toxic effect in the animal, often with associated pain and/or distress – causing harm to the animal is integral to the experimental procedure; and

- limited access to experimental data produced in a commercial setting (for reasons of confidentiality) – this may result in duplication of experiments with animals and exclude useful information from comprehensive assessments of how well animals are functioning as predictive models for humans.

In 2001, the ICLAS and the CCAC hosted the International Symposium on Regulatory Testing and Animal Welfare[8]. As a follow up to this symposium the second and third CCAC fellowships in animal policy development have been offered in the area of regulatory testing and animal welfare. The second fellow carried out a case study to determine the opportunities and challenges in the implementation of the Three Rs in shellfish toxin testing.

3.4.3.2   Perceived needs

A solid understanding for the CCAC is needed on current regulatory requirements; emerging trends in regulatory toxicity testing; and validation status of new methods. Improved engagement with key representatives from the various regulatory agencies is needed to determine where the CCAC can assist in the implementation of the Three Rs.

As the CCAC has already embarked on work related to the implementation of the Three Rs for shellfish toxin testing, sustained efforts are needed to follow up with recommendations emerging from the case study in line with efforts made in other jurisdictions, leading to an international satellite workshop to WC8.

3.4.3.3   Requirements

Identification of, and regular meetings with, regulatory agency representatives are required, particularly with those individuals engaged in international dialogue concerning the implementation of the Three Rs in regulatory testing (e.g., Canada's National Coordinator for the Organization for Economic Cooperation and Development (OECD), Canada's representative on the newly formed International Cooperation on Alternative Test Methods (ICATM) working group, and the Chair of the US National Academies of Science (NAS) working group on Toxicity Testing in the 21st Century).

Workshops with representatives from regulatory agencies are required for such areas as following up with recommendations emerging from case studies and/or encouraging implementation of the NAS report recommendations in Canada.

The CCAC subcommittee on testing has not been active in the past two to three years. Re-engagement of the testing subcommittee is required, in particular to review international test guidelines such as those from the OECD.

The CCAC has not devoted substantial resources to the implementation of the Three Rs in regulatory testing. However, the fellowship program provides an opportunity to have a limited involvement in this area. The work of the CCAC's third fellow in animal policy development in matters relating to

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[8]   http://dels.nas.edu/ilar_n/ilarjournal/43_supp/v43supGriffin.pdf

implementation of the Three Rs in a particular area of regulatory testing is required to continue this engagement. In addition, regular updates to the Table of Alternative Test Methods: Regulatory and Validation Status to be posted on the CCAC Three Rs microsite and active solicitation of input to the table from regulators will be required for the CCAC to maintain current information.

3.4.3.4 Outcomes

A clearer understanding of current regulatory requirements will assist institutions in the evaluation of protocols for testing, and will assist assessment panels during visits to contract research labs and other institutions carrying out animal-based tests for regulatory purposes. Engagement with Canada's regulatory agencies and interface with the international community involved in the development and validation of alternative methods for regulatory testing purposes will ultimately translate to Canada being more engaged in the implementation of the Three Rs in this area.

3.5 Human Resources

3.5.1 Background

The 2008-2011 CIHR/NSERC grant does not include the requested funding for a Three Rs program director. A re-organization within the Secretariat resulted in a combined Guidelines and Three Rs Sector, responsible for implementing the five-year plan for each program. Permanent members of the Guidelines and Three Rs Sector, include:

- guidelines and Three Rs programs director;
- director of guidelines development;
- scientific translator/research assistant;
- research assistant; and
- Three Rs coordinator (part-time contract)

The Sector is also the home of the CCAC fellows in animal policy development, one of whom will be targeted towards the Three Rs Program, and the other towards the Guidelines Program. The CCAC fellowship program received sufficient funding in the 2008-2011 funding cycle to offer two concurrent fellowships.

3.5.2 Perceived needs

Appropriate distribution of human resources is needed to maintain a flourishing Guidelines Program and to build the Three Rs Program, reflecting funding realities from the CIHR/NSERC grant.

3.5.3 Requirements

Staff resources to implement the five-year plan for the Guidelines Program and the Three Rs Program will be stretched; therefore, creative means of tackling some of the planned activities will be required. This will include:

- integration of the fellowships within the two programs, with detailed work plans contributing to the implementation of activities listed in the five-year plan supervised by the guidelines and Three Rs programs director and the director of guidelines development, and overseen by advisory committees composed of members with expertise in the area of study; and
- harnessing student work (undergraduate or graduate directed studies) to provide literature reviews or draft papers as a basis for guidelines documents, implementation tools, discussion papers, etc.

3.5.4   Outcomes

Appropriate management of the human resources available to the Guidelines and the Three Rs Programs will result in the successful implementation of these sections of the five-year plan by the end of March 2014.

3.6   Summary of Plans and Priorities

The plans presented above draw together the key elements for the CCAC's Three Rs Program. As this is a new program, the individual elements will be built as the Three Rs Committee and Secretariat staff work together through the coming five years.

Building the program will require keen attention to the fundamental basis for the CCAC as a whole, involving close links with each of the other programs: Assessment; Education, Training and Communications; and Guidelines. In this respect, development of the theoretical basis of the Three Rs Program will be important, as will the promotion of the Three Rs within the CCAC's constituency.

Keeping the Three Rs microsite up-to-date with periodic addition of new tools and information will ensure that the microsite is a valuable resource for members of Canadian institutions. Use of the information provided should assist investigators in implementing best practices, which will ultimately benefit both the quality of science and the welfare of animals used in science.

The CCAC already has standing as Canada's Centre for the Three Rs within the international community. It will be key to the success of the program to continue to work collaboratively with international colleagues while building the credibility of the program through collaborations with Canadian institutions.

Prioritization of the Three Rs Program projects is critical to providing an appropriate balance for each of the main areas of the use of animals in science: research, teaching, testing and production. Access to a database of recommendations made in assessment reports is required to provide objective information concerning challenges faced by institutions. In addition, the continued gathering and analysis of animal use data, which will be completed in partnership with the Assessment Program, is required to identify animal welfare and ethical issues.

4.   Education, Training and Communications

The primary role of the Education, Training and Communications (ETC) Program is to communicate CCAC guidelines documents and information elements, and develop and implement education and training opportunities for participants in the CCAC Program. This requires close collaboration with the Assessment and Guidelines Programs to transform content provided by these two programs into user-friendly tools for CCAC participants. As the national organization responsible for overseeing the care and ethical use of animals in science, it is essential that the CCAC communicates effectively with the research community, those involved in the care of animals used in science and the general public.

Therefore, the main goals of the ETC Sector are to:

*   develop educational opportunities and resources for animal users and members of institutional ACCs, including new training modules for the National Institutional Animal User Training (NIAUT) Program, workshops and training sessions;

*   encourage support for training opportunities for veterinarians and animal care personnel;

*   enhance public education on the CCAC's role in ethical review and oversight of the use of animals in research, teaching, testing and production of biologicals, in collaboration with other partners; and

*   provide enhanced communications services and tools, including an informative and user-friendly website.

4.1 Education and Training

The CCAC provides crucial information to participants in its programs and the general public by developing education and training tools, and by making comprehensive information available through the CCAC website and workshops.

4.1.1 NIAUT Program

4.1.1.1 Background

The NIAUT Program currently consists of five components: the *CCAC guidelines on: institutional animal user training* (1999); the CCAC *Recommended Syllabus for an Institutional Animal User Training Program* (1999); twelve web-based modules covering the general core topics for all animal users; specific core topics for the Laboratory Animal/Teaching Stream published in 2003; and a list of resource materials to support the development and implementation of the core and non-core topics of an institutional training program by animal care committees.

Animal users can access theoretical training on the ethical use of animals to develop and upgrade their skills through the 12 modules on the CCAC website. This comprehensive and objective source of information on the use of animals for scientific purposes is also available to the public.

4.1.1.2 Perceived needs

Additional web-based training modules are required to address particular types of animal use (such as field studies or agricultural research), which are not covered by the current laboratory animal-based training modules. Existing resource materials produced by the CCAC also need to be regularly reviewed and updated.

The mechanism to prioritize the development of new training modules or the revision of existing training modules needs to be refined.

The format of the modules needs to be modified to make them more user-friendly and increase their use and impact in teaching settings.

4.1.1.3 Requirements

The ETC Committee needs to refine its prioritization matrix to facilitate decision-making regarding the development of new training modules, the review of existing ones, and the preparation of new questions and answers associated with these modules. The prioritization of modules should be based on a scoring system that includes the following criteria: relevance, usefulness, complexity, cost, and the related work of the Guidelines and Assessment Programs. The availability of training materials shortly after publication of a guidelines document should be fostered when possible and appropriate to provide thorough support for CCAC participants.

Members of the ETC Committee need to develop mechanisms to receive comments and annually review feedback on available materials, and oversee the review of existing training modules in light of that feedback. When appropriate training materials already exist, the CCAC will pursue access to, and distribution privileges for, these materials.

The present HTML format of the training modules does not allow flexibility for use as didactic tools for teachers as, for example, a PowerPoint format would. The ETC Committee needs to look into changing the format of training modules to increase their usefulness for teaching.

4.1.1.4 Outcomes

The availability of comprehensive and quality educational material will result in better-trained animal users in support of Refinement of animal use, and improved scientific outcomes of animal-based research.

By providing updated, quality educational material, the CCAC will also foster consistency while providing flexibility in animal user training across institutions.

4.1.2   Training of Members of ACCs

4.1.2.1   Background

As highlighted during the CCAC Forum 2008 by the CCAC's legal adviser, public law norms require consistency of decisions, which in turn indicate the need for training and resource support to ACCs and assessment panel participants. Furthermore, the CCAC's "community-based" structure and volunteer participation make training an important component of the CCAC Program.

4.1.2.2   Perceived needs

At present, there are few national venues that offer education and training opportunities tailored to specific positions represented on institutional ACCs, such as chairs, coordinators, veterinarians, animal care staff and community representatives. Gatherings for ACC members to exchange best practices and discuss emerging issues of common interest are needed to facilitate improvements in institutional animal care and use programs. Documents such as the *CCAC-CFHS Manual for Community Representatives* (2006) are helpful in providing basic information for ACC members, but interactive opportunities are also much needed.

4.1.2.3   Requirements

The ETC Program needs to organize meetings where constituents holding the corresponding positions on institutional ACCs have opportunities to discuss the different issues they face in their respective institutions. For example, role-specific group discussions during CCAC national workshops would provide members of ACCs with such opportunities. The application of distance education tools like webinars could also permit meetings of this nature to occur more frequently at lower costs for participants.

4.1.2.4   Outcomes

Bringing together constituents holding the same positions on institutional ACCs will foster consistency among institutions and enable timely discussions of emerging issues. ACC members will be better equipped to fulfill their role on institutional ACCs, the keystone of the CCAC system.

4.1.3   Distance Education Tools

4.1.3.1   Background

As identified in the report of the CIHR/NSERC Evaluation Committee reviewing the CCAC for the 2008-2011 grant submission and at the CCAC Forum 2008, the use of webinars and/or other distance education tools could make it easier for the CCAC to meet the needs of its constituents and enhance its national presence. This was identified by the granting Agencies as an area requiring urgent attention in the next few years.

4.1.3.2   Perceived needs

Respondents to the CCAC May 2008 strategic planning questionnaire identified the need to develop IT approaches for disseminating information, including novel communication tools, the use of webinars and other e-learning opportunities.

4.1.3.3   Requirements

The CCAC needs to develop a comprehensive IT strategy to enhance its process for external delivery of information. The ETC coordinator, the directors of the other programs, and the ETC Committee need to

evaluate available distance education and communication tools, and make recommendations on their acquisition.

4.1.3.4 Outcomes

The use of distance education tools would increase the impact of regional and national workshops, seminars and training as they would be more accessible to CCAC constituents. These learning opportunities would also be more affordable to participants, increasing their ability to attend a number of events and participate in knowledge dissemination. This interactivity should generate more feedback from the community, and greatly assist the ETC Committee in refining training and educational materials and their timely delivery.

Enhanced IT support would make workshops, training materials, documentation, guidelines documents and policies more readily available, and lead to improvement in the efficiency and consistency of training.

4.1.4   Training of Veterinarians

4.1.4.1   Background

Training of consulting veterinarians and long-term specialized training in laboratory animal medicine were recognized as priorities in the *CCAC Five-Year Plan 2004-2009*, the CCAC's grant submission 2008-2011 and at the CCAC Forum 2008.

In collaboration with the granting Agencies, the CCAC was instrumental in the creation of a short-term training program for consulting veterinarians in 2004 and 2005. The CCAC has also sent letters of support for the proposals submitted to CIHR and NSERC in October 2008 by the colleges of veterinary medicine for specialized training programs.

4.1.4.2   Perceived needs

Short and long-term training requirements of veterinarians in laboratory animal medicine need to be addressed in a sustainable manner. In particular, long-term training is needed to increase the pool of veterinarians properly qualified in laboratory animal medicine and the use of animals in research.

Participants in the CCAC Forum 2008 called for better educational and training programs that create veterinary and technical personnel with skills in science, medicine and animal care.

4.1.4.3   Requirements

The CCAC must continue to assist in the development of training programs that address the continuing education needs of veterinarians employed by research institutions. The CCAC will also work with other sectors and with the colleges of veterinary medicine to meet long-term needs through the development of post-graduate programs in laboratory animal medicine and to raise the profile of laboratory animal medicine in undergraduate professional (DVM) programs.

4.1.4.4   Outcomes

A larger pool of veterinarians qualified in laboratory animal medicine would ensure sufficient and appropriate veterinary care of laboratory animals used in research in Canada, and high quality of the research projects conducted.

4.1.5   CCAC Workshops

4.1.5.1   Background

The CCAC formerly offered regional workshops to its participants, but the workload of the CCAC staff members and the cost of such events have prevented the CCAC from pursuing these education and training opportunities.

Since 2005, the CCAC has organized an annual one-day national workshop. Attendees have confirmed that the CCAC National Workshop provides a unique opportunity to acquire training and up-to-date information on the CCAC's latest policies and guidelines. Attendees also have the opportunity to network with peers from different institutions. This unique opportunity for discourse benefits the research community at large by contributing to the consistency of the work performed by ACC members across the country. It has also become a focal point for small satellite meetings. The program of each national workshop is designed to attract a broad audience, including technicians, scientists, community representatives, researchers, veterinarians, and administrators of institutional animal care programs.

4.1.5.2   Perceived needs

Attendees of the national workshop expressed the need for the CCAC to expand the duration of its workshop and increase the number of workshops offered. Respondents to the questionnaire circulated prior to the CCAC Forum 2008 also stated that they would appreciate the opportunity to attend regional workshops and training sessions.

The granting Agencies' Evaluation Committee Report 2008 identified the need for technology to be used to increase the efficiency and expand the capacity of the workshops.

4.1.5.3   Requirements

The CCAC National Workshop will be extended to a two-day event to permit greater opportunity for CCAC constituents to exchange views with peers from similar research institutions or on issues of common interest. The extended format would also provide more opportunities to acquire training and up-to-date information on the CCAC's latest policies and guidelines documents or other topics of interest.

Starting in May of 2009, CCAC national workshops should be two-day events to provide sufficient time for plenary sessions and breakout group discussion, and to encourage satellite meetings. Furthermore, distance education tools such as webinars should be used to reach out to more CCAC constituents and build on these workshops.

4.1.5.4   Outcomes

The increase in the duration of the national workshop combined with the exploration of other ways to expand its impact in providing education, training and communications through advanced technology (e.g. webinars and other distance education tools) would allow the CCAC to meet the needs of the attendees and others who could not attend. This technology would also allow the offering of targeted workshops that would take the form of a webinar with a subject of interest to CCAC participants in a particular region or to a certain type of institution.

Targeted distance education opportunities will meet the needs of more participants and will result in better and more frequent training and education opportunities in support of increased consistency in the functioning of ACCs across the country.

4.2   Communications

As the national organization responsible for overseeing the care and use of animals in science, it is essential that the CCAC communicate effectively with the research community, those involved in the care of animals used in science and the general public. Furthermore, for the last 40 years, the CCAC has developed an international profile through its work on the care and ethical use of animals in science, as a leader in this important area. Therefore, it is crucial to improve the CCAC's communication system to deliver its mandate effectively at the national level, and support the international recognition of its guidelines documents.

4.2.1 Publications

4.2.1.1 Background

The CCAC produces many official publications, including guidelines documents, policies, training modules, the *CCAC Annual Report,* the *CCAC Survey of Animal Use* and the CCAC newsletter *RESOURCE* (approximately 3500 copies are distributed in print while an electronic version is made available on the website). The CCAC also communicates with the public through the website and also by replying to direct requests for information sent to the members of the Secretariat by the public.

4.2.1.2 Perceived needs

The continued publication of *RESOURCE* and all other official publications is needed as it allows for the dissemination of in-depth, specialized information.

Participants in the CCAC Forum 2008 called for more education and training materials. Members of the ETC Committee have also identified the need to develop appropriate material for primary and secondary school audiences to educate the future generation about the CCAC's mandate and create greater public awareness of the CCAC's role in the years to come.

4.2.1.3 Requirements

The ETC Program needs to continue to produce effective, traditional communication tools, such as *RESOURCE*, brochures and posters. Some educational material should be produced in a collaborative project with the Canadian Federation of Humane Societies and the Youth Science Foundation, as suggested by members of the ETC Committee, with the goal of creating and/or compiling appropriate information on the ethical care and use of animals in primary and secondary schools, specifically tailored for teachers, students and school boards.

4.2.1.4 Outcomes

The CCAC's communication strategy will be more thorough, as it will involve regular contact with ACC members and will work toward educating the public at a younger age.

4.2.2 Publication Procedure

4.2.2.1 Background

The CCAC produces several official publications every year, including guidelines documents, policies, training modules, *RESOURCE* and the *CCAC Annual Report*. Since 2005, all publications have been formatted in-house and made available in both official languages simultaneously. This practice will be continued.

Each time the CCAC publishes a document, an electronic info-capsule is sent to its participants, informing them of the new publication. The great number of capsules being sent every year potentially results in the desensitization of the target audience.

4.2.2.2 Perceived needs

As highlighted by participants in the CCAC Forum 2008, communication tools, procedures, and mechanisms need to be optimized to ensure good and appropriate delivery of the CCAC's education and training information.

Granting Agencies and regulators in some Canadian provinces need to be quickly made aware of the most recent CCAC publications that are referenced in the regulations to their respective legislation.

4.2.2.3   Requirements

The ETC Program, in collaboration with other CCAC programs, should develop a consistent publication procedure. Such a procedure would include the publication of official CCAC documents such as guidelines documents, policies, training modules, and *RESOURCE* at fixed dates. A new section should be created on the CCAC website, where the new publications are advertised and the next publication date is announced. Participants in the CCAC Program would then have to consult the website in order to download the publications. The frequency of publication will need to be determined in consultation with other programs.

4.2.2.4   Outcomes

A more consistent publication procedure, allowing CCAC constituents to expect publications at fixed dates, would improve the efficiency of the CCAC's communication system by increasing the number of visitors to the website at predictable dates and decreasing the number of capsules sent by the CCAC.

4.2.3   Website redesign

4.2.3.1   Background

The website is an essential service and plays a vital role in fulfilling the organization's mandate, building the CCAC's presence online and ensuring that CCAC policies and guidelines documents are widely available. The CCAC's website is a resource for members of ACCs and specialists working with animals. It is also extensively used by the international community, including research teams across the world. The number of website visits (approximately 1000/day) and the diverse countries of origin of the visitors reveal the importance of the CCAC as a trusted resource. The CCAC's website is an essential component of its external communication strategy, and acts as the CCAC's window to the world.

4.2.3.2   Perceived needs

The CCAC website currently lacks user-friendliness and organization, making it difficult for a visitor to easily find specific information or documentation. Renewing the design and look of the CCAC's website in order to meet the expectations of visitors and successfully deliver the CCAC's message, while including comprehensive educational resources on the use and care of animals used in science, is a need that was identified by participants in the CCAC Forum 2008.

4.2.3.3   Requirements

The first step required is the consultation with the ETC Committee, the CCAC staff and the CCAC Board of Directors for feedback on the design of the website. Based on this information, the ETC coordinator needs to work with the webmaster to redesign the website.

4.2.3.4   Outcomes

Making more efficient use of information technology will result in an enhanced capacity for the CCAC to deliver its mandate and to achieve its education, training and communications objectives, both at the national and international levels.

4.2.4   Communication Strategy

4.2.4.1   Background

The ETC Program is responsible for communications with the constituents from academic, government and private sectors, institutional ACCs, researchers, granting Agencies and the public.

4.2.4.2   Perceived needs

Participants in the CCAC Forum 2008 called for an integrated communication strategy which would ensure tailored communications to targeted audiences.

The need to align the CCAC's name with its mission for more effective promotion of its products and public image should also be evaluated as part of the communication strategy.

Ways of better communicating with researchers need to be evaluated, especially in the context of the new Three Rs Program. Contacts with communication departments of the granting Agencies need to be established in order to identify efficient means to communicate with researchers across the country.

4.2.4.3   Requirements

The CCAC website should be redesigned to permit the creation of specific sections targeted to different audiences, types of constituents and sectors. Each section should encompass all relevant information that is useful and appropriate to the targeted group.

A marketing specialist should be hired to determine if the CCAC's name is correctly and effectively aligned with its mission, as well as any potential impacts of modification of the name.

To ensure official and tailored communication with individual researchers across the country, the CCAC should co-opt the collaboration of the granting Agencies to publish important announcements on their websites and in their electronic newsletters.

4.2.4.4   Outcomes

An integrated communication strategy would:

- result in greater visibility of the CCAC's work and mandate among researchers;
- ensure tailored communications to targeted audiences;
- permit a better understanding of the CCAC's mandate by the public;
- increase the impact of CCAC's products such as guidelines documents, policies, training modules and workshops; and
- enhance CCAC's visibility and public image.

4.3   Summary of Plans and Priorities

The development of targeted educational opportunities and resources for animal users, veterinarians, members of institutional ACCs, and the scientific community, including new training modules for the NIAUT Program, workshops and training sessions will be continued.

Long-distance education tools will be used to communicate with, and more efficiently educate, animal users, veterinarians, members of institutional ACCs, and the scientific community.

Enhanced communication services, methods, and tools (including a well-organized, user-friendly website and a consistent and efficient publication procedure), tailored to targeted audiences, will be provided as part of an integrated communications strategy involving CCAC stakeholders and its institutional and individual constituents.

5.   Planning and Finance

The main responsibilities of the Planning and Finance Committee (PFC) are:

- to develop and recommend to Council long-range goals and objectives for the CCAC;
- to assist in the development of action plans designed to meet the long-term objectives approved by Council;

- to review, evaluate and make recommendations on the effectiveness of the CCAC's distributed management governance system;
- to provide oversight on expenditures;
- to conduct long-term financial planning to ensure the financial viability of the CCAC and its programs; and
- to recommend to Council changes to the list of responsibilities for the committee.

5.1 Planning

5.1.1 Developing and Monitoring of Long-range Goals Through a Sound Planning Process

5.1.1.1 Background

The CCAC's first integrated strategic planning process involved consultation with 54 selected constituents at the March 1998 *CCAC Forum – Charting the Future* and a questionnaire prepared by a consultant which the participants responded to prior to the Forum. Action plans were subsequently developed by the standing committees based on suggestions made at the Forum, and associated budgets were submitted to the Finance Committee. Prioritization of the proposed projects was conducted by the Board of Directors. This process led to the development of a five-year vision. The *CCAC Five-Year Plan 2004-2009* was later developed through a similar process, although there was no prior consultation with constituents. In both cases, the universal implementation of the CCAC Program and client satisfaction were central themes.

Ten years later, the CCAC organized its second long-term planning forum, *CCAC Forum 2008 – Building on Strength*, through a refined and transparent process involving:

- 13 open letters sent to the granting Agencies by academic institutions as part of the review of the CCAC 2008-2011 grant submission; and
- 184 anonymous responses from individual constituents to a questionnaire made broadly accessible five months before the Forum with the assistance of the granting Agencies.

Issues identified from the letters and responses to the questionnaire formed the basis of a 'brain-storming' exercise by the Forum attendees to explore possible courses of action for the CCAC. The attendees were selected for their active and sustained participation in CCAC programs.

5.1.1.2 Perceived Needs

A comprehensive and inclusive planning process involving the CCAC's individual and institutional constituents needs to be undertaken on a regular basis.

5.1.1.3 Requirements

Given the rapidly changing nature of science and the related ethical considerations of new approaches and discoveries, a forum with an accompanying comprehensive consultation process (including a questionnaire and open letters to the granting Agencies) should be held every five years. For maximum benefit, this should be synchronized with every second triennial grant submission of the CCAC to the CIHR and NSERC.

5.1.1.4 Outcomes

By eliciting optimal engagement of the CCAC's individual and institutional constituents, the CCAC will obtain an increased awareness of their views, and be in a better position to validate any new initiatives. As a result, the CCAC Program will resonate well with constituents across the country in support of improved quality of science and enhanced animal welfare.

5.1.2 Action Plans to Meet Long-term Objectives

5.1.2.1 Universal Implementation of the CCAC Program

5.1.2.1.1 Background

The September 1998 legal opinion of Osler, Hoskin & Harcourt, Barristers and Solicitors to CCAC, *Legislative Jurisdiction Over Animals Used in Research, Teaching and Testing*, concluded that federal legislation enabling the CCAC's mandate was unlikely to be available, and that even if legislation could be enacted and was not challenged, it would not be able to satisfy the broader aims of the peer review system of the CCAC. This legal opinion also recommended a multifaceted approach involving: the creation and promotion of a publicly recognized CCAC standard; and the pursuit of existing provincial legislation and regulations, as well as relevant policies and programs linked to federal spending power. These efforts were recommended in support of animal-based research, with the aim of having CCAC policies and guidelines documents recognized as national standards. This multifaceted approach was adopted by Council in September 1998, with action plans carefully developed, successfully implemented and closely monitored under the authority of the Planning and Priorities Committee (now the PFC).

The CCAC received a Certificate of Registration for the trade-mark GAP – Good Animal Practice® from the Canadian Intellectual Property Office of Industry Canada, in relation to CCAC's assessment services, effective August 15, 2000. This certification identifies "*services which meet a standard set by a governing organization*". The CCAC Certificate of GAP – Good Animal Practice® is referenced as a mandatory requirement in: the *Memorandum of Understanding* signed between the federal granting Agencies (CIHR, NSERC and SSHRC) and all institutions receiving their funds for animal-based research since 2002; and Public Works and Government Services Canada *Standards Acquisition Clauses and Conditions* since 2006, the latter ensuring compliance by most third parties receiving funding for animal-based research from federal departments and agencies. Several provincial funders of animal-based work also require CCAC certification for animal-based science. There are several other important reasons for which institutions seek CCAC certification:

- the Canadian Food Inspection Agency (CFIA) requires the CCAC certificate for institutions importing several types of animals into Canada for scientific purposes;
- the US Food & Drug Administration requires companies making new drug applications (NDAs) and conducting related animal-based work in Canada to be CCAC-certified;
- several charities that fund animal-based research require CCAC certification;
- the Canadian Veterinary Medical Association (CVMA) requires that colleges seeking CVMA accreditation for animal health/veterinary technician programs be CCAC-certified; and
- more and more scientific journals are requiring that animal-based studies be conducted according to appropriate standards, which can be demonstrated through CCAC certification.

The CCAC certificate is also recognized at the international level by the Office of Laboratory Animal Welfare of the US National Institutes of Health for the purpose of Public Health Services funding to Canadian institutions, and by the American College of Laboratory Animal Medicine (ACLAM) for the purposes of ACLAM accredited programs undertaken by Canadian institutions, among others. In addition, the *CCAC guidelines on: choosing an appropriate endpoint in experiments using animals for research, teaching and testing* (1998) and the *CCAC guidelines on: the care and use of wildlife* (2005) have received international recognition by the International Council for Laboratory Animal Science (ICLAS) and by the UK Royal Society for the Prevention of Cruelty to Animals, respectively.

CCAC assessment services are based on CCAC standards, namely its guidelines, policies and associated documents. Those standards are now referenced in regulations to relevant legislations in six of the seven provinces having adopted such legislation. Advances at these national and international levels led the CCAC legal advisors to conclude in their 2004 and 2008 legal opinions that, given its mix of public purpose and reference made by relevant regulatory and non-regulatory authorities to its guidelines documents and policies, the CCAC is best characterized as a "quasi-regulatory body".

5.1.2.1.2 Perceived Needs

The multifaceted strategy to achieve national and international recognition of CCAC standards must be sustained, with a special focus on all funders of direct costs of scientific activities involving the use of animals.

5.1.2.1.3 Requirements

Legislative initiatives must be continued with the view to maintaining or increasing the scope of reference to CCAC guidelines documents and policies in current regulations, and developing tailored strategies to approach provinces that have not adopted legislation in the matter.

While several federal science-based departments and agencies (SBDAs), such as Health Canada, Fisheries and Oceans Canada, Environment Canada, the Canadian Food Inspection Agency, and the National Research Council of Canada, make reference to and use CCAC guidelines documents and policies, federal SBDAs currently relate to CCAC on the basis of informal goodwill for their own use of animals for scientific purposes and in delivering regulatory duties involving the ethical use of animals by third parties. Discussions on a Memorandum of Understanding (MOU) between the CCAC and the federal SBDAs, initiated in 2005, should be catalyzed and monitored closely to maintain core elements while allowing flexibility to tailor the MOU to the specific mandate of each organization.

The CCAC should approach the Canada Foundation for Innovation, Genome Canada and other relevant federal and provincial public funders, as well as other funders of direct and indirect costs of animal-based research to promote mandatory reference to the CCAC Certificate of GAP-Good Animal Practice® for eligibility to their funds. The mandatory requirement for work to be carried out in a CCAC-certified institution should be a necessary condition for eligibility to receive funding from foundations providing grants for animal-based scientific activities.

Other groups that fund, approve, accredit or publish animal-based science will be approached to encourage them to use the CCAC certificate as evidence of sound standards of animal care and use in science.

The CCAC should sustain efforts to have CCAC guidelines documents and policies used and referenced at the international level, and to gain access to relevant guidelines to assist the CCAC in developing its own.

5.1.2.1.4 Outcomes

Expansion of the CCAC's recognition provincially, nationally and internationally, firmly establishes it as the body overseeing most animals used for scientific purposes in Canada. Increased requirements for adherence to CCAC standards by legislators and research funding agencies would reassure the Canadian public that <u>all</u> publicly and privately funded animal use for scientific purposes complies with the CCAC's guidelines documents and policies on the care and ethical use of animals in science.

An MOU-based relationship between the CCAC and federal SBDAs would ensure that departmental units are provided with appropriate resources to meet CCAC guidelines documents and policies. Resources should include crucial items such as the training of animal users, and animal facility maintenance and management. A formal agreement between regulatory departments/agencies and the CCAC would also provide a firmer ground for using CCAC guidelines documents and policies in the responsible delivery of their regulatory duties to third parties, when appropriate.

5.1.2.2 Communications with Granting and Regulatory Agencies

5.1.2.2.1 Background

The March 2008 report of the NSERC-CIHR Evaluation Committee for the CCAC grant submission 2008-2011 commended the management structure of the CCAC for its responsive action to emerging issues of concern for the animal-based community.

A case in point used by the Evaluation Committee was the timely input provided by the CCAC into, and facilitation of, the development of revised regulations for Environment Canada's Notification of New Substances Regulations for Organisms other than Micro-organisms. This was conducted in relation to the development of the *CCAC guidelines on: genetically-engineered animals*. The NSERC-CIHR Evaluation Committee invited the CCAC to consider formalizing relationships with Canadian regulatory agencies to serve as the "go to" point for legislation relating to the mandate of the CCAC.

Between 2004 and 2009, there have been excellent interactions between the CCAC (including all Secretariat sectors) and the federal granting Agencies, to ensure that the work undertaken by all parties is well understood, and that there are no misunderstandings or work carried out at cross-purposes.

5.1.2.2.2 Perceived Needs

The CCAC management, in collaboration with relevant Secretariat sectors, needs to continue to hold regular meetings with federal granting and regulatory agencies to serve CCAC constituents well.

5.1.2.2.3 Requirements

Key lines of communication and regular structured meetings with the relevant agencies are required.

5.1.2.2.4 Outcomes

Enhanced communications with the granting and regulatory agencies will improve services to constituents. The visibility and credibility of the CCAC will be heightened through the development of fora that will facilitate regular interface with key players and prevent the organizations from working at cross-purposes.

5.1.3 Effectiveness of the Distributed Management System

5.1.3.1 Review of the CCAC Governance System

"Governance refers to the processes and structures used to direct and manage an organization's operations, and activities. Good Governance systems are designed to help organizations focus on the activities that contribute most to their overall objectives, use their resources effectively, and ensure that they are managed in the best interests of their stakeholders."

– Governance of Not-for-Profit Organizations, Deloitte & Touche LLP, 2004

5.1.3.1.1 Background

In 1995, the CCAC adopted a distributed, parallel management structure to address the twin problems of establishing mechanisms for the parallel development of policy and ensuring that representatives of member organizations were able to accomplish their legal responsibilities. 'Distributed' meant the establishment of separate groups, each responsible for a subset of the duties of the CCAC. 'Parallel' meant the independent and interactive operation of these groups. This distributed management system is overseen by the Board of Directors, which includes the chair of each standing committee, the Executive Committee and the Executive Director.

5.1.3.1.2 Perceived Needs

As a publicly accountable organization, the CCAC faces numerous critical challenges in responding to the growing expectations of its stakeholders and its constituents, within an increasingly complex operating environment. The CCAC must review and adapt the key elements of its governance system to address those realities.

Although the Board of Directors, Council, management, staff and volunteers all have a part to play in the governance system, the Board of Directors' stewardship role is clearly central to the system. The Board of Directors is a subset of the Council and includes a majority of members who are appointed upon being elected by members of their respective standing committees. This unusual structure, coupled with the

decentralization of decision making towards the standing committees over the years as their workload increased, and the lack of clear definition of those decisions made by standing committees that require the prior approval of the Board of Directors, has resulted in the need to review the CCAC's governance system.

While they have indeed operated independently and effectively, the original intention of having the committees interact has not been actively carried out: little interaction has taken place between the standing committees other than a small number of joint committee meetings on issues of major importance that have emerged sporadically since 2004.

The Education, Training and Communications Committee is the only standing committee with the responsibility of working with the Assessment and the Guidelines Committees stated in the CCAC Standing Rules. A similar need to work in collaboration with the Guidelines Committee has been expressed by the Chair of the recently created standing committee on the Three Rs.

5.1.3.1.3 Requirements

Beyond the minimum legal obligations defined in the CCAC By-Laws, the Board of Directors needs to review and define a process to prioritize decisions relating to the activities of the standing committees requiring in depth discussion and prior approval.

The Standing Rules require updating to clarify and formalize the ongoing horizontal communications on relevant deliverables as a responsibility of all standing committees.

5.1.3.1.4 Outcomes

The development of a clear process for the Board of Directors to prioritize its decisions relating to the proposed activities of the standing committees will ensure that no expectation gaps exist among the Board of Directors, the standing committees, management and other stakeholders and that resources are optimally used.

Better alignment of the responsibilities of the standing committees with the current needs of the four programs should result in more efficient use of resources and more effective knowledge transfer between programs, in support of the optimal functioning of a more coherent oversight system.

5.1.3.2   Structure and Size of Council

5.1.3.2.1 Background

The publication of the September 2000 *Report of the Planning and Priorities Committee on the Structure and Size of the CCAC Council* led to the decision by Council to cap the size of Council at 28 representatives from member organizations, and to create three new limited term (three years) seats to provide the flexibility needed to include new expertise on Council, as needed. The Planning and Priorities Committee (now the Planning and Finance Committee) developed a *Process for Identifying and Appointing Limited Term Members to CCAC Council*.

5.1.3.2.2 Perceived Needs

Students often play an important role in animal use in academic institutions. The CCAC has been requiring that academic institutions include student representation on their ACCs through the *CCAC policy statement on: terms of reference for animal care committees* since 1997.

The NSERC-CIHR Evaluation Committee 2008 recommended that the CCAC strive to broaden student involvement in animal care and use oversight in science, and include student representation on the CCAC Council.

5.1.3.2.3 Requirements

An appropriate mechanism is required to include research trainees (students) within the CCAC's formally recognized constituency.

5.1.3.2.4 Outcomes

Active and visible participation of student representatives on Council would enhance their perspective; foster student contributions to the CCAC programs; and help the CCAC better understand cultural changes in attitudes about the use of animals, and begin feedback of fact-based information to the next generation of scientists about the safeguards associated with animal-based science.

5.1.3.3 Recognition of CCAC Volunteers

5.1.3.3.1 Background

As reiterated below in the Report of the NSERC-CIHR Evaluation Committee 2008, the CCAC relies heavily on over 2,000 volunteers to perform its work in assessment, guidelines development and implementation, and education for those using animals for scientific purposes.

> "The genius of this [CCAC oversight] system involves coordination by a trusted Secretariat guided by a Council of stakeholders in harnessing, without honorarium, the wealth of Canadian expertise for the common purpose enunciated in the mission statement."

> *Report of the NSERC-CIHR Evaluation Committee Reviewing the CCAC*,
> March 31, 2008

Recognizing that the degree to which CCAC Council is able to meet its goals depends on the quality and commitment of its volunteers, the *CCAC Volunteer Procedures* have been developed and implemented since 2002 with the intent to: guide Member Organizations in nominating representatives; provide an indication of the expectations that the CCAC has of serving representatives; and recognize the contributions of volunteers who have served on CCAC Council.

5.1.3.3.2 Perceived Needs

There is a need to recognize the essential contributions of a large number of volunteers serving on assessment panels, on guidelines development subcommittees and on all other ad hoc committees assisting the CCAC in delivering its mandate through its four programs.

5.1.3.3.3 Requirements

A database of volunteers involved with all CCAC programs should be developed and maintained. Procedures to recognize volunteers should be developed by the standing committees for each program, in collaboration with the Secretariat.

5.1.3.3.4 Outcomes

The development of a CCAC volunteer database could be used to identify individuals for recognition during specific assessment visits or public events, such as the CCAC annual national workshop, presentations by CCAC staff to scientific societies, and others. These individuals would enjoy the recognition of their local or national peers through their name being mentioned in the context of the broad interface of the CCAC with its constituents.

5.2   Finance

5.2.1   Oversight on Expenditures

5.2.1.1   Background

Semi-annual financial reports are produced for each program, namely: Assessment; Guidelines; the Three Rs; and Education, Training and Communications. These reports are reviewed by the PFC. Each standing committee also receives its financial report to review.

The PFC activities are part of the CCAC mid-year and year-end performance reports that are circulated to members of Council for reporting purposes. The two semi-annual reports are then merged into the CCAC Annual Report which is published on the CCAC website in both official languages, in fulfillment of the CCAC's accountability to the Canadian public.

5.2.1.2   Perceived Needs

The financial reporting process needs to be reviewed periodically for its efficiency.

5.2.1.3   Requirements

The PFC should consult all the individuals involved in the financial reporting, with the view to improving the process.

5.2.1.4   Outcomes

Informative financial reports that are developed through a streamlined process will be useful for planning purposes and provide accountability.

5.2.2   Long-term Financial Planning to Ensure Financial Viability

5.2.2.1   Background

At the June 10, 2005 meeting of the CCAC Board of Directors, it was agreed that a business model would be developed to look at CCAC clients and services, the cost of performing services, and the potential for growth. The consulting firm Deloitte & Touche was commissioned to produce the *CCAC Limited Business Review*, which was submitted to the CCAC on February 16, 2006.

The Finance Committee studied the report and submitted their recommendations to the Board of Directors in March 2006. Based on this work, annual cost recovery fees for non-academic participants were adjusted for 2007-2008. On April 1, 2007, the CCAC also implemented a fee schedule for services not covered under the CIHR and NSERC grant for the academic institutions, and for services not covered under the fee for non-academic institutions.

The report from the NSERC-CIHR Evaluation Committee 2008 also suggested that the CCAC investigate the possibility of obtaining complementary sources of funding, such as the Canada Foundation for Innovation and Genome Canada, without an impact on the current grants received from the granting Agencies.

5.2.2.2   Perceived Needs

The PFC needs to continue to implement the recommendations contained in the business model, mainly the gradual increase in fees for the non-academic sector, without creating a financial burden on these institutions. Implementation of charges to institutions for services not covered, i.e. review of plans, conduct of special visits, etc., also needs to be continued.

5.2.2.3   Requirements

Fees for non-academic institutions and fees for services need to be revised on a yearly basis, in consultation with the PFC and the Assessment Committee. The CCAC must also pursue discussions with the Canada Foundation for Innovation and Genome Canada with the view to investigate the possibility of receiving funding in relation to the workload generated for the CCAC as a result of the activities they fund.

5.2.2.4   Outcomes

Appropriate adjustments in the fee structure will assist in providing the necessary funds to support all the programs of the CCAC.

5.2.3 Changes to the Finance Committee

5.2.3.1 Background

With Council membership capped at 28 representatives since 2000, the continuing challenge to recruit representatives interested in joining the FC was exacerbated by the March 9, 2008 decision of Council to create a sixth standing committee, namely the Standing Committee on the Three Rs. As a result, the FC and the Planning and Priorities Committee will be joined to form the Planning and Finance Committee, in early 2009.

5.2.3.2 Perceived Needs

The PFC needs to ensure that the financial aspects continue to be given the efficient scrutiny they currently receive.

5.2.3.3 Requirements

The newly merged PFC requires strategic recruitment of representatives of member organizations with the proper financial skill sets.

5.2.3.4 Outcomes

The formation of a solid PFC will maintain all 'reality checks' to ensure accountability, while providing a comprehensive awareness of CCAC initiatives, as the same individuals will be responsible for reviewing both planning and financial aspects of those activities.

5.3 Summary of Plans and Priorities

5.3.1 Planning

Given the rapidly changing nature of science and related ethical considerations of new approaches and discoveries, future forums and accompanying comprehensive consultation processes should be held every five years and synchronized with every second triennial grant submission to the CIHR and NSERC.

The multifaceted strategy to achieve national and international recognition of CCAC standards must be sustained with a special focus on all funders of direct and indirect costs of scientific activities involving the use of animals.

The CCAC Board of Directors needs to define a process to prioritize decisions relating to the proposed activities of the standing committees requiring in depth discussion and prior approval, to ensure an efficient use of resources, and effective knowledge transfer between programs, and the optimal functioning of CCAC's governance in support of a coherent oversight system. The concomitant review of the Standing Rules will clarify the responsibilities of specific standing committees.

The identification of an appropriate mechanism to include research trainees (students) within the CCAC's formally recognized constituency will facilitate greater exchange of information with future scientists.

The development of a database of volunteers involved with all CCAC programs and the elaboration and implementation of procedures to recognize their contributions will strengthen the relationship between the CCAC and the many volunteers on which its programs depend.

5.3.2 Finance

The financial aspects of the programs will continue to be given efficient scrutiny by the new Planning and Finance Committee.

The financial reporting process implemented since 1999 will be continued to ensure accountability to CCAC stakeholders and the general public.

The implementation of recommendations contained in the business model and discussions with the Canada Foundation for Innovation and Genome Canada regarding complementary funding will be pursued to ensure the long-term financial viability of the CCAC.