Canadian Pharmaceutical Bar-Coding and Database Standards

(Phases II and III)

September 15, 2008

Joint Project Proposal

Institute for Safe Medication Practices Canada
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A Key Partner in the Canadian Medication Incident Reporting and Prevention System
Un partenaire clé du Système canadien de déclaration et de prévention des incidents médicamenteux

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency committed to the advancement of medication safety in all health care settings. ISMP Canada works collaboratively with the health care community, regulatory agencies and policy makers, provincial, national, and international patient safety organizations, the pharmaceutical industry, and the public to promote safe medication practices.

ISMP Canada's mandate includes collecting, reviewing, and analyzing medication incident and near-miss reports, identifying contributing factors and causes, and making recommendations for the prevention of harmful medication incidents.

The Canadian Patient Safety Institute (CPSI) is a not-for-profit corporation, operating collaboratively with health professionals and organizations, regulatory bodies and governments to build and advance a safer healthcare system for Canada. CPSI performs a coordinating and leadership role across health sectors and systems, promotes leading practices and raises awareness about patient safety by working in collaboration with partners, patients, their families and the general public. For more information, visit www.patientsafetyinstitute.ca.

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Background

The Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI) are pleased to present a proposal for a two-year project which will see the collaborative development of national bar-code standards for commercially-marketed pharmaceutical products in Canada. The joint project is rooted in ISMP Canada's established expertise in medication system analysis and design, the development of pre-emptive safety strategies for the avoidance of serious medication errors, and CPSI's leadership in patient safety initiatives in Canada.

Bar-coding is established outside of the healthcare industry as a superior method of identifying and transferring products in a safe and efficient manner. One does not need to look far to see well-established bar-coding systems in use in retail business systems, from products verification, to document control, to package delivery assurance systems. The accuracy and validity of bar-coding methods are well-proven in thousands of applications and over several decades. Its introduction to healthcare however is just beginning.

Healthcare is now moving into new environments wherein positive identification of patients, lab specimens and other medical products are performed by hand-held equipment, rather than verification by a sometimes fatigued and busy human. Where local testing of bar-coding has been tried in healthcare, it has clearly demonstrated a significant reduction in "Wrong Patient" or "Wrong item" errors, in the neighbourhood of 85% fewer incidents. (Refer to Appendix A for additional information, and references).

Unfortunately, currently, there are no formal Canadian national standards for the use of bar-code identification on medication products. Hence, manufacturers must themselves develop product identification strategies, with codes which are potentially only partially useable "downstream" in health systems. In a Canadian commercial marketplace of 30,000 drug products, no organization has yet undertaken a coordinated and unified approach to bar-code identification. In January 2008, ISMP and CPSI co-hosted a national stakeholder roundtable discussion on bar-coding in Canada. The group reached consensus on the need for a national bar-coding strategy. (Appendix A)

This is a unique and important opportunity for all stakeholders of the Canadian medication system, from manufacturer to frontline healthcare worker, to collaborate on a comprehensive strategy for bar-coding standards. By cooperatively developing agreement on symbologies and product identification codes, the health care system stands to benefit from a series of patient safety improvements, such as dispensing, compounding and dose administration checks, and other efficiencies along the medication supply chain.

Funding Requirements

A number of project funding sponsors are being sought from not-for-profit and for-profit organizations based on the varied collective responsibilities of all levels of healthcare.

We estimate the development and communication of Canadian standards can be achieved within a two-year window, and will require a project budget of $250,000 to $300,000. The two year financial requirements are outlined in the budget, appended to this proposal.

Funders of this major initiative will constitute a strategic sponsor alliance. They will be formally recognized for their foundational contribution to patient safety through this sentinel Canadian project.

A funding commitment of $20,000 from several sponsors we hope will support the creation and communication of standards, and, hopefully, allow us to consider post-implementation surveys of compliance and effectiveness.

ISMP Canada Expertise

ISMP Canada is an independent Canadian not-for-profit agency established in 1999 for the collection and analysis of medication incident reports and the development of recommendations for the enhancement of patient safety. The Canadian Medication Incident Reporting and Prevention System (CMIRPS) (refer to http://www.ismp-canada.org/cmirps.htm) is currently our sole national resource for medication incident data collection, analysis and reporting.

Since its inception, ISMP Canada has demonstrated expertise in the collection and analysis of medication incident data. Products and services developed by, or in collaboration with, ISMP Canada include:

- The *Canadian Root Cause Analysis Framework*, a standardized approach to the retrospective analysis of critical incidents and near-miss events in health care that makes it possible to determine what happened, why it happened and what can be done to reduce the likelihood of a recurrence (refer to http://www.ismp-canada.org/rca.htm);
- *Failure Mode and Effects Analysis* (FMEA), a proactive, systematic tool that allows teams to consider ways that a medication safety process might fail, why it might fail, the effects of the failure and how the process can be made safer (refer to http://www.ismp-canada.org/fmea.htm);
- *Analyze-Err*, a software documentation tool that enables institutions to track and analyze medication errors (refer to http://www.ismp-canada.org/analyze-err.htm);
- *Medication Safety Self-Assessment* tools tailored to meet the needs of hospitals, long-term care facilities, complex continuing care and rehabilitation facilities and community/ambulatory pharmacies and recommended for implementation as a standard by the Canadian Council of Health Services Accreditation (refer to http://www.ismp-canada.org/mssa.htm);
- *Ontario Medication Safety Support Service*, a joint initiative with the Ontario Ministry of Health and Long-term Care and the Ontario Hospital Association, which assists Ontario hospitals to implement strategies and safeguards for the prevention of patient injury (refer to http://www.ismp-canada.org/msss.htm); and
- Timely, effective, accessible communication of findings and recommendations through its *Safety Bulletins* (refer to http://www.ismp-canada.org/ISMPCSafetyBulletins.htm), position statements, publications in scientific and industry journals, and presentations.

ISMP Canada acts as the intervention lead for medication reconciliation in the Safer Healthcare Now! Campaign and supports over 200 frontline teams as they implement medication reconciliation (refer to http://www.ismp-canada.org/medicationreconciliation.htm). And, ISMP Canada is working on several national High Risk medication strategies, through separate projects.

Expertise has been developed in providing consultation on medication systems in health service organizations and other health care settings. An example of a publicly available Root Cause Analysis Consult is the Fluorouracil Incident Root Cause Analysis Report (available from:*http://www.cancerboard.ab.ca/NR/rdonlyres/2FB61BC4-70CA-4E58-BDE1-1E54797BA47D/0/FluorouracilIncidentMay2007.pdf*) [1]

ISMP Canada is a contributing safety organization to national accrediting bodies, and is affiliated with a broad range of Canadian and international safety organizations. The organization is also engaged by provincial and regional healthcare quality and safety committees to provide input into the assessment and improvement of medication use systems.

CPSI Expertise

The Canadian Patient Safety Institute (CPSI) has a mission and mandate to better understand patient safety occurrences and develop strategies to assist healthcare institutions, legislative bodies, providers, patients and families in preventing adverse events. Providing national leadership and advocacy for increased patient safety within the health system, it is the goal of CPSI to champion change and with the many committed health care providers and organizations demonstrate together how all can improve patient safety in Canada

The strategic direction for CPSI from 2008-2013 is focused on four key areas: education; research; tools and resources; and interventions and programs. These areas will be supported through six core processes allowing CPSI to build support, affect change, communicate and evaluate its progress.

Areas of Focus

Education

To prevent occurrences from the outset, CPSI will work with education stakeholders, professional associations and providers to develop relevant curriculum for post-secondary institutions, provide patient safety training and certification programs, and provide simulation training as a core element for health professionals and providers. We will also promote the development of “communities of practice” regarding patient safety practices to expand knowledge and resources.

Research

Research is the cornerstone of advancing the science and practice of patient safety initiatives and programs. By consolidating and analyzing past, present and current knowledge, we will be able to fully determine the scope and opportunities that exist for patient safety within our health system. CPSI will also research trends, gaps and initiatives from other countries that impact patient safety. Based on research outcomes, we will work with all levels of government and decision-makers to incorporate this knowledge into healthcare policies and procedures throughout Canada.

Tools and Resources

CPSI, in partnership with leading experts in healthcare and other relevant fields, will create tools and resources that can be effectively applied in clinical settings.
The accurate reporting and tracking of patient safety incidents is essential to determine the scope of the issue and the impact that programs are having on patient outcomes. To accomplish this goal, CPSI will promote the use of pan-Canadian reporting systems that will provide consistent and accurate information regarding the occurrence, type and frequency of adverse events among patients/clients.

Interventions and Programs

Healthcare professionals, providers and their associations are dedicated to the delivery of safe, evidence-based care. For individual professionals, providers and organizations, interventions (local programs that have a small to medium scope) and programs (large activities that facilitate action on patient safety) provide opportunities to expedite current and relevant evidence into action across the health continuum. CPSI strategic priorities will be supported through *six core processes* that outline how we will approach our four areas of focus and conduct our activities: understand the Issues; engage stakeholders; build capacity; communicate; measure and evaluate; and influence change.

Project Objectives

The goal of both ISMP Canada and CPSI, and indeed all healthcare partners, is to reduce all avoidable medication patient harm through the development of safer health systems.

The two-year objectives of the current bar-coding initiative are;

- To identify the key medication stakeholders within the Canadian pharmaceutical industry and the public and retail systems.
- To reach agreement on the technical standards for a national bar-code identification system, including both fixed and variable data elements.
- To promote the development and use of a Canadian pharmaceutical database for the housing of pharmaceutical information related to individual current and future Canadian pharmaceutical products.
- To contract with an international bar-code standards organization, for both assignment of trade numbers and contribution to a Canadian national pharmaceutical database.
- To provide a timeframe within which all Canadian pharmaceutical manufacturers will be asked to comply with the voluntary Canadian bar-code standards and database submission.
- To develop a sustainability strategy to help ensure compliance with voluntary standards, and support manufacturers who do comply.
- To facilitate the expanded use of pharmaceutical bar-codes within both institutional and retail healthcare settings for safety checks.
- To seek support of software and safety organizations within Canada, to establish an environment of software and equipment development related to the Canadian bar-code standards.

Future phases will be used to oversee the variable data elements contained within the bar-code, and to determine the success of the Canadian pharmaceutical bar-code system.

Methodology

The current two-year project encompasses two of the five phases contemplated within the overall initiative. Table 1 outlines the five phases. Phase I, which has been completed, achieved a national roundtable consensus on Pharmaceutical Bar-coding technology, with its proceedings distributed in June 2008 (Appendix A)

Table 2 outlines the goals and deliverables of Phases I-V. The phases include the development, communication and implementation of bar-code standards for manufacturers, plus the development of sustainability strategies for the health industry by August 2010.

Table 3 outlines the final two phases, Phases IV and V, which relate to future post-implementation activities. They are concerned with the future implementation of variable data bar-codes, and a national effectiveness review.

Table 1: Phases of Canadian National Bar-Coding Implementation and Review

Phase I	*National Consensus on Pharmaceutical Bar-Coding Initiative*	*Completed June 2008*
Phase II	*Development and Approval of Bar-Code Standards*	*August 2008 through June 2009*
Phase III	*Sustainability and Growth of Bar-coding Safety*	*December 2008 through February 2010*
Phase IV	*Implementation of Variable Bar-code Elements (Out of Scope)*	*Out of Scope of Two-Year Project*
Phase V	*Post-Implementation Interventional Change (Out of Scope)*	*Out of Scope of Two-Year Project*

Table 2: Phase I through III Deliverables

	Phase	Major Deliverables	Status
Phase I		***National Consensus on Pharmaceutical Bar-Coding Initiative***	
	I-1	**2006 Stakeholder Meeting (ISMP/CPSI)**	**Completed**
	I-2	**Ottawa Roundtable Consensus (ISMP and CPSI): January 2008**	**Completed**
	I-3	**Issuance of Ottawa Proceedings: June 2008**	**Completed**
Phases II		***Development and Approval of Bar-Code Standards***	
		Hire part-time project lead: September 2008	**Completed**
		Invite Implementation (Steering) Committee members	Begun
	II-1	**Two year funding commitments**	Begun
	II-2	**Implementation Steering Committee (IC) Initial Meeting** [1]	December 2008
		Approve documents ➢ Terms of Reference ➢ Two-year Deliverables and Timelines ➢ Business Case, including budget proposal ➢ Corporate Strategic Alliance Partners	
		Establish necessary task forces: Technical Task Force (Advisory)	
		Discuss Phase II Communication strategy	
		Approve post-implementation sustainability strategy	
	II-3	**National Hospital Contracting Groups: Cooperation Achieved** [2]	January 2009
	II-4	**Retail Contracting Groups: Cooperation Achieved** [2]	January 2009
	II-5	**Approve Technical Bar-code and Database Standards: (Both Fixed and Variable data elements): IC**	May 2009
		Including formal agreement with Standards Organization	
	II-6	**Phase II Communications Strategy Approved: IC**	May 2009
	II-7	**ISMP/CPSI Industry Standards Issued and Communicated**	June 2009
		Pharmaceutical Industry and Professional Organizations	
		Public and Healthcare organizations	
	II-8	**Standardized Pharmaceutical Code Emerges: Fixed Elements**	January 2010 (est)
	II-9	**"Full" Pharmaceutical Codes "Deadline": Fixed Elements**	July 2010 (est)
Phases III		***Sustainability and Growth of Bar-coding Safety***	
	III-1	**Pharmacy Information (Software) Vendor Consultation**	October 2009
	III-2	**Clinical Implementation Best Practices Issued: Using above Standards**	December 2009
	III-3	**Safer Health Now Initiative Application?** (Adoption of manufacturer and internal Hospital barcode processes)	February 2010
	III-4	**National Buying Groups Apply Barcode Requirement in Contracting**	July 2010

1. ISMP and CPSI will utilize a national Implementation Committee (IC) comprised of key stakeholder organizations. The IC will approve and communicate barcode standards to all health system users. As required, technical task forces will be established to provide input into the recommendations.

2. Collaborative national medication contracting groups of public institutions and retail health systems, such as retail pharmacies, will be formed. Such groups will be instrumental in assuring continuity of the Canadian marketplace standards.

Measures of success for Phases II (roughly Year One) will be;

- Formation of an Implementation Committee, with approved terms of reference
- A formal Agreement with an international Healthcare Bar-code standards organization.
- Approval of a sustainability strategy for Industry compliance
- Approval and Issuance of Canadian pharmaceutical standards for fixed-data and variable-data bar-codes.
- Availability of a pharmaceutical product data base, based on unique identifier code for each product.
- 10-20% compliance of pharmaceutical Vendors within 6 months of issuance of standards
- 50-60% compliance of pharmaceutical Vendors within 18 months of issuance of standards

Measures of success for Phases III (roughly Year Two) will be;

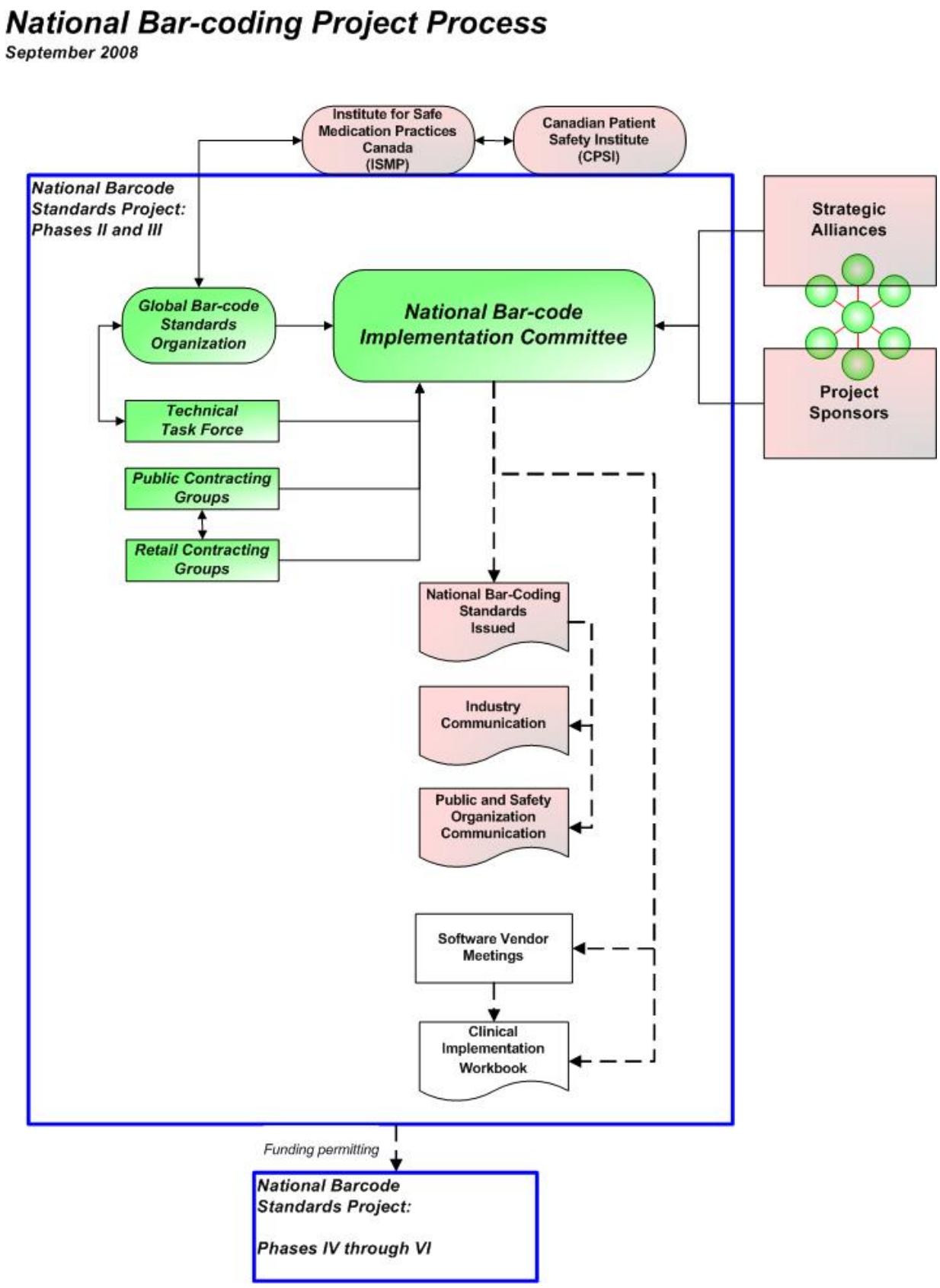
- >80% compliance of pharmaceutical vendors within 24 months of issuance of standards
- Completion of Major institutional and retail software vendor communications
- Issuance of an clinical implementation workbook (Best clinical practices)
- Application to CPSI for a Safer Healthcare Now! National initiative for a bar coding intervention.

Should funding continue to be available for subsequent phases, the following phases are envisioned.

Table 3: Phase IV and V Deliverables

	Phase	Major Deliverables	Status
Phase IV		***Implementation of Variable Bar-code Elements (Out of Scope)***	
	IV-1	**Environment Scan of Industry and Professional Readiness for Variable Code Elements**	
	IV-2	**Variable Code Communications Issued**	
		Pharmaceutical Industry and Professional Organizations	
		Public and Healthcare organizations	
	IV-3	**Industry Compliance: Variable Bar-Code Data Elements**	January 2015 (est)
Phase V		***Post-Implementation Interventional Change (Out of Scope)***	
	V-1	**Form National Bar-code Practice Committee**	
	V-2	**Safer Healthcare Now Project approved, or, alternatively, self-funded "PDSA" method determined**	
	V-3	**Environmental Scan: Industry Compliance and Feedback**	
	V-4	**Environmental Scan: Contracting and Professional Commitment**	
	V-5	**Establish Post-Project Communication and Support Plan**	
	V-6	**Communicate and Issue Best-Practices Tools Utilized**	

The process and interrelationships of groups will be as follows;



Budget

Expense Budget: Year One: Sept 2008 through Aug 2009

Personnel		Unit Cost	Extended Unit Costs	Extended Category Cost	Category Expense
ISMP Office				$ 59,190	$ 59,190
Part-time Salary and Benefits	One Year	30,334	30,334		
Administrative Support	One year	22,856	22,856		
Related Travel Allowance	2	3,000	6,000		
Operating	**Number**	**Unit Cost**	**Extended Unit Costs**	**Extended Category Cost**	**Category Expense**
IC Meeting(s) (15 Attendees)	**2**			$ 13,225	$ 26,450
Hotel	8	250	2,000		
Air Travel	8	800	6,400		
Ground Travel	15	100	1,500		
Per diem	15	55	825		
Meeting Room/Food	1	2,500	2,500		
Task Force Meeting(s) (8 Attendees)	**2**			$ 7,820	$ 15,640
Hotel	4	250	1,000		
Air Travel	4	800	3,200		
Ground Travel	8	100	800		
Per diem	8	40	320		
Meeting Room/Food	1	2,500	2,500		
Communication/Knowledge Transfer				$ 13,000	$ 13,000
Reproduction/Printing	1	3,000	3,000		
Press and Publication	1	3,000	3,000		
Conference Atendance	1	2,000	2,000		
Telephone	1	4,000	4,000		
Miscellaneous	1	1,000	1,000		
Other	1			$ -	$ -
			-		
			-		-
Subtotal (Operating and ISMP)					**$ 114,280**
Contingency (10%)				-	11,428
Total Expenses					**Net Expense**
					$ 125,707

Expense Budget: Year Two: Sept 2009 through Aug 2010

Personnel		Unit Cost	Extended Unit Costs	Extended Category Cost	Category Expense
ISMP Office				$ 59,910	$ 59,910
Part-time Salary and Benefits	One Year	31,244	31,244		
Administrative Support	One year	22,666	22,666		
Related Travel Allowance	2	3,000	6,000		
Operating	**Number**	**Unit Cost**	**Extended Unit Costs**	**Extended Category Cost**	**Category Expense**
IC Meeting(s) (15 Attendees)	**2**			$ 13,622	$ 27,244
Hotel	8	258	2,060		
Air Travel	8	824	6,592		
Ground Travel	15	103	1,545		
Per diem	15	57	850		
Meeting Room/Food	1	2,575	2,575		
Task Force Meeting(s) (8 Attendees)	**1**			$ 8,178	$ 8,178
Hotel	4	258	1,030		
Air Travel	4	824	3,296		
Ground Travel	8	103	824		
Per diem	8	57	453		
Meeting Room/Food	1	2,575	2,575		
Communication/Knowledge Transfer				$ 18,000	$ 18,000
Workbook Production: SHN	1	3,000	3,000		
Reproduction/Printing	1	3,000	3,000		
Press and Publication	1	3,000	3,000		
Conference Atendance	2	2,000	4,000		
Telephone	1	4,000	4,000		
Miscellaneous	1	1,000	1,000		
Other	1			$ -	$ -
			-		
			-		-
Subtotal (Operating and ISMP)					**$ 113,331**
Contingency (10%)				-	11,333
Total Expenses					**Net Expense**
					$ 124,664

Appendix A: Phase I – A Canadian Perspective Discussion Paper

Appendix B: Phase I - Proceedings of a Stakeholder Invitational Roundtable