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LETTER OF INTEREST
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Title - Sujet MEDICAL EQUIP. AND MEDICAL SUPPLIES	
Solicitation No. - N° de l'invitation E60PV-12MS00/A	**Date** 2012-05-09
Client Reference No. - N° de référence du client E60PV-12MS00	**GETS Ref. No. - N° de réf. de SEAG** PW-$$PV-890-60426
File No. - N° de dossier pv890.E60PV-12MS00	**CCC No./N° CCC - FMS No./N° VME**
Solicitation Closes - L'invitation prend fin **at - à 02:00 PM** **on - le 2012-06-01**	**Time Zone** **Fuseau horaire** Eastern Daylight Saving Time EDT
F.O.B. - F.A.B. **Plant-Usine:** ☐ **Destination:** ☐ **Other-Autre:** ☐	
Address Enquiries to: - Adresser toutes questions à: Hennessey, Lisa	**Buyer Id - Id de l'acheteur** pv890
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Canada

REQUEST FOR INFORMATION (RFI)

Based on a preliminary review of Medical Equipment and Medical Supplies (MEMS) procurement by government departments, Public Works and Government Services Canada (PWGSC) is pleased to release the draft National Procurement Strategy for MEMS.

PWGSC's objective is to provide a single, consistent, national approach that will improve the ease and effectiveness of the procurement process for all stakeholders, including government departments, suppliers, and Canadians. You are invited to review the details and provide your feedback on the draft MEMS National Procurement Strategy as your insight will help form the Government of Canada's approach to the procurement of MEMS.

Responses to this RFI may be in either of Canada's both official languages, English or French. This RFI is not a bid solicitation and will not result in the award of any contract.

This RFI contains a draft National Procurement Strategy for MEMS.

There are two ways that you can provide us with your feedback:

1) Once you have read the draft Strategy, you may respond to an on-line questionnaire at: http://tpsgc-pwgsc1.sondages-surveys.ca/surveys/osmepd/mems-suppliers/langeng/

OR

2) E-mail your comments to: EMFM.MEMS@tpsgc-pwgsc.gc.ca

The Office of Small and Medium Enterprises, PWGSC, is facilitating input from suppliers on this strategy and will provide consolidated responses, without specific supplier information, to the Commodity Team.

Thank you for participating in this Strategy.

Public Works and Government Services Canada
Travaux publics et Services gouvernementaux Canada
Canada

Respect ◆ Integrity ◆ Excellence ◆ Leadership

Serving GOVERNMENT, Serving CANADIANS.

Draft National Procurement Strategy Medical Equipment and Medical Supplies

May 2012

www.pwgsc-tpsgc.gc.ca

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Executive Summary

Introduction

Public Works and Government Services Canada (PWGSC) has undertaken a review of the procurement of Medical Equipment and Medical Supplies (MEMS) with the objective of developing a National Procurement Strategy (NPS).

Fundamental to this review has been the engagement of government departments and industry to assess how current PWGSC procurement practices are addressing their concerns while meeting the requirements of government departments. The resulting draft NPS is being published to seek further input that will help PWGSC refine the procurement strategy that will be approved and implemented over a period of five years.

This draft NPS aims to provide a uniform and consistent national approach that when implemented, will improve the efficiency and effectiveness of the procurement process for government departments, suppliers and Canadians.

Definition

The draft NPS for the Government of Canada (GC) MEMS category includes medical equipment (e.g. patient exam and monitoring equipment, rehabilitation equipment and physical occupational therapy equipment) and medical supplies (e.g. including dialysis and clinical nutrition supplies, emergency and field medical system products).

The draft NPS excludes items such as vaccines, chemicals, and/or pharmaceuticals, as supplier offerings and government department needs tend to differ between these three sub-categories. The sub-categories are considered to be apart by industry.

Additionally, Dental Equipment, Accessories and Supplies; Laboratory Equipment and Laboratory Supplies and Optical/Vision Correction Accessories do not form part of this draft NPS.

Background

Revenues in the Canadian MEMS industry amounted to $9.5 billion in 2010 (Datamonitor, 2011). The recent economic downturn has had a negative impact on this industry. With the economy stagnating, the demand is not expected to increase significantly over the next few years; the industry is forecast to reach $10.8 billion by 2015 (Datamonitor, 2011).

Based on a three-year period (FY07/08 – FY09/10), the Government of Canada (GC) spent on average $73 million on MEMS[1] annually. Over the FY05/06 -

[1] Source: Spend Cube based on 3-year average FY07/08 to FY09/10. The Spend Cube currently contains approximately 85% of all Government of Canada expenditures. This information represents departmental data provided by departmental financial systems.

FY09/10 period, the average value awarded for this category by PWGSC was approximately $38 million[2] per year.

Demand for MEMS originates from hospitals, clinics, outpatient facilities and medical offices, and is impacted notably by health care budgets, population demographics, and product innovation (First Research, 2011). Main suppliers compete on the basis of quality, performance, technology and reliability of their products (IBISWorld, 2010). Competition is considered as moderate given the wide range of products and the variety of industry segments (Datamonitor, 2011).

Government departments typically have delegation of authority to a maximum $25,000 for goods and up to $2,000,000 for services[3], allowing them to contract directly with suppliers. PWGSC will conduct the procurement in circumstances where government departments' requirements exceed their delegated contracting authorities and where government departments lack required procurement expertise.

The primary drivers in this industry revolve around performance, durability, and quality. In order to best satisfy these drivers, PWGSC has established contracts as the main method of supply for equipment purchases, as they are the preferred approach for both government departments and suppliers for the majority of medical equipment requirements. Contracts ensure that the scope of work is well defined (e.g. specifications relating to equipment performance) and, can be customized to specific government department requirements. Contracts are most often awarded to the lowest-priced bidder complying with all the conditions of the solicitation.

National Master Standing Offers (NMSOs) for the supply of medical supplies have been established through non-competitive processes. These standing offers (SOs) typically represent the repetitive, low cost, and commercially available off the shelf items required for day-to-day work within the GC. Additionally, two prime vendor NMSOs were established to address four categories of consumables: medical laboratory, clinical, surgical and physiotherapy. The goal was to provide a 'one-stop-shop' ordering process by purchasing items directly from a prime vendor eliminating the need to issue numerous Regional Individual Standing Offers, National Individual Standing Offers, individual contracts and local purchase orders.

In a national health emergency or disaster, the Office of Emergency Response Services is responsible for supporting emergency health and social services in the provinces, territories and abroad. It manages the National Emergency Stockpile System (NESS), which gives them the capacity to provide 24 hour rapid emergency response capacity in support of the provinces and territories.

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[2] Source: Acquisitions Information System (AIS) based on 5-year average FY05/06 to FY09/10. AIS contains contractual data for contracts and standing offers awarded by PWGSC only. Contractual data for contracts and standing offers awarded by government departments directly is not included.

[3] Treasury Board Contracting Policy in English: http://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=14494&section=text#appC

Included in the NESS are medical, pharmaceutical and related emergency supplies. [4]

Findings

Many current procurement practices employed by PWGSC are well received by government departments and industry. Some of the positive practices indicated include:

- Flexibility. PWGSC has established SOs with numerous suppliers to facilitate choice, reduce product compatibility concerns and to respect certain manufacturers who often restrict distribution rights;
- NMSOs provide an efficient and effective method for responding to the repetitive nature of the GC MEMS demand;
- Government departments appreciate the lowest price, technically compliant approach for commercially available off the shelf (COTS) equipment as a complex evaluation methodology is inefficient and adds little value to supply purchases; and
- Government departments and industry prefer contracts for larger equipment purchases (e.g. X-Ray machines). Contracts are an effective means to mitigate risk to the GC because terms and conditions can be specific to the individual requirement.

The review also identified that opportunities exist for improvement with respect to how MEMS are procured and managed.

The following chart provides a high level summary of key findings and recommendations resulting from PWGSC's category review of MEMS. Additional details are provided in the document.

Key Findings	Recommendations
Methods of Supply • The current qualification process for MEMS NMSOs has resulted in many suppliers having little or no usage; questioning the administrative costs for both the GC and suppliers. • The Prime Vendor standing offers has defaulted to a defacto National Individual Standing Offer as it has been customized to meet specific needs of one principal government department, making it difficult for others to use. • Duplication of products offered and	**Demand Management (Recommendation 9.1)** <u>Revised Competitive Process for establishing Standing Offers (SOs) for MEMS</u> (Recommendation 9.1.1) • Implement revised competitive supplier selection processes to award MEMS SOs. • Publish product catalogues to facilitate ordering MEMS and to ensure supplier offerings are clearly identified. • Establish demand profile for

[4] http://www.phac-aspc.gc.ca/publicat/roa-cepr/roa-cepr06-09-eng.php

lack of an online SO product catalogue has lead to confusion leaving government departments unsure of which procurement instrument to use and suppliers not entirely certain where their products fit. • Suppliers find it difficult to accurately forecast pricing over the life of a standing offer as catalogue pricing isn't always current and they may not have the most recent price from the distributor/manufacturer.	repetitive buys to allow for a product catalogue that is current and indicative of GC demand. <u>Continue the use of Contracts for Equipment Purchases (Recommendation 9.1.2)</u> • Industry and government departments prefer contracts for complex and unique equipment requirements where stand- alone contracts are necessary to ensure that the demand is accurately managed.
Environmental Considerations • The majority of MEMS requirements currently don't include considerations for the environment. • There are limited opportunities for suppliers to add green products. • Green Procurement scorecards that provide information to industry regarding PWGSC's direction have not been completed. • There are opportunities for improvement to better manage the life cycle (e.g. disposal) of products purchased in this category.	**Environmental Considerations (Recommendation 9.2)** • Provide government departments the flexibility to introduce greening requirements into their solicitations. • Provide more opportunities for suppliers to self-identify environmentally responsible goods. • Develop and publish PWGSC's strategic environmental direction for MEMS through its Green Procurement Plan's scorecard. • Implement greater life cycle considerations into the procurement process. Government departments are encouraged to repair, re-use and recycle equipment whenever it is feasible. • Investigate with government departments the benefits of incorporating point rated criteria in solicitations.
Vendor Performance • More tools for monitoring vendor performance post contract award to ensure vendors are adhering to all contractual terms and conditions are to investigated and implemented. • Typically in multi-year and follow-on contracts, suppliers are not required to provide on-	**Vendor Performance (Recommendation 9.3)** • PWGSC will reference information regarding the supplier's history recorded in PWGSC's Vendor Information Management (VIM) System. • PWGSC will investigate with government departments the benefit of introducing the evaluation of

going proof that they continue to meet the certifications and requirements of the initial contract (e.g. Medical Devices Establishment License, Federal Contractors Program for Employment Equity, etc.).	supplier experience in solicitations. • Enhanced emphasis will be placed on monitoring vendor performance post contract award to ensure vendors are adhering to all contractual terms and conditions. • Medical Device Establishment License applications are to be monitored throughout the life of any procurement instrument, with evidence of a request to renew an application to be made annually on anniversary of SO.
Communication and Training • Departments would like more frequent and simpler communication with PWGSC to improve their understanding of how to use the electronic tools and procurement instruments. • The methodology of some procurement instruments have unavoidably provided some suppliers with more information than is otherwise publicly available regarding GC demand patterns.	**Enhanced Communication (Recommendation 9.4)** • Ensure that suppliers and departments are informed about new processes through an enhanced communication process. • Consolidate communication tools to facilitate understanding of available procurement instruments. • Work with departments and industry to improve information management for use in the procurement planning lifecycle - including placing emphasis on enhanced supplier reporting requirements to measure GC demand.
Improvements to the Procurement Process • Government departments appreciate the technical advice that PWGSC can provide and would prefer to facilitate a process whereby PWGSC plays a larger role in this function rather than acting as the gatekeeper to the purchasing process. • Frustrations exist with government departments and industry over how the MEMS category is structured.	**General Improvements to the Procurement Process (Recommendation 9.5)** • Incorporate a government department requisition checklist to ensure all necessary information is captured as early as possible in the procurement process. • Validate draft MEMS category definition.

1 Purpose

Public Works and Government Services Canada (PWGSC) has undertaken a review of how it procures Medical Equipment and Medical Supplies (MEMS) on behalf of government departments, agencies (government departments). Areas of opportunity have been identified that, if leveraged, will benefit government departments, suppliers and Canadians.

The strategic direction for this category is described in this draft National Procurement Strategy (NPS). It is based on findings from government departments, suppliers, and PWGSC daily operations. Government departments and suppliers are encouraged to review the draft NPS and provide comments. All comments will be taken into consideration when finalizing the NPS for MEMS.

2 Scope

The draft NPS examines the procurement of MEMS by PWGSC on behalf of government departments.

2.1 Definition

MEMS is defined as equipment and supplies acquired by the Government of Canada (GC) for the day-to-day use of employees in their official functions. MEMS purchased by the GC range in scope from basic consumables that are generally available across a range of suppliers to more complex purchases of technically advanced equipment. The more complex equipment is often subject to numerous specifications, regulations and international agreements with respect to form, fit and functionality that may only be available from a single/sole source.

The medical, equipment and supplies sub-categories included in this review are:

- Medical Equipment: Examples of products in this sub-category include medical equipment, patient exam and monitoring equipment, medical facility equipment, medical diagnostic imaging and nuclear medicine equipment, physical occupational therapy and rehabilitation equipment, and respiratory and anaesthesia resuscitation equipment.

- Medical Supplies: Examples of products in this sub-category include medical supplies, including dialysis and clinical nutrition supplies, emergency and field medical system products, patient exam products, intravenous and arterial products, and sports medicine products, physiotherapy and rehabilitation products (including mostly non-durable products).

Excluded from the Definition

The draft NPS excludes items such as vaccines, chemicals, and pharmaceuticals, as supplier offerings and government department needs

tend to differ between these three sub-categories. The sub-categories are considered to be apart by industry.

Dental Equipment, Accessories and Supplies; Laboratory Equipment and Laboratory Supplies; and Optical/Vision Correction Accessories will be reviewed in the future.

3 Background

For background on the topic of Category Management[5], refer to the 'Introduction to Goods and Services Management' document[6]. Key items documented are:

- Methodology;
- Guiding Principles;
- Description of Category Management; and
- Regulatory and Policy Framework.

Additional details on the MEMS review are provided in Annex 'A' –National Category Review – Medical Equipment and Medical Supplies.

4 Canadian Industry – Market Information

The Canadian MEMS market has experienced positive growth since 2005 (Datamonitor, 2010). In 2010, the industry was valued at $9.5 billion (Datamonitor, 2011). It should be noted that this industry has been less severely impacted by the economic crisis compared to other sectors given that some medical products are always in demand, notably due to aging population (Mergent 2011). Experts forecast that this industry will continue to grow at a slower pace, reaching $10.8 billion by the end of 2015 (Datamonitor, 2011).

According to Industry Canada, the commercial activity is geographically concentrated in the provinces of Ontario and Quebec. In 2010, there were over 6,000 establishments, most of which were micro and small firms. As a whole, this industry employed nearly 40,000 people across Canada in 2009.

In the Canadian market, there are some large players that compete at the international level, operate in many different segments of the industry and benefit from scale economies (Datamonitor, 2011). The similarity between products and players increase the lack of diversity in the market and thus the rivalry (Datamonitor, 2011).

The fact that this industry has grown over the last few years has attracted new entrants; however government regulations, the high investment in research and development (R&D) and the continuous technological advancements present barriers of entry into this market (Datamonitor, 2011).

[5] Category Management was previously referred to as Commodity Management.
[6] http://www.gcpedia.gc.ca/gcwiki/images/e/e8/CM_Framework.pdf

5 Government of Canada Spend Analysis[7]

According to the Spend Cube data collected by PWGSC, GC spent an average of approximately $73 million on MEMS annually over the period FY07/08 to FY09/10.

Table #1. Average Annual Spend on MEMS

Fiscal Year	Total
FY 07-08	$66.7M
FY 08-09	$70.9M
FY 09-10	$82.0M
3-Year Average	**$73.2M**

Source: Spend Cube Data based on a 3-year average. Spend Cube Data: FY 07/08 to FY 09/10.
Note: Spend data represents invoices that have been paid.

Medical Supplies represents the largest portion (60%) of GC spending over the three fiscal years.

6 PWGSC Contract Activity - MEMS

Over a five-year period (FY05/06 to FY09/10), the average value awarded by PWGSC for MEMS was approximately $38 million per year, while on average there were 429 documents awarded annually. Contracts accounted for 47% of the number of documents awarded and 42% of the value awarded. Amendments, which are used to modify contracts and standing offers including exercising options, accounted for a large proportion (44%) of the annual business volume.

Table #2. Number of Documents and Value Awarded by Document Type

Document Type	Value Awarded	% of the total value awarded	# of documents	% of the total documents
Contract	$15,970,546	42%	200	47%
NMSO	$10,869,102	28%	12	3%
Amendments	$7,349,545	19%	188	44%
NISO	$1,560,526	4%	12	3%
RISO	$1,505,080	4%	4	1%
RMSO	$1,055,000	3%	10	2%
Call Up Against DISO	$101,862	0.3%	2	0%
Total	**$38,411,706**	**100%**	**429**	**100%**

Source: AIS based on 5-year average. AIS Data: FY05/06 to FY09/10.
Notes:

- DISO = Departmental Individual Standing Offer

[7] Source: Spend Cube based on 3-year average FY07/08 to FY09/10. The Spend Cube currently contains approximately 85% of all Government of Canada expenditures. This information represents departmental data provided by departmental financial systems.

- NMSO = National Master Standing Offer
- RISO = Regional Individual Standing Offer
- RMSO = Regional Master Standing Offer
- NISO = National Individual Standing Offer
- Contracts include Formal Agreements, Store Transfer Orders, Purchase Orders, Contracts.
- Amendments include Normal amendments, Pre-approved amendments, Contract termination by mutual consent, Contract termination for convenience of the Crown, and Contract termination for default.
- These figures exclude the following standard document exclusions: Supply Arrangements, Transfers into the Supply Revolving Fund and Consultant Open Agreements (RP Only). The estimated total values of DISO are excluded but call ups against that instrument are accounted for in the tables.

The highest usage government departments (Department of National Defence, Public Health Agency of Canada, National Research Council, Veteran Affairs Canada, and Health Canada) accounted for 51% of the annual value awarded.

See Annex A: 'National Category Review', Section A1, PWGSC Contract Activity Analysis for more information.

7 Overview of the Procurement Process

MEMS Procurement Processes

PWGSC will procure MEMS directly on behalf of government departments when government departments exceed their delegated contracting authorities or when the use of an existing procurement instrument is not an option. Government departments typically have a delegation of authority to purchase MEMS to $25,000 for goods and $2,000,000 for services.

Contracts are the primary method of supply in place for medical equipment and provide an effective means to assist the GC manage demand and delivery. Contracts ensure that the scope of work is well defined (e.g. specifications relating to equipment performance), and customized to the specific requirement. Contracts are also beneficial in the event MEMS items are unavailable through the NMSOs or the requirement exceeds the maximum call-up limitation.

Government departments and suppliers have identified SOs as the preferred method of supply for medical supplies. SOs are preferred for the following reasons:

- Clear requirement for a determined period of time;
- Easy to manage;
- Decreased administrative and procurement lead-times;
- Increased government department flexibility to purchase directly; and
- Open and fair:
    - For existing and potential suppliers

There are currently two sets of NMSOs in place

- Prime Vendor Standing Offers, 2 NMSOs
- Medical Equipment and Medical Supplies, 27 NMSOs

Prime Vendor Standing Offers

Two Prime Vendor NMSOs were awarded as a result of a competitive Request for Standing Offer (RFSO) and has a call-up limitation of $100,000.

Products were authorized by category (Physiotherapy, Operation Room, Surgical and Labs). One supplier currently provides physiotherapy products and the other handles the remaining three categories.

The Offerors must be capable of stocking at least 90% of the items listed. It is the SO holder's responsibility to supply and update catalogues on a monthly basis.

Despite the fact that they are NMSOs, they are very focused on the needs of one principal government department, making it extremely difficult for other government departments to use the procurement instrument.

Additional factors that have been limiting the success of the Prime Vendor SOs is the fact that it is difficult for other suppliers to qualify for the NMSO as ineffective reporting and lack of ability to track purchases, makes it difficult for the GC to accurately outline demand.

MEMS NMSOs

There are currently 27 NMSOs in place for MEMS which were awarded through an open qualification process with no direct competition to determine awards. Call-up limitations were capped to $40,000 with no individual line item being able to exceed $25,000.

This method of supply has had mixed success. Many suppliers are seeing little or no usage, unauthorized products are being purchased, there is no competitive pricing and government departments are not sure where to find products.

Medical Device Establishment Licensing[8]

Medical Device Establishment Licensing (MDEL) was implemented to allow users to be made aware of who is importing and/or selling medical devices in Canada. It requires establishment licence holders to provide to Health Canada the assurance that they have met the regulatory requirements and have documented procedures in place, where applicable, related to distribution records, complaint handling, storage, delivery, installation and servicing, with respect to the medical devices they sell. PWGSC currently

[8] http://webprod3.hc-sc.gc.ca/el-le/index-eng.jsp

asks for a MDEL only at the initial bid award and has not been asking suppliers to provide annual certifications.

Any person who imports into Canada, or sells in Canada, a medical device for human use requires an MDEL license. For a listing of exceptions, please visit http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui-0016-eng.php#a2

8 Summary of Analysis

Standing Offers

- Outside of the Prime Vendor program, there currently isn't a competitive process in place for awarding MEMS NMSOs.
- These NMSOs often result in many suppliers having little or no usage; questioning the administrative costs for both the GC and the supplier.
- Although established as a NMSO, the Prime Vendor SOs have defaulted to a defacto National Individual Standing Offer as it has been customized to meet specific needs of one principal government department, making it difficult for others to use.
- Confusion amongst government departments as there is considerable overlap between products being offered through the Prime Vendor and the other MEMS NMSOs leaving clients unsure which tool to use.
- Loose reporting and low inventory control processes have resulted in unfair advantages for incumbent suppliers resulting from not all of the historical usage data being made available at bid solicitation for the Prime Vendor SOs.
- Participating suppliers are not justifying sole distributorship/exclusive rights each year and certifications not provided on new products.

Equipment

- A lack of standardization by government departments when submitting statements of work and purchase requisitions to PWGSC (e.g. extended warranties, training, installation, optional items) has led to unnecessary delays and general frustrations in the procurement process. Earlier involvement between PWGSC and the respective government department would ensure that all required information is captured early in the procurement process.

Environmental Considerations:

- The majority of the MEMS methods of supply in place by PWGSC do not contain category specific environmental considerations.
- PWGSC has not completed a green scorecard for this category.

General Observations

- PWGSC should work towards improving supplier performance post delivery to ensure necessary support; and
- Frustrations exist with government departments and industry over how the MEMS category is structured.

9 Recommendations

The basis of the recommendations is a continuous improvement strategy. Details on the recommendations associated with each strategic element are provided in the following sub-sections.

9.1 Demand Management

9.1.1 Revised Competitive Process for establishing MEMS NMSOs

Recommendation

It is recommended that PWGSC revise its current evaluation process to select NMSO holders for MEMS. This recommendation will replace the current Prime Vendor and MEMS NMSOs with a single competitive framework focusing on open and fair competition.

Successful NMSO holders will have the opportunity to refresh their pricing annually; and, in the event that there is a price increase, the increase must not exceed the Consumer Price Index. This will provide NMSO holders the opportunity to account for market and economic shifts in their industry. Once awards have been allocated, a product catalogue will be developed and the information will be published for GC use only.

Based on the proposed approach, it is anticipated that the current number of SOs will be significantly reduced. Suppliers who are not initially awarded a competitive MEMS SO will have to wait until the SO is re-competed.

Should a product not have sufficient demand to be placed into the general catalogue or if it is a sole sourced item, government departments can continue to use Local Purchase Orders (LPOs) for lower dollar value requirements, manage the procurement themselves if it falls within their current level of delegated contracting authority or submit a funded requisition to PWGSC.

If a government department believes that they have a requirement for an alternative Method of Supply, they will be responsible to identify the situation to PWGSC. PWGSC will review the requirement and its historical data, recommend the best procurement strategy, and work with the government department to implement it.

The implementation of this recommendation will result in:

- Standardized business rules associated with the purchasing of MEMS products;

- Competitive processes to determine NMSO holders;
- Annual price refreshes;
- Enhanced reporting requirements to assist the GC in establishing and subsequently managing its demand profile;
- Reduction of product overlap between medical and lab supplies offerings to minimize government department confusion; and
- Sufficient product selection from qualified suppliers to support government department requirements.

Context
SOs provide government departments with a degree of assurance relating to the quality and availability of products and that the pricing offered is within industry standards.

The proposed approach is described below:

Evaluation
In order to be considered for evaluation, bidders must reply to a minimum of 70% of the products listed on the solicitation and those who offer a best price on a minimum of 20% of the total catalogue of products will be awarded a NMSO for those items in which they have submitted the lowest price.

SO Duration
The duration of the SO will be one year with the option to extend for two additional one-year periods**.**

Limitation of Call-Ups
Individual call-ups against the standing offer by identified users must not exceed an aggregate value of $40,000.00 including goods GST/HST, as applicable. Data provided in Annex A shows that from June 1, 2008 to June 1, 2011, over 99% of the total number of call-ups issued are within this threshold[9].

The Standing Offer Authority may issue call-ups for requirements up to $100,000.00 GST/HST included, as applicable.

All requirements valued over $100,000.00 (GST / HST included) the Identified User must send a funded requisition (form 9200) to PWGSC Central Allocations by fax or e-mail for appropriate action.

Catalogue Availability and Price Refresh
PWGSC will work with key government departments to develop a standard catalogue that will serve to represent the primary items required. Critical to this review will be a cleansing of legacy data to ensure that overlaps with

[9] Supplier SO activity reports. PWGSC data June 1, 2008 - June 30, 2011

other sub-categories (e.g. lab supplies) are reduced and that the products listed are needed by government departments.

An electronic product catalogue will be available for all government departments through internal GC tools. The catalogue will clearly organize all supplier offerings to assist any government department in its ordering process.

NMSO holders will be able to refresh pricing in the catalogue once a year. As mentioned in the recommendation section, any potential price increase will not exceed the identified Consumer Prime Index. Once prices are submitted, PWGSC will be responsible for updating the product catalogue. By establishing a consistent process; it should serve to reduce the administrative efforts for suppliers and ensure that government departments have consistent expectations of when changes to the catalogue will occur.

Reporting

To address inefficiencies in reporting and to assist in analysing the GC demand, NMSO holders will be required to provide detailed usage reports. Historically, reporting received has not given the GC the level of information required to effectively analyze demand on a consistent basis. Based on purchasing patterns, the GC will be in a better position to evaluate product offerings and maintain the relevancy of the product catalogue.

Implementation Plan

PWGSC will implement the recommendation as follows:

Activity	Timeframe
Work with key government departments to validate and develop the product listing for the Request for Standing Offer.	Ongoing
Development of Request for Standing Offer.	Fiscal Year 2012-2013
Finalization and dissimulation of the electronic product catalogue to government departments upon establishment of NMSOs.	Fiscal Year 2012-2013
Through enhanced reporting, establish the GC demand profile, especially for preferred items or items that are purchased most often.	Fiscal Year 2012-2013
Continued monitoring of catalogue to ensure it meets government department needs.	Ongoing after initial award
Identify strategy to streamline catalogue maintenance, and improve presentation to government departments.	July 2014

9.1.2 Methods of Supply for Medical Equipment Purchases

Recommendation

Government departments and industry have expressed a preference to continue using contracts as the primary method of supply for medical equipment purchases. Individual contracts provide greater cost certainty for managing demand and allow the GC to detail precise specifications as they relate to the actual purchase. Often, these purchases are unique and do not lend themselves to a method of supply that would benefit from repetitive purchases of similar equipment.

Context

Some of the key factors that make contracts the preferred procurement instrument for equipment requirements are:

- The complex and unique nature of the equipment requirements often mandate that stand alone contracts be put in place to manage the demand accurately;
- Allow for more open and fair competition for existing vendors and new entrants, and for every size business (various capacity requirements);
- Necessity to manage risk on a situation by situation basis; and
- Contracts allow PWGSC and government departments to clearly outline any specific performance specifications and services that would be required.

Depending on the specific nature and complexity of the requirement, the GC may use established solicitation/contract templates as a base. However for more complex purchases, additional/custom clauses, and terms and conditions may be developed through negotiation.

Implementation Plan

PWGSC will implement these recommendations as follows:

Activity	Timeframe
Continue use of contracts as the primary method of supply.	Ongoing
Continue to review the current procurement process to see if opportunities exist across various government departments to identify potential efficiencies for medical equipment.	Ongoing

9.2 Environmental Considerations

Recommendation

PWGSC encourages the use of Green Products and intends to initiate greening of MEMS procurement. In consultation with government departments and industry, PWGSC will phase in appropriate and consistent environmental considerations in the procurement process for MEMS.

To facilitate this, PWGSC will demonstrate environmental leadership by supporting suppliers and government departments in the use of environmentally preferable goods, services and processes. The incorporation of green point-rated criteria could allow government departments the opportunity to outline environmental considerations and allow them to manage the criteria on a case-by-case basis.

One of the key steps towards accomplishing this objective will be the development and subsequent publishing of PWGSC's strategic environmental direction for MEMS through the Green Procurement Plan scorecards. These scorecards will outline the multi-year plan(s) for the incorporation of environmental criteria. PWGSC publishes the Green Procurement Plan scorecards for goods and services at http://www.tpsgc-pwgsc.gc.ca/app-acq/ae-gp/paer-cgpp-eng.html.

Additionally, PWGSC is recommending:

- Solicitations issued by PWGSC introduce the ability for suppliers to self identify environmentally responsible goods. Suppliers will be asked to identify the item(s) being proposed that meet the "Green Product" and/or "Green Company" Guidelines below. Suppliers that identify a product or service under these criteria will be asked to indicate which certification is met.
    - **Green Product or Service**: Any product or service that has been certified through any legitimate "eco-labelling program", such as the Global Eco-Labelling Network located at http://www.globalecolabelling.net, will be considered by PWGSC as "green" or "environmentally responsible". Canada's program in the eco-labelling network is called the "Environmental Choice Program" and can be found at http://www.ecologo.org/en/index.asp. If a product or service that is not registered on GLOBAL ECO-LABELLING NETWORK, but it is labelled, certified or an endorsed product under a recognized third party program or a product manufactured in an ISO 14001 registered facility, it is considered as green if the supplier provides proof that the products have eco-label, certification or endorsement or the manufacturer's facility ISO registration.
- A product produced by a green company (see below) may also be considered environmentally responsible.
    - **Green Company**: A "green" company is defined as a company having an Environmental Management System (EMS) in place at a production facility. Manufacturers must operate with an EMS certified by a qualified registrar as complying with the ISO 14001 standard.

In addition, MEMS solicitations and resulting contracts will investigate including a variety of environmental considerations, specific to particular sub-categories. Examples of environmental considerations include:

- ISO 14001 certification;
- Consumables Container Recycling Programs;
- Hardware recycling;
- Packaging recycling;
- ENERGYSTAR certifications - design for reduced energy consumption for testing and diagnostic electronic equipment;
- Restriction of Hazardous Substances Directive (RoHS) and Waste Electrical and Electronic Equipment Directive (WEEE)
- Third Party Environmental Performance Labelling.

Context

The draft NPS aims to raise the awareness of environmental issues to suppliers and demonstrate that the GC is implementing its *Policy on Green Procurement* http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/achats-procurement/politique-policy-eng.html.

The Policy on Green Procurement was created in 2006 with the mandate to advance the protection of the environment and support sustainable development by integrating environmental performance considerations into the procurement decision-making process.

Setting Green Procurement targets is one of the requirements of the Policy. Departments and agencies in Section 2 of the Financial Administration Act are expected to report annually on these targets through their Report on Plans and Priorities and Departmental Performance Report.

As part of the 2011-2014 Federal Sustainable Development Strategy, participating departments and agencies must develop an organizational Sustainable Development Strategy that reflects the targets specific to their organization for each of the key areas.

Green procurement has been outlined as a key target area in the 2011-2014 Federal Sustainable Development Strategy (FSDS): "As of April 1, 2011, each department will establish at least 3 SMART green procurement targets to reduce environmental impacts." To help government departments meet green procurement targets, procurement instruments that include environmental considerations and/or identify environmentally preferable products or suppliers must be put in place.

The incorporation of appropriate and consistent environmental considerations in MEMS solicitations and contract documents will simplify the process for all stakeholders and be contributing factors in helping GC meet the objective of the Policy on Green Procurement.

Analysis has shown that the majority of PWGSC MEMS methods of supply do not include any special provisions specifying that suppliers are to use “green” or “greener” materials unless at the specific request of the government department.

Feedback provided during the initial consultations indicated that industry and government departments accept that environmental considerations can be a factor in government purchasing decisions. Both parties indicated that any environmental considerations should be developed within a reasonable timeframe so as not to negatively impact the industry and/or service to government departments.

While PWGSC acknowledges that the form and function of some of the goods and services within this category may preclude the application of greening considerations across all elements of the sub-categories at this time, PWGSC will demonstrate environmental leadership by providing support and guidance to suppliers and government departments to enable the identification and incorporation of environmentally preferable goods, services and processes. This will be in the context of striving for the optimal balance of client requirements, supplier capacity and ensuring value to Canadians.

Life cycle considerations are also implemented into the procurement of MEMS. Extended warranties are available on most equipment methods of supply and government departments are encouraged to use the electronic waste recycling SO for product pick-up, recycling, re-use and disposal.

Green Products and Disposal

Considering the wide variety of products (including hazardous substances) available through MEMS, disposal is an important consideration. PWGSC will investigate with industry what environmentally friendly disposal services are available in the marketplace to assist the GC in managing the entire product lifecycle.

The Guideline for Disposal of Federal Surplus Electronic and Electrical Equipment provides a detailed overview of the federal e-waste strategy: http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/dechets-waste/dechets-waste-eng.html.

Implementation Plan

PWGSC will investigate implementing this recommendation as follows:

Activity	Timeframe
Data collection and analysis through publication of draft NPS.	Analysis will commence with feedback from formal consultation period.

Activity	Timeframe
Continue to work with government departments to support emerging environmental technologies and demonstrate environmental leadership by proposing the use of mandatory and/or point-rated environmental criteria.	Analysis will commence with feedback from formal consultation period.
Introduce supplier self-identification of environmental responsible goods.	Fiscal Year 2012-2013
Publish the Green Scorecard to communicate PWGSC's direction to industry, government departments and PWGSC contracting officers at http://www.tpsgc-pwgsc.gc.ca/app-acq/ae-gp/paer-cgpp-eng.html	Fiscal Year 2012-2013
Investigate environmentally friendly disposal programs for MEMS.	Analysis will commence with feedback from formal consultation period.

9.3 Vendor Performance

Recommendation
One of the benefits of the draft NPS is the opportunity to introduce a process to improve the monitoring and measuring of vendor performance across the entire procurement lifecycle for MEMS.

As such, PWGSC is proposing the following:

- PWGSC will reference information regarding the supplier's history recorded in PWGSC's Vendor Information Management (VIM) System.
- Enhanced emphasis will be placed on monitoring vendor performance post contract award to ensure vendors are adhering to all contractual terms and conditions. Included in this will be the validation of post delivery support and maintenance.
- Stricter enforcement of the requirement to provide evidence of applicable Medical Device Establishment Licenses (MDEL). As a condition of being awarded a procurement instrument, all MDEL holders will be required to provide proof that an application for annual review has been made to the Establishment Licensing Unit on the anniversary of procurement instrument award.

Context
PWGSC has recently introduced a revised Vendor Performance Policy[10] to assist with mitigating procurement risk. A fundamental principle of this policy is the fair, open and transparent treatment of vendors.

[10] www.tpsgc-pwgsc.gc.ca/app-acq/arp-pns/ap11r1-pn11r1-eng.html

It must be emphasized that the success of any vendor performance program is early notification of issues by government departments to PWGSC. PWGSC will assess the severity of the issue and will take reasonable corrective measures ranging from informally dealing with the situation through to the enactment of the Vendor Performance Policy.

Consistent use of vendor performance clauses will enable government departments to receive their products and services that meet their requirements, and provide a standardized process for remedial action should performance issues occur. It will also allow suppliers to receive meaningful feedback on their contractual performance and support the development of positive ongoing relationships.

Implementation Plan
PWGSC will implement these recommendations as follows:

Activity	Timeframe
PWGSC to work with industry to establish a baseline indicating suppliers' current status with respect to implementing a quality control program.	Analysis to commence with feedback from formal consultation period.
Based on the results of the formal consultation, PWGSC will work with government departments to determine and implement acceptable evaluation criteria to measure quality control.	Fiscal Year 2013-2014
Medical Device Establishment License (MDEL) holders must provide proof that application for annual review was made to the Establishment Licensing Unit.	Annually, on anniversary of SO issuance or contract award.
Enhance emphasis on monitoring vendor performance post contract award to ensure vendors are adhering to all contractual terms and conditions.	Ongoing

9.4 Enhance Communication

Recommendation
Over the life of this NPS, PWGSC will work to continue to improve communication with government departments, industry and with other PWGSC regional procurement operations to bring greater transparency and consistency to the procurement process.

To support communication, PWGSC recommends:

- Implementing mechanisms for obtaining information and reporting on demand patterns for GC spend;
- Engaging government departments early in the procurement process for more complex projects; and

- Creating a MEMS communication process (e.g. Web presence) to better communicate with government departments, PWGSC regional offices and industry about developments relating to the MEMS category.

Context

While initial feedback from government departments reflected a general appreciation of the current communication process in place, there was a desire to enhance (more frequent and simpler) communication with PWGSC to improve understanding of how to work within the procurement processes available.

The development of stronger communication channels should permit PWGSC to become involved earlier in the government departments' procurement planning, leading to smoother and reasonable procurement timelines as well as earlier identification of opportunities for improvement. This enhanced communication should help identify to PWGSC critical elements for end users and allow PWGSC to get a better understanding of the demand across the entire procurement for MEMS.

Government departments are encouraged to identify to PWGSC issues or concerns, which will be escalated by PWGSC as needed. In turn, this should lead to smoother interaction with industry, providing all an opportunity to offer comments and suggestions on how to improve the overall process.

Through the implementation of more defined reporting requirements, PWGSC could receive pre-determined information that would facilitate the ability to understand purchasing trends. Further, the availability of this information would allow PWGSC to be more proactive in the managing and maintaining the relevancy of its MEMS product catalogues.

Implementation Plan

PWGSC will implement this recommendation as follows:

Activity	Timeframe
Review communication needs with selected government departments.	Analysis to commence with feedback from formal consultation period.
Establish community of practices with other PWGSC regions to ensure consistency of messaging and approach with government departments.	Fiscal Year 2012-2013
Messaging to government departments to encourage them to engage PWGSC in advance for larger more complex requirements.	Ongoing over the life of the NPS

Activity	Timeframe
Through enhanced reporting, develop and share information with respect to the GC MEMS demand patterns.	Fiscal Year 2012-2013

9.5 General Improvements to the Procurement Process

Improving the procurement process deals with elements such as the complexity of procurement instruments, duplications within those instruments, and the lack of clear detailed instructions. It is important to reduce this process burden in order to increase government department satisfaction and simplify suppliers' interaction with the GC.

9.5.1 Data Integrity/Checklist

Recommendation

PWGSC will work with government departments to implement simplified purchase requisition checklists in an attempt to ensure that all required information is identified upfront so as to minimize delays later in the procurement process.

A copy of the recommended requisition checklist, Policy Notification 99 can be located at http://www.tpsgc-pwgsc.gc.ca/app-acq/arp-pns/ap99-pn99-eng.html#anna

Context

PWGSC is committed to reducing delays in the awarding of procurement instruments for MEMS. Missing information can lead to delays and frustrations over the length of the procurement process.

The development and incorporation of a consistent checklist will ensure that all relevant information is included with the initial purchase requisition as well as assist government departments in considering all options.

Implementation Plan

PWGSC will implement these recommendations as follows:

Activity	Timeframe
Work with government departments to assess the benefit of adopting an enhanced requisition checklist specific to MEMS.	Analysis to commence with feedback from formal consultation period
Validate the data fields proposed and determine if any category specific fields should be included.	Analysis to commence with feedback from formal consultation period
Test the process with certain government departments to determine the impact and expand to other departments.	Fiscal Year 2012-2013

9.5.2 Definition of the MEMS Category

Recommendation

It is recommended that PWGSC validate its draft MEMS definition with industry and government departments and incorporate changes as applicable. By standardizing the definition it will make it easier for government departments to determine in which category their requirement falls (e.g. lab supplies versus medical supplies). A standardized definition will permit suppliers to align their product offerings more effectively to GC requirements.

Context

Uncertainty over terminology used within this category (e.g. consumables versus non consumables as well as what should be considered lab supplies versus medical supplies) has led to confusion by both government departments (in determining in where their requirements should reside) and suppliers (in marketing their product offering to the GC). This ambiguity has resulted in delays to the overall procurement process, creating frustration for both government departments and suppliers.

Implementation Plan

PWGSC will implement these recommendations as follows:

Activity	Timeframe
Validate the proposed MEMS definition.	Analysis to commence with feedback from formal consultation period
Finalize MEMS definition based on input collected through the formal consultation with industry and government departments.	Fiscal Year 2012 - 2013
As procurement instruments come up for renewal and/or award, changes will be made to align with the new definition.	Fiscal Year 2012 - 2013
Continue to monitor and evolve the definition as necessary.	Ongoing

10 Next Steps

The draft NPS will incorporate feedback received from the consultation as appropriate. The draft NPS will then be finalized and subsequently approved. Suppliers and government departments should anticipate that the NPS for MEMS will come into effect during Fiscal Year 2012-2013.

Appendix A: Medical Equipment, and Medical Supplies (MEMS) Definition

For the purposes of the MEMS Standing Offers, Medical Equipment and Medical Supplies are defined as a device which can be classified into one of Classes I to IV by means of the classification rules set out in Schedule 1 of the Medical Device Regulations[11].

Essentially this includes medical devices as defined by the World Health Organization[12], which "means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacture to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- Investigation, replacement, modification, or support of the anatomy or of a physiological process;
- Supporting or sustaining life;
- Control of conception;
- Disinfection of medical devices; and
- Providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Note: An accessory is not considered to be a medical device. However, where an accessory is intended specifically by its manufacturer to be used together with the 'parent' medical device to enable the medical device to achieve its intended purpose it is included in this definition.

Note: The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes.

Note: Products, which are considered to be medical devices, also include:

- aids for disabled/handicapped people

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[11] Medical Devices Regulations in English: http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/index.html

[12] Source: Medical Device Regulations Global overview and guiding principles in English: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf

- devices for the treatment/diagnosis of diseases and injuries in animals
- spare parts for medical devices”

Annex A: National Category Review: Medical Equipment and Medical Supplies

A1 PWGSC Contract Activity Analysis

Over a five-year period (FY05/06 to FY09/10), the average value awarded by PWGSC for Medical Equipment and Medical Supplies (MEMS) was $38 million per year, while on average there were 429 documents awarded. Contracts accounted for 47% of the number of documents awarded and 42% of the value awarded. Amendments, which are used to modify contracts and standing offers including exercising options, accounted for a large proportion (44%) of the annual business volume.

Table A-1 demonstrates that on average, between FY05-06 and FY09-10, CASMS accounted for 59% of the number of documents awarded and 75% of the value awarded. Western region, on the other hand, handled 8% of the number of documents but accounted for 8% of the average annual contracts awarded.

Table A-1. Value Awarded by Region/Sector

Region / Sector	Average Value Awarded	% of the Value Awarded	Average # of Documents	% of Documents
CASMS	$28,951,592	75.4%	253	59.0%
WESTERN	$3,011,757	7.8%	34	8.0%
PACIFIC	$2,094,006	5.5%	48	11.3%
ONTARIO	$2,070,486	5.4%	34	8.0%
QUEBEC	$1,278,656	3.3%	36	8.4%
ATLANTIC	$967,250	2.5%	17	4.0%
DMPS	$40,743	0.1%	2	0.5%
STAMS	$19,684	0.05%	0.4	0.1%
SSAMS	-$22,467	-0.06%	3	0.7%
Total	**$38,411,706**	**100%**	**429**	**100%**

Source: AIS based on 5-year average. AIS Data: FY05/06 to FY09/10.
Notes:

- CASMS = Commercial Acquisition and Supply Management Sector (HQ – Gatineau)
- DMPS = Defence and Major Project Sector (HQ – Gatineau)
- SSAMS = Service and Specialized Acquisitions Management Sector (HQ – Gatineau)
- STAMS = Service and Technology Acquisitions Management Sector (HQ – Gatineau)
- PACIFIC also includes Yukon.
- WESTERN also includes Northwest Territories.
- These figures exclude the following standard document exclusions: Supply Arrangements, Transfers into the Supply Revolving Fund and Consultant Open Agreements (RP Only). The estimated total values of DISO are excluded but call ups against that instrument are accounted for in the tables.

A2 Additional Market Information

This market analysis focuses on medical equipment and medical supplies. The draft NPS excludes items such as vaccines, chemicals, and pharmaceuticals, as supplier offerings and government department needs tend to differ between these three sub-categories. The sub-categories are considered to be apart by industry.

A2.1 Market Characteristics for Medical Equipment and Medical Supplies

In 2010, the Canadian medical equipment and supplies market was valued at $9.5 billion, which represent an increase of approximately 5% annually since 2005 (Datamonitor, 2010 and 2011). However, it should be noted that this positive growth has slown down significantly in 2010; for instance, the growth rate was above 5% annually from 2005 to 2009, but it dropped at 2% only in 2010 (Datamonitor, 2011). The market is forecast to reach $10.8 billion by 2015 (Datamonitor, 2011).

According to Industry Canada, Canada's commercial activity is geographically concentrated in Ontario (45%) and Quebec (21%). As of December 2010, there were 6,385 establishments involved in manufacturing and wholesaling-distributing medical equipment and supplies. More than 85% of these establishments were either micro (1-4 employees) or small businesses (5-99 employees), which render the concentration levels quite low. As a whole, this industry employed nearly 40,000 people across Canada in 2009.

This industry is import-oriented, with the United States representing 62% of the exports and 50% of the imports in 2010. With the economic recession, total Canadian exports and imports have declined over the course of the past two years (Industry Canada, 2011).

Competitive Landscape

Overall, firms in this industry compete primarily on the basis of quality, performance, technology and reliability. Competition is considered as moderate but is increasing partly due to the presence of large international players who try to benefit from economies of scale and differentiate themselves via extensive R&D investments and product innovation (Datamonitor, 2011; First Research, 2010).

With the recent positive growth in this industry, new players have been attracted to enter the market, which explain the increase in rivalry. However, a number of barriers to entry exist, such as: strict government standards and regulations in terms of product labelling, promotion and marketing, quality, record keeping and medical devices reporting; and, significant investment in R&D as they need to adapt to continuous technological and scientific advancements to remain competitive (Datamonitor, 2011). Furthermore, considering the unpredictability in client demand, suppliers in this industry are required to keep high inventory levels on-hand in order to accommodate short notice purchases, which can pose a significant barrier to new entrants as they

face high start-up and capital costs when trying to access suppliers and establish distribution channels (IBISWorld, 2010).

Given that this industry is driven by innovation, product life cycles are short compared to other manufactured products. Indeed, medical instruments and equipment are usually replaced on a regular basis. On the other hand, many Canadian health establishments such as hospitals and clinics reprocess or re-use some medical devices despite inherent risks related to such practices (Mergent, 2010). There are not many substitutes for the medical equipment and supplies. During less prosperous times, many medical institutions usually turn to pre-owned or refurbished medical equipment in an effort to reduce their operating costs (Mergent, 2010).

Demand Analysis

Demand determinants in this industry include health care budgets, population demographics and product innovation (First Research, 2011). For example, during the economic downturn, medical institutions that endured budget cuts tried to reduce their operational costs; consequently, the demand for refurbished medical equipment or reprocessing of single-use medical devices increased for some segments of this industry (Mergent, 2010).

Moreover, with the aging global population, an increase in hospital visits and consequently the demand for medical equipment and supplies is expected. Also, with the prevalence of certain medical conditions, the demand for specialized instrumentation and consumables will also go up (IBISWorld, 2010).

As advances in science and engineering evolve, new products are developed, which increases demand for these new innovations and, in turn, their large-scale production. The age of the capital equipment also serves as a demand indicator seeing as it dictates when products need replacement (IBISWorld, 2010).

The main consumers of medical equipment and supplies are hospitals, clinics, outpatient facilities, and medical offices. The fact that there are only few buyers present in the Canadian market raises their purchasing power, especially when they regroup themselves to buy (Datamonitor, 2010).

Supply Analysis

Typical inputs used to produce medical equipment and supplies include metal, plastic, glass, semiconductors, electronic products, and several others (IBISWorld, 2010). Given that this industry requires such a variety of inputs, it has very little control over prices. Manufacturers' production costs, profitability and purchasing power have been negatively impacted by increases in the price of raw materials between 2009 and 2010 (Datamonitor, 2010).

In this industry, suppliers of raw materials are numerous and vary by market

segment. Given the low differentiation between raw materials and low switching costs, supplier power is reduced as a result of manufacturers purchasing various inputs from different supplies (Datamonitor, 2010).

It should be noted that the degree of transformation of raw materials into finished goods is high in this industry compared to the manufacturing sector in general (Industry Canada, 2011).

Given the importance of R&D and intellectual property in this industry, human resources are critical. Skilled labour is in high demand and workers can earn higher wages compared to other manufacturing industries (IBISWorld, 2010).

Industry Trends

One recent trend in this industry is the more common use of robots to perform various surgeries in Canadian hospitals, as they are considered cost-effective and safer for patients (Mergent, 2011). Additionally, demand for portable medical devices have increased over the last few years, because of factors such as the aging population, healthcare costs, and accessibility in remote regions (Mergent, 2011).

Technology, intellectual property and R&D are key elements in this industry. While most of the R&D is done in-house by firms, part of it is acquired through the licensing of products from smaller companies, or as a result of mergers and acquisitions (IBISWorld, 2010). In Canada, mergers and acquisitions of medical device companies have recently been on the rise as the banking and credit environment has been loosened (Mergent, 2011).

It should be noted that the Government of Canada has been promoting partnerships for medical devices between the industry and public research institutions in various forms of fiscal incentives for R&D over the years, and continues on the same trend in its Economic Action Plan of 2012 (Mergent, 2011; OECD, 2011; Government of Canada, 2012).

Standards and Regulations

In Canada, Health Canada imposes high standards and many regulations on medical device manufacturers compared to other sectors, given the potential consequences of introducing unsafe products in the marketplace. This industry is subject to the Food and Drugs Act and Medical Devices Regulations. Regulations are in place to assess the safety, the effectiveness and the quality of new products before they are sold in Canada by categorizing them based on the risks associated with their use (Health Canada, 2010). According to the World Health Organization (WHO), this classification system is similar to the ones in place in the European Community and the United States (WHO, 2003). Health Canada has put in place tools and requirements to control the products, the establishments, the advertising and the vendor after-sale obligations; they are also monitored through annual license renewals (Health Canada, 2010). The WHO mentions that the practice of requiring establishments to be licensed is quite effective to

keep good records of the vendors compared to sale notifications.

There have been efforts to harmonize such regulations between countries, in order to facilitate international trade and standardize the quality and availability of medical devices globally. As an example, Canada has taken the European regulations as an example, thus smoothing the approval process for certain Canadian products in the European market; nevertheless, many challenges remain and usually result in increased time and cost of product development (WHO, 2003).

A3 Initial Engagement

PWGSC launched initial consultations with suppliers and government departments to provide them the opportunity to get their thoughts on the overall process and offer suggestions for improvement.

Government Departments

Government department feedback was solicited in the development of the draft NPS. Initial informal consultations were conducted with government departments in August 2010, where government departments provided comments and suggestions for improvement on the current procurement process.

Suppliers

To support the development of the draft National Procurement Strategy, the Office of Small and Medium Enterprises (OSME) was engaged to gain industry perspective through an initial consultation process and provided comments on the current procurement process and made suggestions for improvement. Recipients of a questionnaire were identified using suppliers registered against MEMS categories on the GC's Supplier Registration Information system.

A4 General Management of the Category

Contracting Approach

Government departments can purchase MEMS valued within their delegation of authority (typically to a maximum of $25,000 for goods and $2,000,000 for services). If government departments don't have the necessary expertise or financial authority to procure their requirement, PWGSC will manage the procurement on their behalf. The current procurement processes respect GC procurement policies and practices.

Methods of Supply

Contracts

Contracts are the preferred method of supply for medical equipment purchases. Some of the key factors that government departments and suppliers prefer include:

- Allows for clear and individual performance specifications, with additional clauses, and terms and conditions often being custom-built for the requirement;
- Equipment purchases may contain deviations from regulated terms and conditions, requiring negotiation, discussion and review by both procurement experts, clients and/or Departmental Legal Counsel;
- Evaluation is not based on price alone and requires some commodity-specific procurement knowledge and experience to oversee the evaluation/selection process;
- Necessity to manage risk on a situation by situation basis;
- Impossible to compose generic specifications for the high number of products covered under this category;
- Contracts permit open and fair competition for all suppliers and for every size of firms (various capacity requirements).

Standing Offers

Government departments and suppliers have identified SOs as the preferred method of supply for Medical Supplies and replacement parts. This method of supply has a high degree of acceptance for the following reasons:

- An administrative means to obtain goods from suppliers at pre-arranged pricing or pricing methods with set conditions, for specific periods of time or as requested;
- Easy to manage the repetitive nature of the purchases;
- Eliminates the need to purchase set quantities and associated warehousing and inventory challenges;
- Decreased administrative and procurement lead-times; and
- Open qualification results leading to multiple standing offer holders:
    - Facilitates Choice. Eases compatibility concerns as not all distributors have distribution rights for all manufacturers;
    - Ease of entry for existing and potential suppliers of various capacity requirements

NMSOs are available for use by all federal government departments and agencies for the purchase of products.

The current NMSO suppliers offer a mix of exclusive and generic products. All medical supplies and some low value medical equipment are addressed in the NMSOs. Capital asset medical equipment is contracted individually.

Suppliers offer complete product catalogues, however the catalogue formats and categories are proprietary to the suppliers. In this case, the current pricing methodology is based on discounts against distributor's published price lists.

No minimum order restrictions are established within the parameters of the standing offers. The absence of defined order quantities increases the risk

that suppliers will have to fulfill low value orders and the inefficiencies associated with it. While every effort is made to place regular orders containing multiple items, the NMSO holder must be prepared to ship in small quantities if requested to do so.

Prime Vendor Standing Offer

For the Medical Supplies "Prime Vendor" Standing Offers, 2 NMSOs were issued after a competitive process via MERX. The Offeror must be capable of stocking at least 90% of the items listed and must deliver products within three working days of receipt of an order, at an order fill rate of at least 95%. The Prime Vendor standing offer provides physiotherapy; operating room (OR); surgical; and labs consumables. One supplier currently provides physiotherapy products and another supplier handles the remaining three categories. Call-up limitations are $100,000 per individual call-up and it is the SO holder's responsibility to supply and update catalogues on a monthly basis.

The catalogue is required to include the following information for each available product:

- Generic description of the item (including a photo or illustration, if available);
- Package size (unit of issue);
- Name of manufacturer;
- Manufacturer's item name and product code;
- Offeror's assigned product code, cross-referenced to NATO Stock Number;
- Price (delivery, all contractor up-charges/discounts included, GST/HST extra); and
- Minimum stock quantity normally held in warehouse.

Despite the fact that it is an NMSO, it is very focused on the requirements of one key government department in that it contains specific clauses and is extremely difficult for other government departments to navigate and use the SO as well as for new suppliers to qualify. In fact, according to PWGSC SO reporting data, over 98% of the spend rests with DND[13].

Additionally, the NMSO contains an option for warehousing capability. For those items that are not normally stocked by the NMSO holder and for which they do not have a distribution agreement with the manufacturer/supplier, the Government of Canada has the option to purchase the item(s) directly from the manufacturer and have the NMSO holder warehouse and distribute the item(s) on the Government of Canada's behalf for a cost.

[13] Supplier SO activity reports. PWGSC data June 1, 2008 - June 30, 2011

In total, there were 14,426 call ups issued against these standing offers with the following observations[14]:

- Over 98% of the call-ups value was less than $100,000.
- Approximately 86% of the call-up value was less than $40,000.00

Table A-2. Call-Up Data Relative to Prime Vendor Program

Value Range ($)	Number of Call-Ups	Percentage of Call Ups	$ Value	Percentage of Dollar Value
<$0*	163	1.13%	-$29,152	-0.1%
>0<= $500	6,222	43.13%	$1,301,920	4.61%
>$500 <=$1,000	2,763	19.15%	$1,999,713	7.07%
>$1,000 <=$5,000	4,180	28.98%	$9,081,199	32.12%
>$5,000 <=$10,000	608	4%	$4,220,874	14.93%
>$10,000 <=$25,000	360	2.5%	$5,531,548	19.57%
>$25,000 <=$40,000	68	0.47%	$2,146,521	7.59%
>$40,000 <=$100,000	59	0.41%	$3,569,682	12.63%
>$100,000	3	0.02%	$443,855	1.57%
Grand Total	14,426		$28,266,160	

Note:

* Values included in this category were issued as credits.

MEMS Standing Offers

The second series of NMSOs relate to products that are consumables and non-consumables, typically the repetitive, low cost, commercially off the shelf items. There is a non-competitive process established and potential NMSO holders need only to show compliance to the following requirements some requirements in order to be awarded a NMSO:

- Offerors must be capable of representing and supplying products nationally;
- Proposed product must comply with and adhere to any applicable ISO standards;
- Offerors must be in compliance with the Medical Devices Regulations of Health Canada's Therapeutic Products Program, including the requirement for a Medical Device Establishment License (if applicable);
- Offerors with an annual business volume of at least $500,000.00 for the determined commodities relating to the applicable NMSO in the course of the last three years were considered.

Call-up limitations are set at $40,000 per individual call-up and a maximum of $24, 999 per line item. 99% of the call-up value was less than $40,000.00.[15]

[14] Supplier SO activity reports. PWGSC data June 1, 2008 - June 30, 2011
[15] Supplier SO activity reports. PWGSC data June 1, 2008 - June 30, 2011

Table A-3. Call-Up Data Relative to Medical Supplies SOs

Value Range ($)	Number of Call-Ups	Percentage of Call Ups	$ Value	Percentage of Dollar Value
<$0	432	3.12%	-$129, 062	-1.6%
>$0<= $500	10,839	78.29%	$1,545,724	19.4%
>$500 <=$1,000	1,234	8.91%	$863,115	10.8%
>$1,000 <=$5,000	1,047	7.56%	$2,161,331	27.1%
>$5,000 <=$10,000	158	1.14%	$1,056,988	13.3%
>$10,000 <=$25,000	110	0.79%	$1,690,467	21.2%
>$25,000 <=$40,000	23	0.17%	$713,558	8.96%
>$40,000 <=$100,000	1	0.01%	$58,981	0.74%
>$100,000 Total Value	0 13,844	0.00%	$0.00 $ 7,961 102	0%

There are currently 27 NMSO to respond to Government of Canada demand. Not all suppliers have exclusive rights to provide all products and are awarded according to specific product groupings determined by United Nations Standard Products and Services Code (UNSPSC) families.

The open qualification process encourages access to the Government of Canada market, avoiding a competitive process to determine SO holders.

Should product not have sufficient demand to be placed into the general catalogue, government departments can use Local Purchase Orders (LPOs) for lower dollar value – lower complexity requirements.

Supplier selection methods are generally consistent with “Lowest responsive technically compliant financial proposal”.

Special Considerations

Environmental Considerations

The National Procurement Strategy for MEMS aims to raise the awareness of environmental issues to vendors and demonstrate that the Government is implementing its Policy on Green Procurement. This policy ensures that purchasing decisions made by federal departments and agencies consider environmental performance along with other factors, such as cost, performance, quality and availability.

Analysis showed that the majority of MEMS procurement instruments put in place by PWGSC do not include any special provisions specifying that suppliers offer environmentally preferable products, unless at the specific request of the government department.

PWGSC has committed to internal greening initiatives that serve to measure progress towards greening goals, however, the decision to include green

considerations is often at the government department's discretion. The nature of the requirement will determine whether to include green considerations and to what extent they are used.

Aboriginal Access

Aboriginal firms are offered the same access to view and bid on opportunities as non-aboriginal firms. In collaboration with government departments and suppliers, PWGSC ensures that the objectives of the Procurement Strategy for Aboriginal Businesses (PSAB) and comprehensive Land Claims Agreements (CLCAs) are integrated into the procurement decision-making process.

Aboriginal Affairs and Northern Development are part of the current approval process for Requests for Standing Offers.

PWGSC will continue to work with government departments and suppliers to ensure potential aboriginal bidders are notified during bid solicitation periods, specifically if the opportunity is applicable to the (PSAB) and (CLCAs).

Small and Medium Enterprise (SME)

SMEs play a fundamental role in the supply chain for the procurement of MEMS within the GC as they work with the larger suppliers as part of a distribution network and/or for replacement and repair services. This allows SMEs who do not have the research and development capacity or ability to complete on very technical equipment requirements to fully participate in the GC market.

Small and Medium enterprises accounted for 63% of the value awarded for MEMS between FY05/06 and FY09/10.

Table A-4. Documents Awarded by Business Size

Business Size	Average Value Awarded	% of the Value Awarded	Average # of Documents	% of the Documents
Small	$18,831,460	49%	289	67%
Medium	$5,388,377	14%	49	12%
Large	$10,451,445	27%	45	11%
Other	$3,740,425	10%	45	11%
Total	**$38,411,706**	**100%**	**429**	**100%**

Source: AIS based on 5-year average. AIS Data: FY05/06 to FY09/10.
Notes:

- Other includes self-employed, foreign, and unknown.
- Small business enterprise: 1-100 employees
- Medium business enterprise: 101-499 employees
- Large business enterprise: 500+ employees
- These figures exclude the following standard document exclusions: Supply Arrangements, Transfers into the Supply Revolving Fund and Consultant Open Agreements (RP Only). The estimated total values of DISO are excluded but call ups against that instrument are accounted for in the tables

Vendor (Supplier) Performance

Supplier performance is monitored on an on-going basis by PWGSC Contracting Officers in collaboration with the government department. PWGSC will act as an

intermediary between the supplier and government department to ascertain the severity of the issue. PWGSC's actions can range from documenting the performance in the supplier's history file maintained in the Vendor Information Management (VIM) system through to contract termination for default.

Commonly used supplier performance measures include:

- Random spot checks with government departments;
- Quarterly business volume reports;
- Investigation of a government department's claims;
- Quality of goods and deliveries;
- Comparison of received invoices against delivery slips; and
- Monitoring of invoices.

Failure by a supplier to fulfill its contractual obligations could impact a supplier's ability to bid on future opportunities and/or the application of a vendor performance corrective measure[16].

Standards and Specifications

Third party specifications such as the Canadian General Standards Board and the Canadian Standards Association are used as applicable. Manufacturers are mandated to ensure that their products conform to basic regulations and standards.

The various procurement offices manage; based on the government departments request, which (if any) standards are to be used as part of the bid solicitation. The potential inclusions of standards and specifications may be subject to a number of federal, provincial and municipal laws and regulations as well as international agreements that the GC may be participating.

Contract Management

Within the Acquisitions Branch of PWGSC contracting officers are encouraged to use templates to assist in the management of low, medium and high complexity procurement where appropriate.

Failure of suppliers to follow any of the identified terms and conditions could result in the setting aside of the procurement instrument, or termination of the contract and the application of a vendor performance corrective measure.

[16] Policy Notification PN-11R1 dated November 4, 2010 is to be referenced for the Vendor Performance Policy (VPP): http://www.tpsgc-pwgsc.gc.ca/app-acq/arp-pns/ap11r1-pn11r1-eng.html.

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