

Sample Template Statement of Work

A Statement of Work (SOW) is a narrative description of the required work. It stipulates the deliverables or services required to fulfill the contract, and it defines the task to be accomplished or services to be delivered in clear, concise and meaningful terms.

E1.0 Scope:

E1.1 Title:

The title is how the work will be referred to.

E1.2 Introduction:

Provides a brief description of the tasks or services required.

E1.3 Estimated Value:

Provides a total estimate of the overall value of the requirement, including the cost of the professional services, the travel and living costs, translation, miscellaneous costs, GST/HST and any other costs which will be associated with the requirement.

E1.4 Objectives of the Requirement:

Describes what is to be achieved or delivered by the completion of the contract. It also identifies the intended use of the completed requirement.

E1.5 Background and Specific Scope of the Requirement:

Identifies the situation leading up to the requirement. It describes the range, extent, and parameters around the work to be completed in association with the contract and those events and circumstances leading to the need for this contract.

This section may also include a description of the organization, end users, previous contract work and its success or failure, bibliography, references, technical experts in the field, previous contractors, etc. - anything that will assist the contractor in formulating a good bid.

It identifies how the requirement which is the subject of the SOW fits within a particular drug submission/ medical device application and highlights the relevant performance targets overall.

E2.0 Requirements:

The requirements describe the tasks or activities to be performed by the Contractor. It also includes a detailed description of what is required for each of the identified deliverables. The description will provide sufficient information so that all parties will be able to understand what will signal completion of a phase or milestone in the work. In most situations, this Section will identify what methodology and sequence each of the deliverables will need to meet, how the deliverable will need to be delivered and what will be the relationship of one deliverable with another. This section will provide information on the language, format, version and content requirements for each task or activity and each deliverable or milestone in the work. It will also reference the Schedule and Estimated Level of Effort expected for completion of the work; any Specifications or

Standards which will be used; and the Method and Source of Acceptance which will be applied by Health Canada to the deliverables. This information may help to establish a progress payment schedule.

You may see all this information included in a table (see below) and/or text.

E2.1 Tasks, Activities, Deliverables and Milestones (Work Breakdown Structure):

TASKS/ACTIVITIES	DELIVERABLES/ MILESTONES	CONTRACTOR LEVEL OF EFFORT	HEALTH CANADA ACTIVITIES & REVIEW	MILESTONE PAYMENT	TIME TENTATIVE SCHEDULE

E2.2 Specifications and Standards:

This section identifies the manner in which the work is to be delivered and will be measured as completed. In some cases, the information provided in the Deliverable or the Method and Source of Acceptance Sections of the SOW will be sufficient. In other cases, specific reference will be made to the details and qualitative and quantitative measures which will be used by Health Canada to determine completion and satisfaction with the work. It also identifies the guidelines and templates that must be followed or used by the Contractor in completing the work. Some relevant examples might be the reference to the specific section of the International Committee on Harmonization Guidelines or the use of the PSEAT or other guidelines.

E2.3 Technical, Operational and Organizational Environment:

Provides details on the technical, organizational and operational environment in which the work will be completed. It is more significant in work where technical compatibility issues may arise. In some cases, it is important to describe in this Section how the work will fit within other initiatives and who will be the ultimate end user of the requirement.

E2.4 Method and Source of Acceptance:

*Provides a description of the performance, quality, format and testing requirements which will be used to measure whether the work is acceptable or not.
The following language might be used:*

All deliverables and services rendered under any contract are subject to inspection by the HC Project Authority. Should any deliverables not be to the satisfaction of the HC Project Authority, as submitted, the HC Project Authority shall have the

right to reject it or require correction before payment will be authorized.

E2.5 Reporting Requirements:

Describes any performance or status reporting requirements which will be expected of the Contractor during the life of the Contract. Includes the format, frequency, number of copies and specific content requirements. It will also identify the need for presentations, conferences or status meetings, if required between the Contractor and the Project Authority.

E2.6 Project Management Control Procedures:

Provides details of how the Project Authority will control the work (progress meetings, demonstrations, prototypes etc.). It will identify how the payment schedule will be matched to the measurement of performance throughout the contract. Contract management and controls in the SOW should be specific to the work and tasks.

The following language might be used:

The HC Project Authority shall ensure the contract will be brought in on time, on budget and of an acceptable quality; i.e. submission of progress reports, system tests, etc.)

E2.7 Change Management Procedures:

Provides a description of the process by which any changes to the Scope will be handled. It clearly defines that no changes will be implemented without first obtaining the approval of the Contract Authority in writing and as required the complete processing of a Contract Amendment.

The following language might be used:

Health Canada does not anticipate any changes to the requirements detailed in this SOW. However, if changes do arise they must be done in writing by the HC Project Authority, and an amendment must be prepared to reflect these changes.

E2.8 Ownership of Intellectual Property:

It is expected that there will be no intellectual property created as a result of the Contract. In most cases, the Crown will own Copyright.

The following language might be used:

The Crown will own Copyright.

Health Canada has determined that any intellectual property arising from the performance of the work under the contract will vest in Canada, as per Section 6.5 of the Treasury Board Policy on Title to Intellectual Property Arising Under a Crown Procurement Contract which states that the Crown may retain ownership of the intellectual property:

“Where the Foreground consists of material subject to copyright with the exception of computer software and all documentation pertaining to that software.”

E3.0 Other Terms and Conditions of the SOW:

E3.1 Authorities:

Identifies who will perform the role of the Project Authority and the Contracting Authority and the person who will handle Administration and Invoicing Questions. It also clarifies how the Contractor is to interact with and obtain direction from the Project Authority.

E3.2 Health Canada's Obligations:

Identifies the access to facilities, the loan or use of Government Furnished Equipment, the access to documentation, networks, etc. which Health Canada will provide to the Contractor. The following are examples of the contents that may be included under this heading:

- access to Drug library, government and departmental policies and procedures, publications, reports, studies, etc.
- ensure availability of staff with whom the contractor may need to consult;
- access to appropriate guidelines (ICH guidelines and templates, if applicable);
- provide comments on draft reports within five working days from receipt of report;
- schedule teleconferences, if required;
- provide applicable documentation as per Section E6.1;
- provide other assistance or support.

E3.3 Contractor's Obligations:

The following are examples of the contents that may be included under this heading:

- keep all documents and proprietary information confidential;
- meet all tasks, deliverables and milestones as identified in Section E2.1;
- return all materials belonging to Health Canada upon completion of the contract;
- delete all electronic forms of correspondence (e.g. emails, etc.);
- submit all written reports in hard copy and electronic Microsoft Office Word;
- attend meetings with industry, if necessary;
- participate in teleconferences, as needed;
- maintain security clearance with no conflict for the duration of the contract;
- conduct and maintain all documentation in a secure area;
- attend meetings at Health Canada's site, if required;

This section will also clarify all other obligations of the Contractor which have not already been identified.

E3.4 Location of Work, Work site and Delivery Point:

Identifies where the work is expected to be completed.

The following language might be used:

Due to existing workload and deadlines, all personnel assigned to any Contract must be ready to work in close and frequent contact with the Departmental Representative and other departmental personnel in the NCR. The work will be performed at the Contractor's personal residence or private clinic.

E3.5 Language of Work:

Identifies if the work must be conducted in a particular language and if so by which role or for which task.

E3.6 Special Requirements:

Indicates if there will be any requirements for special licenses, information on patents, permits, bonds or import/export details which may be required of either Party.

In most cases, this Section is considered Non-applicable.

E3.7 Security Requirements:

In order to undertake the work the Contractor will need to demonstrate that they meet the security requirements in advance of Contract Award. Attached is the web link for your information.

Link: http://www.tbs-sct.gc.ca/pubs_pol/gospubs/forms/330-23e.pdf

Contractors/Sub-Contractors are required to meet the Government of Canada's Security Policy for collecting, controlling, storing and transporting sensitive information up to the Protected "B" level on behalf of Health Canada. Before forwarding any "Protected" information, Health Canada's Project Authority shall first ensure that the contractor/sub-contractor has been security screened to the "Reliability Status" security level (formerly Enhanced Reliability).

Health Canada's Project Authority must also ensure that the appropriate physical security safeguards for Protected "B" information are met at the contractor's/sub-contractor's facilities. The minimum storage and handling requirements for Protected "B" information are as follows:

- All information should be stored and processed in an "Operations Zone" (An Operations Zone is an area where access is limited to security screened personnel who work there (need-to-know principle) and to properly-escorted visitors.
- All information must be locked up (all lockable commercial office furniture, commercial door locks are suitable) when not in use.
- Periodic monitoring on a regular basis must also be conducted by the contractor/sub-contractor to ensure there has not been a breach of security.

The following language might be used:

It is a condition that, prior to performance of any obligation under any contract, the Contractor and sub-contractors and their employees assigned to the performance of such contract will be cleared by the federal government at the Reliability level.

E3.8 Insurance Requirements:

In most cases, this Section is considered Non-applicable.

E3.9 Travel and Living Expenses:

If travel is required, the estimated amount will be specified. Note that the current TBS Travel Directive will apply.

E4.0 Project Schedule:

E4.1 Expected Start and Completion Dates:

Identifies the period in which the work is to be completed. More details are provided in the section of the SOW which identifies the specific schedule which will be required for completion of the work.

The following language might be used:

The services of the Contractor will be required for a period of approximately (*weeks, months or years*) commencing on or about (*day, month, year*). The expected completion date of this project is (*day, month, year*).

E4.2 Schedule and Estimated Level of Effort (Work Breakdown Structure):

See Section 2.1 for work breakdown structure.

E5.0 Required Resources or Types of Roles to be Performed:

Provides a brief description of the roles to be performed by the Contractor's resources, if applicable and the specific expertise or minimum requirements for each role.

The following language might be used: (*Add experience required*)

- ***Medical Licence to practice in Canada***
- ***Good standing with the provincial College of Physicians and Surgeons, etc.***

E6.0 Applicable Documents and Glossary:

E6.1 Applicable Documents:

Appends any relevant background documents, drawings, specifications, samples or information which will be important to demonstrate what, how and when the work will need to be completed.

E6.2 Relevant Terms, Acronyms and Glossaries:

Provides an explanation of any relevant terms, acronyms or wording used in the body of the SOW.

The following language might be used:

*HC - Health Canada
TPD - Therapeutic Product Directorate
OBT - Office of Business Transformation
TBS - Treasury Board
SOW - Statement of Work*

E6.3 Sign-off for proposed resource:

The following phrase will appear at the end of each Statement of Work.

NOTE: Before signing the Statement of Work, if you have any questions or concerns,

please call the Project Authority indicated above to negotiate any issues.

If you agree to the requirements of this Statement of Work, please sign and date the document which will be accepted as your proposal by Health Canada, and return to my attention by facsimile (613) 946-0729 no later than 2 working days from receipt of the document.

Please return an original signature copy by mail.

Signature: _____ Date: _____

SAMPLE