Business requirements and solution strategies

NNHPD Legal Opinion Database

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Version 0.1

NNHPD

Health Products and Food Branch

Health Canada

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# Document revisions

|  |  |  |  |
| --- | --- | --- | --- |
| Date | Version Number | Document Changes | Author |
| 2017/03/20 | 0.1 | Initial Draft | Peijun Zhang |
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# Introductions

## Project summary

### Objectives

Deliver a tool used to manage the data of legal opinions related to natural health products, over-the-counter drug products and related or parallel issues. The database will be scalable to house information and metadata for other related stakeholders within and outside of the Health Products and Food Branch (HPFB) and have the following features:

* + User -friendly interfaces for initial data entry
  + User- friendly interfaces for data audit, modification, and basic workflow
  + User -friendly reports generation capabilities
  + Search functionality

### Background

The purpose of the NNHPD legal-opinion database is to assist NNHPD in tracking, gathering, organizing, storing and searching legal opinions which concern Natural-Health and Over-the-Counter (OTC) drug products as well as related or parallel issues.  This database will enable NNHPD to efficiently track, co-ordinate, and store legal opinion requests and receipt of said legal opinions between NNHPD and Health Canada’s Legal Services (DLSU).  In addition, the database will serve as a very useful tool to permit Bureaux to effectively and efficiently identify legal opinions which touch on regulatory and policy projects and functions to enabling different program areas to understand past opinions and inform future work and decisions.  Also, the database will limit the duplication of redundant requests and provide NNHPD a single repository for completed and active opinions.   It would also serve a critical IM preservation function in storing legal opinions, limiting the likelihood that they are misplaced or inadvertently deleted.  The principal functional requirements of the database would be to allow NNHPD to track the progress of the requests, to have basic reporting capabilities, to search on key fields and keywords, and to manage the process of requesting, organizing and storing legal opinions.  The chief constraint of the system is that it will require a security element of user restricted access to store solicitor-client and litigation privileged documents and will require a capacity for multiple users to access it simultaneously.  Users also need to be informed that the database is not intended to replace consultations with and requests of legal opinions from DLSU on current issues.

The primary users of this database will be NNHPD staff -- especially those in the Bureau of Licensing Services and Systems (BLSS), Bureau of Product Review and Assessment (BPRA) and Bureau of Program Policy, Risk Management and Stakeholder Engagement (BPPRMSE)  --  involved in policy and regulatory work.  Outside of NNHPD, the Manager and Senior Litigation Officer of the Litigation Support and Document Management Services (LSDSMS) of the Resource Management Operations Directorate (RMOD) would be included as users.  It is expected that upwards of twenty (20) users could be logged in at the same time.  Users would access the system through a username and password protocol. User accounts would be managed by the Systems group of BLSS.   In line with the security constraints of the data held on this system, users would require a minimum enhanced reliability security clearance.

The estimated data size for this database is 10 Gb.  Data will be entered in the form of coding by NNHPD Central Registry staff, supervised and quality controlled by the Senior Advisor of BLSS.  Data entry will not require an approval form from designated users.    Viewing rights will be accorded all users for whom a user account is created.  The proposed data model will closely mirror that established by the Regulatory Operations and Regions Branch for its legal-opinions database.

User interface for the proposed NNHPD legal-opinions database will not provide off HC intranet login.  The policy will be the same as any other off site access where the user would need to log in through HC intranet (VPN or web office) and access the site through this way.  Direct access to HRE and the site will not be provided.

## Project Scope

### In scope functionality

* Data capturing functionality and user interfaces
* Data displaying, searching, and reporting functionality
* Data modification, audit, and workflow functionality
* User administration functionality
* Bilingual user interfaces (English, French)

### Out scope functionality

* Historical data loading/transferring
* Fully functional workflow

## System perspective

### Assumptions

* Users are able to access to the Health Canada intranet.

### Constraints

### Risks

### Issues

# Business process overview

## Current business process (As-is)

Not available. This is the first stage of development

## Proposed business process (To-be)

* Users collect related data
* Users enter /modify data
* Users sort data to generate reports



# Business requirements and proposed solutions

## Requirement priorities

The requirements in this document are prioritized as follows:

|  |  |  |
| --- | --- | --- |
| Value | Rating | Description |
| 4 | Critical | This requirement is critical to the success of the project. The project will not be possible without this requirement. |
| 3 | High | This requirement is high priority, but the project can be implemented at a bare minimum without this requirement. |
| 2 | Medium | This requirement is somewhat important, as it provides some value but the project can proceed without it. |
| 1 | Low | This is a low priority requirement, or a “nice to have” feature, if time and cost allow it. |

## User Management, Permissions, User Roles, and Access Controls

### Summary

* No anonymous users are allowed to access to the system
* User account creation and modification must be conducted by designated users only with proper permissions
* Users should be able to view and modify (limited fields) their account
* User permissions and roles must be implemented

### Functional requirements

|  |  |  |
| --- | --- | --- |
| ID | Requirement | Priority |
|  | Blocking the access to the system by anonymous users | Critical |
|  | Creating user accounts | Critical |
|  | Login and logout | Critical |
|  | Designating role(s)/permissions to users | Critical |
|  | Changing account status (active/blocked, roles ) by specified users | Critical |
|  | Creating user roles | Critical |
|  | Viewing ‘my account’ and changing profile(limited fields) | High |
|  |  |  |
|  |  |  |

### User roles and permissions

|  |  |
| --- | --- |
| Role | Permissions |
| Administrator | System administration |
| Coordinator | User account administration, pick list references |
| authenticated user | Data management |

## User interface

The system must supply full bilingual user interfaces, language switching trigger.

### Functional Requirements

|  |  |  |
| --- | --- | --- |
| Requirement | Priority | Note |
| Full bilingual user interfaces | Critical |  |
| Language Switcher | Critical |  |
| Web based user interfaces | High |  |
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### Non-functional Requirements

|  |  |  |
| --- | --- | --- |
| Requirement | Priority | Note |
| HC intranet- wide access | Critical |  |
| Concurrent multiple user login | Critical |  |
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## Data model and requirements

### Data model



#### Priority

Bilingual data: Full

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality |
| Name |  | text | yes |  | 1 |
| Description |  | Long text | No |  | 1 |
| priority ID |  | Hidden, number | Yes |  | 1 |

#### Status

Bilingual data: Full

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality |
| Name |  | text | yes |  | 1 |
| Description |  | Long text | No |  | 1 |
| Status ID |  | Hidden, number | Yes |  | 1 |

#### Requesting unit

Bilingual data: full

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality |
| Name |  | text | yes |  | 1 |
| Description |  | Long text | No |  | 1 |
| Requesting unit ID |  | Hidden, number | Yes |  | 1 |

#### Requester

Bilingual data: no

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality |
| First Name |  | text | yes |  | 1 |
| Surname |  | Text | yes |  | 1 |
| Requester\_id | Hidden, number | Yes |  |  | 1 |
| Requeting\_unit\_id | reference | Requesting unit |  |  | 1 |

#### DLSU Contact

Bilingual data: no

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality |
| First Name |  | text | yes |  | 1 |
| Surname |  | Text | yes |  | 1 |
| Dlsu\_contact\_id | Hidden, number | Yes |  |  | 1 |

#### Bureau/project

Bilingual data: full

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality |
| Name |  | text | yes |  | 1 |
| Description |  | Long text | No |  | 1 |
| Bureau ID |  | Hidden, number | Yes |  | 1 |
| Directorate ID |  | Reference | yes | Directorate | 1 |

#### Directorate

Bilingual data: full

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality |
| Name |  | text | yes |  | 1 |
| Description |  | Long text | No |  | 1 |
| Directorate ID |  | Hidden, number | Yes |  | 1 |

#### Legislation

Bilingual data: Full

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality |
| Name |  | text | yes |  | 1 |
| Description |  | Long text | No |  | 1 |
| legislation unit ID |  | Hidden, number | Yes |  | 1 |

#### Format

Bilingual data: Full

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality |
| Name |  | text | yes |  | 1 |
| Description |  | Long text | No |  | 1 |
| Format unit ID |  | Hidden, number | Yes |  | 1 |

#### Legal Opinion

Bilingual data: Full

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Field label English | Field label French | Type | Required? | Picklist reference | Cardinality | Allow to add, edit reference/picklist inline |
| Priority |  | reference | yes | priority | 1 | no |
| status |  | reference | yes | status | 1 | no |
| requester |  | reference | yes | requester | 1 | yes |
| Bureau |  | reference | yes | Bureau | 1 | yes |
| DSLU contact |  | reference | yes | DSLU contact | 1 | yes |
| Tag |  | text | yes |  | 1 |  |
| background |  | Long text | no |  | 1 |  |
| Relevant chronology |  | Long text | no |  | 1 |  |
| issue |  | Long text | Yes |  | 1 |  |
| Subject line |  | Long text | yes |  | 1 |  |
| Legal opinion request |  | Long text | yes |  | 1 |  |
| Summary of legal opinion |  | Long text | no |  | 1 |  |
| Department approach taken |  | Long text | no |  | 1 |  |
| Related legal opinion |  | reference | no | Legal opinion | unlimited | no |
| Relevant legislations |  | reference | no | legislation | unlimited | no |
| Main date |  | date | yes |  | 1 |  |
| Create date |  | date | yes |  | 1 |  |
| Receive date |  | date | yes |  | 1 |  |
| Date sent to DLSU |  | date | no |  | 1 |  |
| Attachment |  | file | no |  | unlimited |  |
| format |  | reference | yes | format |  |  |
| Impacted NNHPD Bureaus/projects |  | reference | no | NNHPD Bureaus/projects | unlimited |  |

#### Picklists

### Functional requirements

The legal opinion entries must be organized by groups. The members of a group can add, edit, view all legal opinion entries of the group. Non-members cannot access to the contents of groups.

|  |  |  |
| --- | --- | --- |
| Requirement | Priority | Note |
| Legal opinion entries organized by groups | Critical |  |
| Creation of groups | Critical |  |
| Group member management | Critical |  |
| Group member permission management | Critical |  |
| Data locking to prevent concurrent data editing | critical |  |
|  |  |  |
|  |  |  |
|  |  |  |
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### Group member roles and permissions

|  |  |
| --- | --- |
| Role | Permissions |
| Administrator | Administer members, data management |
| member | Data management |
|  |  |

## Reports

### This database will enable the administrator and users to generate reports on all data fields. Including such routine reporting as the number of requests by unit (or impacted units) sent to DLSU on a monthly or annual basis. This database would also enable to report on outstanding requests or time spans between the initial request for opinions and the delivery of opinions. It would also be able to generate reports on the impacted legislation/regulation.

### Report format