National Occupational Standard for

Regulatory Affairs Associate in Bio-Health

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CONTENTS

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One additional expert contributed to the standard however they wished to remain unacknowledged.

2 A COMPETENCY FRAMEWORK FOR INDIVIDUALS WORKING IN THE BIO-ECONOMY

2.1 What is a National Occupational Standard?

In Canada, National Occupational Standards are industry-developed and validated documents that identify and group tasks/competencies associated with a particular occupation. They also describe the knowledge and skills that a worker must demonstrate to be considered competent.

The former Alliance of Sector Councils (TASC) outlined 11 guiding principles for creating National Occupational Standards (NOS). NOS for the Canadian bio-economy meet all 11 principles and are developed to meet the current and future human capital management needs of the Canadian bio-economy.

2.2 How are we defining a competency?

We define a competency as ***a set of related behaviors that describe successful performance in a designated area. It is a behavioural expression of how people integrate knowledge, skills, attributes, and attitudes to produce a value-adding result in a defined situation.***

The competency statement includes a description that integrates skills, knowledge, and actions into a sequence of activities that deliver a value-added product or service.

Performance Indicators is the term we use for the behaviours grouped under each competency that describe the level of mastery the incumbent role must demonstrate when executing a task.

For this project, we have organized the competencies into four categories.

Core Competencies are those competencies that describe the "essence of the role" — that is, they are the one to three most critical competencies that may be applicable across multiple roles in a function or job family. All levels of personnel in this function would typically share them. These competencies may also act as qualifiers that differentiate the function from other functions.

Technical Competencies are those competencies related to specific roles or professions that enable an individual to work, function, and succeed in that role. They address the various responsibilities that job incumbents encounter in a role. For example, a surgeon's technical competencies would encompass multiple surgical tools, techniques, and conditions that could be part of the position.

Similarly, technical competencies for a lawyer would contain various legal situations that they encounter in the context of a particular field of practice.

Regulatory Competencies are those competencies that describe compliance with prescribed practices and mandated obligations under applicable laws, regulations, and industry standards. They ensure that critical work processes are implemented and integrated into all work activities. They are of absolute importance where economic behaviours can impact human conditions.

Personal/professional Competencies are those competencies that enable an individual to be successful working with others and fulfilling their responsibilities in a work context. Personal and professional competencies are not necessarily role specific.

2.3 Levels of complexity of work

It is important to recognize how the complexity of work varies along an organizational continuum. At one end of this continuum is low-complexity, clearly-defined, task-driven work. At the other end of the continuum is work that is higher in complexity, not as well-defined, and requires higher-level thinking and decision-making skills and a greater degree of autonomy. Results are recognised over a longer period of time and are more difficult to assess.

Figure 1: Demonstrates how the level of complexity changes with the role responsibilities

Complexity Level	Examples of Work at Different Complexity Levels	Typical Roles/Titles
Most Complex	Construct and pursue worldwide strategic plans in large corporations.	CEOs of the largest trans-global corporations
	Construct and pursue worldwide strategic plans.	C-suite executives at multi-national organizations
	Lead the accumulated impact of multiple business units.	C-suite executive at large, multi-location organizations
	Optimize the function of a single business unit or corporate support staff.	General manager; plant manager
	Manage multiple, interdependent projects; balance resources among departments.	Engineering manager
	Plan and carry out sequential projects while considering contingencies and alternatives.	Maintenance manager
	Accumulate information to diagnose and anticipate problems; proactive; notice trends.	Maintenance technician
Least Complex	Follow predefined procedures; seek help when encountering an obstacle. The ability to anticipate problems is not expected.	Maintenance labourer

We define the complexity levels within the profiles at four levels:

Foundational — performance focus is on the execution of procedures and tasks involving own job role.

Operational — performance focus includes some discretion in the planning and executing of work. The work typically includes assessing the quality of the work outcomes and taking corrective action to ensure quality.

Specialist — performance focus is on translating goals and standards to team members and ensuring that work done under the person's responsibility area complies with all corporate standards.

Strategic — performance focus is on leading work and the accumulated impact of work in an independent business unit or across a whole organization. The impact of work at this level is often not visible until the medium to longer term.

The following example illustrates the different complexity levels within a profile.

Competency Name: Research Ethics **Competency Definition:** Exercises integrity and professionalism to ensure all research is performed responsibly in keeping with the ethical principles of beneficence and nonmaleficence. Competence at this level is demonstrated when the **Research Manager**:			
Performance Indicators			
Foundational	Operational	Specialized	Strategic
Diligently follows research procedures and protocols mandated by legitimate authorities and professional organizations.	Regularly monitors own actions and decisions to ensure they align with professional and organizational values.	Holds self and staff accountable to the organization's values, ensuring compliance with the policies and procedures related to scientific ethics and rules of conduct.	Fosters an organizational culture of integrity and ethical business practices by unwavering personal example.

2.4 Overview methodology for the development of national occupational standards

National occupational standards were developed using a multi-step process.

Step	Description	Result/Output
1	Identify critical roles in the bio-economy through primary and secondary research.	List of 50 key roles
2	Create draft profiles with critical competencies for the roles, performance, and knowledge indicators.	Draft profiles
3	Review the draft profiles with industry subject matter experts to refine the competencies, performance, and knowledge indicators.	Reviewed profile with design inputs from industry experts
4	Further validation and review by industry via online focus group.	Validated profiles by industry experts
5	Broader validation of the draft profiles via national online surveys.	Occupational Standards validated on a national level by experts from the different sectors
6	Addition of the Essential Skills and Canadian Language Benchmark (ES/CLB) ratings.	Nationally validated NOS profiles with ES/CLB profile for each NOS

3 REGULATORY AFFAIRS ASSOCIATE IN BIO-HEALTH COMPETENCY FRAMEWORK

3.1 Competency diagram for Regulatory Affairs Associate in Bio-health

Competencies		Complexity Level			
		1	2	3	4
Core Competency					
1	Ethics/Integrity				
2	Quality Orientation				
3	Regulatory Systems and Documentation				
4	Regulatory Support for Product Development in Bio-health				
5	Post-market Product Registration and Compliance				
6	Developing a Regulatory Strategy for the Organization				
7	Liaising with Regulatory Professionals				
8	Risk Management				
9	Professional Writing for Regulatory Affairs				
10	Digital Skills for Regulatory Affairs				
Industry Regulatory Competencies					
	Included in Technical Competencies above				
Personal and Professional Competencies					
11	Collaboration for Regulatory Affairs				
12	Continuous Learning				

Complexity Level Legend

1. Foundational
2. Operational
3. Specialist/Manager
4. Expert/Executive

Competencies		Competency Level			
		1	2	3	4
Personal and Professional Competencies					
13	Effective Interpersonal Communication for Regulatory Affairs				
14	Judgement/Strategic Thinking in Regulatory Affairs				
15	Planning and Organizing Work				
16	Professionalism/Emotional Intelligence				

3.2 Definition of occupation

The Regulatory Affairs Associate in Bio-health works under the guidance of a manager or external expert to provide regulatory support to the development of new products and maintenance and care of existing marketplace products in the biotechnology industry. They execute the organization's interests and objectives while interacting with regulatory agencies, and work to ensure product and organizational regulatory compliance in the pre- and post-approval stages. They seek to anticipate risks associated with regulations related to product development; contribute to the development of new regulations, policies, and guidelines; help ensure the quality and safety of the product; make recommendations on how products are sold and promoted; and help ensure products meet research standards and quality.

Under the guidance of a manager, the Regulatory Affairs Associate in Bio-health works on the development and completion of a variety of documents to ensure regulatory compliance. They maintain regulatory information systems both electronically and in hard copy, as applicable. They help to ensure that documents are accurately presented, scientifically sound, and encompass all relevant material necessary for a complete submission while still representing the best interests of the organization. They adhere to regulatory Standard Operating Procedures (SOPs), operational SOPs, and internal departmental procedures, and help identify necessary revisions.

Applicable To	Bio-Health	Agri-Bio	Bio-Industrial	Bio-Energy
	■			

The level of complexity of the role is:

Span of Complexity Levels	Foundational	Operational	Specialist/ Management	Expert/Executive
		■		

3.3 Level of education, training, or designations requirements

Typical Education Required	Secondary	College	Bachelor	Master	PhD
			■		
Typical Starting Experience	**0–5 yrs.**	**5–10 yrs.**	**10–15 yrs.**	**15–20 yrs.**	**20+ yrs.**
	■				

- Bachelor's degree in a relevant science (such as food science, biology, biochemistry, pharmacy, medicinal chemistry, biotechnology, biomedical science, or biomedical engineering) is recommended
- Academic research, practical research, or laboratory work experience is an asset
- Experience in a generalist role in regulatory affairs within the biotechnology or biopharmaceutical industry, at a health authority, or other relevant experience is an asset
- Experience working in cross-functional teams
- Experiencewith institutional review boards (IRBs) and ethical committees (ECs) is an asset

3.4 Core competencies list for Regulatory Affairs Associate in Bio-health

3.4.1 Ethics/Integrity

Consistently holds self and staff accountable to a high standard of ethical conduct in all regulatory actions and decisions, including the integrity of data generated and transmitted, in order to foster a positive culture of ethical regulatory compliance within the organization.

Competency in this role is demonstrated when the individual:

- Proactively practices respectful, honest behavior in the workplace.
- Regularly monitors own actions and decisions to ensure they align with professional and organizational values.
- Clarifies ambiguous situations with authority to ensure personal actions and decisions are aligned with regulatory guidelines and requirements.
- Reviews reports to ensure the accuracy and integrity of all information and data collected, generated, and reported by self or staff.

Knowledge required for competency at this level:

- Working knowledge of the organization's code of conduct
- Working knowledge of the code of conduct for regulatory professionals

3.4.2 Quality Orientation

Assures quality through the implementation and monitoring of repeatable and/or auditable processes to confirm that all regulatory activities are appropriately conducted and that regulatory data is generated and managed according to approved standards and best practices.

Competency in this role is demonstrated when the individual:

- Contributes to the development of best practices for all regulatory processes.
- Contributes to the development of SOPs for all regulatory data collection and reporting.

- Reviews regulatory submissions and dossiers for accuracy and compliance to internal quality procedures.

Knowledge required for competency at this level:

- Basic knowledge of quality management systems (QMSs) and best practices
- Basic knowledge of internal and external auditing practices and appropriate terminology during verbal and/or written communication with auditors or auditing bodies
- Basic knowledge of tools commonly used in quality assurance such as flowcharts, check sheets, Pareto diagrams, cause and effect diagrams, histograms, scatter diagrams, and control charts
- Basic knowledge of relevant quality standards (ISO, ICH, Health Canada, FDA, etc.).

3.5 Technical competencies list for Regulatory Affairs Associate in Bio-health

3.5.1 Regulatory Systems and Documentation

Develops and manages regulatory systems to govern compliance with current biotechnology product regulations and communicate corrective action taken as required.

Competency in this role is demonstrated when the individual:

- Clarifies regulatory plans and SOPs for internal stakeholders.
- Prepares appropriate responses to inquiries and citations from regulatory bodies.
- Reports to regulatory authorities on product-associated events such as safety issues and adverse regulatory events.
- Maintains the Regulatory Information Management System that triggers and logs regulatory reporting, where applicable.
- Provides regulatory input, support, and appropriate follow-up for regulatory agency inspections and audits.
- Prepares regulatory submissions such as IND, CTA, IMPD and other product marketing applications and amendments.

Knowledge required for competency at this level:

- Knowledge of guidelines for interpretation of regulatory requirements
- Knowledge of FDA, USDA, CFIA, Health Canada, provincial, and other regulations, as required

- Working knowledge of all relevant best practices (GxP) and industry standards

3.5.2 Regulatory Support for Product Development in Bio-Health

Builds and exercises knowledge of the research and development (R&D), preclinical, and clinical steps as well as related regulations in healthcare in order to facilitate product development to commercialization and beyond.

Competency in this role is demonstrated when the individual:

- Provides support for various studies as required, including health policy, investigator-led, compassionate use, and efficacy studies.
- Advises stakeholders of good practices and regulatory requirements for pre-clinical and clinical data, clinical inspections and product labeling, and investigator relationships.
- Prepares regulatory submissions in compliance with applicable regulatory requirements.
- Monitors the clinical research process to identify and submit mandatory reports or notifications to regulatory authorities on such things as serious adverse events or changes in manufacturing.
- Ensures that the clinical and non-clinical data are consistent with regulatory requirements and support the proposed product claims.
- Acts as the central liaison with regulatory authorities throughout the regulatory authority review process.
- Facilitates interactions between regulatory authorities and stakeholders such as cross-functional teams, panels, and advisory committees.
- Provides support for pharmacovigilance, medical device reporting (MDR), and other post-market surveillance and reporting activities, as required.
- Manages electronic (eCTD) and paper registration development.

Knowledge required for competency at this level:

- Basic knowledge of relevant product development
- Working knowledge of all relevant best practices (GxP) and industry standards
- Working knowledge of regulatory submissions and amendments relevant to the organization’s products

3.5.3 Post-market Product Registration and Compliance

Manages post-market product registrations, complaint handling, recall reporting, labeling, and submissions in order to ensure ongoing compliance with current government and industry regulations.

Competency in this role is demonstrated when the individual:

- Develops processes to maintain annual licenses, registrations, and product listings.
- Develops product summaries and labels that meet post-approval regulatory requirements.
- Manages communications with stakeholders regarding product quality and recalls, e.g., letters to healthcare professionals, patients, distributors, and health authorities.
- Ensures advertising and promotion for new or revised products is compliant with relevant regulations throughout the product development process and life cycle.
- Ensures post-market regulatory documents such as registrations, licenses, reports, and supplemental submissions, are prepared and filed on a timely basis, as required.
- Submits notifiable changes and supplemental dossiers to the appropriate regulatory authorities in order to update product information and/or instructions for use to reflect current state of product knowledge.

Knowledge required for competency at this level:

- Working knowledge of guidelines for interpretation of regulatory requirements

3.5.4 Developing a Regulatory Strategy for the Organization

Develops and implements strategies to create a strong regulatory framework to support the organization's mission.

Competency in this role is demonstrated when the individual:

- Identifies the pertinent regulatory requirements for the organization's products or regulatory projects.
- Consults with regulatory agencies as required to understand and clarify regulations.
- Manages regulatory projects, including planning and implementation, for the development of new or revised regulatory procedures and SOPs.

- Continually monitors the regulatory environment and requirements related to current and future products in the pipeline in order to identify the need for new or revised regulatory procedures and SOPs.
- Reviews regulatory intelligence to contribute to the development of regulatory strategy and strategy updates as regulations change.
- Educates stakeholders on existing and new regulatory requirements to ensure organization-wide compliance.

Knowledge required for competency at this level:

- Relevant scientific knowledge to understand regulatory issues
- Working knowledge of all regulatory requirements relative to the organization's operations from sources such as the CBS, the EMEA, the military, the province, and other regulations, as required
- Basic knowledge of the strategic planning process, including SWOT and gap analysis

3.5.5 Liaising with Regulatory Professionals

Liaises with regulatory bodies and other related professionals and agency authorities to help shape regulatory decisions for the organization's benefit in compliance with regulatory requirements.

Competency in this role is demonstrated when the individual:

- Gathers evidence to support evidence-based decision making.
- Participates in regulatory association meetings to gain insights into the roles and perspectives of colleagues in the biotechnology industry.
- Researches to identify key regulatory professionals and agency authorities and their role in regulatory processes.
- Works to establish relationships with federal and provincial regulatory decision makers and staff.
- Coordinates actions resulting from regulatory agency rulings and regulatory changes.

Knowledge required for competency at this level:

- Knowledge of the organization's business and processes
- Knowledge of effective communication principles

- Working understanding of the regulatory culture and mindset

3.5.6 Risk Management

Applies knowledge and understanding of the organization's research, development, manufacturing, and marketing processes in order to identify potential regulatory risks inherent to these processes and contribute to the development of risk mitigation plans that minimize the organization's exposure and insurance requirements.

Competency in this role is demonstrated when the individual:

- Participates in regular inspections to identify health and safety issues that need to be addressed.
- Participates in the evaluation of identified risks under the guidance of a senior specialist.
- Monitors inspection and incident reports to alert management of potential risks that may require intervention.
- Participates in the development and implementation of identified risk mitigation plans.

Knowledge required for competency at this level:

- Working knowledge of the organization's processes and procedures
- Working knowledge of all regulatory requirements relative to the organization's operations
- Knowledge of the proper use of risk management tools

3.5.7 Professional Writing for Regulatory Affairs

Compiles and maintains regulatory records, scientific reports, and other technical documents in order to ensure that all required written documentation is available to regulatory bodies and the organization, demonstrating compliance with all regulatory requirements.

Competency in this role is demonstrated when the individual:

- Collaborates with cross-functional teams and external experts to compile and prepare responses to routine questions and inquiries from stakeholders.
- Composes email messages to convey complex instructions or to introduce attachments.

- Checks the final draft of documents for consistency with grammar and formatting standards.
- Authors regulatory and occasionally technical documents such as product dossiers based on information submitted from various internal departments and external suppliers or contractors for submission to regulatory authorities.

Knowledge required for competency at this level:

- Fluency in English or French language and grammar, as applicable
- Working knowledge of technical and scientific document structure
- Awareness of language in documentation that may impact staffing, political, and financial resources
- Working knowledge of regulatory guidance documents and the product authorization process

3.5.8 Digital Skills for Regulatory Affairs

Makes effective use of computer software and the Internet in order to maintain data, develop and disseminate documents and presentations, and file documents electronically as per applicable regulatory guidance.

Competency in this role is demonstrated when the individual:

- Sets up standard word processing templates using software such as Microsoft Word for different types of papers, documents, and reports regularly generated.
- Uses internal corporate project tracking software and tools.
- Searches databases on government websites for access to guidance documents, policies, regulations, and regulatory decisions.
- Utilizes databases to track and extract data on regulations and internal/external communications relevant to the role.
- Utilizes ERPS and QMS software, as required.

Knowledge required for competency at this level

- Comprehensive knowledge and skill in the application of the Microsoft Office Suite
- Comprehensive knowledge and skill in the use of the Internet
- Comprehensive knowledge and skill in the use of government websites, databases, and specialized software such as ERP and QMS applications

3.6 Industry Regulatory competencies list for Regulatory Affairs Associate - Bio-health

Included in Technical Competencies above.

3.7 Personal and professional competencies list for Regulatory Affairs Associate - Bio-health

3.7.1 Collaboration for Regulatory Affairs

Works effectively with others in order to foster trust and cooperation in the achievement of common goals and promote a culture of regulatory compliance.

Competency in this role is demonstrated when the individual:

- Routinely interacts with agency and government staff to ensure registration forms and compliance documents are accurate and complete.
- Keep colleagues informed on a timely basis about regulatory and policy changes, compliance issues, etc.
- Shares credit appropriately for the ideas and contributions of others.

Knowledge required for competency at this level:

- Knowledge of effective collaboration models and techniques
- Knowledge of change management processes and techniques

3.7.2 Continuous Learning

Continuously undertakes introspection to understand current knowledge and skills in a changing environment, recognizes personal knowledge gaps, undertakes independent action to actively seek targeted opportunities to acquire new knowledge, and reflects on how new knowledge can be integrated and applied.

Competency in this role is demonstrated when the individual:

- Seeks out new role-related information to expand knowledge and understanding of the field.

- Actively pursues training to advance role-related skills and knowledge or to develop new skills and knowledge.
- Applies prior skills and knowledge to address new situations and challenges.

Knowledge required for competency at this level:

- Basic knowledge of latest adult learning principles as related to learning processes and techniques
- Basic knowledge of training resources that can be utilized for personal and professional development
- Basic understanding of personal learning style

3.7.3 Effective Interpersonal Communication for Regulatory Affairs

Communicates in ways that create a clear understanding of regulatory obligations internally and the organization's position externally in order to facilitate internal compliance and to positively influence the reputation and interests of the organization with government and non-government organizations.

Competency in this role is demonstrated when the individual:

- Provides clear instructions for tasks such as completing a product safety report.
- Clarifies ambiguous information through careful listening and questioning, e.g., interacting with internal staff to clarify the details of an adverse regulatory event.
- Maintains the flow of communication within a cooperative exchange, even when dealing with differences of opinion.

Knowledge required for competency at this level:

- Knowledge of a variety of individual and group communication models and strategies
- Knowledge of conflict management approaches and techniques

3.7.4 Judgement/Strategic Thinking in Regulatory Affairs

Analyzes information and situations rigorously while considering future implications for the organization, and exercises sound judgement to recommend courses of action that strategically benefit the organization.

Competency in this role is demonstrated when the individual:

- Makes decisions on routine matters within defined parameters (e.g., identifying missing information or rectifying filing errors on documents returned by the regulatory agency).
- Alerts management to potential inconsistencies in the application of policies and regulations within the organization.
- Consistently applies internal SOPs for completion of regulatory submissions.

Knowledge required for competency at this level:

- Understanding of internal SOPs for completing regulatory submissions
- Understanding of the principles of conducting a gap analysis
- Working knowledge of regulatory bodies' regulations
- Working knowledge of the organization's processes and workflows

3.7.5 Planning and Organizing Work

Plans, organizes, and prioritizes work in an efficient manner to maximize the use of time and resources and successfully manage the multiple, varied, and time-sensitive responsibilities of the role.

Competency in this role is demonstrated when the individual:

- Manages daily activities to make the most effective use of the time available.
- Adjusts schedule to accommodate unanticipated tasks after assessing their priority relative to the current workload.
- Uses established criteria or guidelines to manage competing or conflicting demands from other departments.
- Coordinates the scheduling of own deliverables to integrate with others' workflow or a larger project plan.

Knowledge required for competency at this level:

- Working knowledge of planning and time management strategies such as Google Calendar

3.7.6 Professionalism/Emotional Intelligence

Applies emotional and professional sensitivity to become aware of own emotions and those of others they interact with in such a way that they can manage personal and professional decorum and maintain productive relationships.

Competency in this role is demonstrated when the individual:

- Consciously practices an understanding of diverse working styles, personalities, and cultures in order to increase trust and collaboration (self awareness).
- Exercises initiative by actively taking opportunities to share information, seek additional work, or offer help to others as time allows (self management/regulation).
- Manages multiple tasks and responsibilities in a timely, efficient, and effective manner (self management/regulation).
- Actively explores different perspectives to identify their merit (relationship management).
- Builds awareness and empathy for the needs of others to increase trust and personal effectiveness in social situations (social awareness).

Knowledge required for competency at this level:

- Basic understanding of the principles of emotional intelligence (see the work of authors like Daniel Goleman and Travis Bradberry)
- Basic understanding of the principles of giving and receiving constructive feedback

3.8 Essential Skills for Regulatory Affairs Associate - Bio-health

Essential Skills (ES) are foundational skills required for all types of work. They are not technical skills, but the core skills people need to acquire knowledge and complete workplace tasks and daily activities.

Understanding the ES requirements for a role can allow individuals to compare their skills to those required, assist training/learning providers in developing appropriate supports to ensure ES levels are developed during training, and provide employers with an additional tool for determining who/how to place in particular roles.

Human Resources and Skills Development Canada has defined Essential Skills as follows:

- Reading
- Document Use
- Numeracy, which is further divided into:
  - Money math; Scheduling, budgeting, and accounting math; Measurement and calculation math; Data analysis math.
  - Several different factors related to estimations, including the presence of a set procedure, the number of items being estimated, the consequences of errors in estimation, the amount of information missing, and the accuracy required.
- Writing
- Oral Communication
- Thinking Skills, which are further divided into:
  - Problem Solving
  - Decision Making
  - Critical Thinking
  - Job Task Planning and Organizing
  - Finding Information
  - Significant Use of Memory
- Digital Skills
- Working with Others
- Continuous Learning

Most of the ES have levels based on complexity, and a role can be analyzed to determine the appropriate levels of ES. The exceptions are noted below:

- "Working with Others" does not have a complexity rating: it simply describes the ways in which the role would be required to interact with other people, either internally within the organization or externally (i.e., with clients, customers, or the public).
- "Continuous Learning" does not have a complexity rating: it describes the types of learning expected in the context of the role (e.g., on the job, being mentored by others, formal training as part of the job, etc.).

NOTE: as of January 2020, ESDC was undertaking a comprehensive review of ES with the intent of adding additional skills, refining existing ones (particularly digital skills) and better aligning ES with similar approaches used in other countries. However the detail was not finalized in time to be used, therefore the profiles developed for this project follow existing standards as of December 2019.

3.9 Canadian Language Benchmark for Regulatory Affairs Associate – Bio-health

Canadian Language Benchmarks (CLB) are a 12-point scale for task-based language proficiency descriptors which were originally developed as a guide for measuring the teaching and assessment of English as a Second Language (ESL) learners in Canada. Since they were originally developed, the Canadian Centre for Language Benchmarks (CCLB) has continued to refine CLB, and it now includes scales for both English and French language proficiency. [1]

The CLB has been validated against both the Common European Framework for Language (CEFL) and the American Council for the Teaching of Foreign Languages (ACTFL) benchmarks and is considered accurate for high-stakes evaluation[2].

The ES levels for Oral Communication were developed with reference to the Canadian Language Benchmarks[3]. Comparative work to determine the alignment between the CLB and other Essential Skills has been ongoing, with recent work providing additional alignment with the ES for Oral Communication in both spoken and listening domains, Reading, Writing, and Document Use.[4]

CCLB has developed a set of crossover tables that align CLB ratings with ES ratings for reading, writing oral communication and document use.

[1] Centre for Canadian Language Benchmarks. Theoretical Framework for The Canadian Language Benchmarks And *Niveaux De Compétence Linguistique Canadiens.* CCLB. Ottawa 2015. p8
[2] Centre for Canadian Language Benchmarks. Canadian Language Benchmarks: English as a Second Language for Adults, CCLB. Ottawa 2012 p.II
[3] Essential Skills Research Group. Readers Guide to the Essential Skills. ESDC. Ottawa ND. p57
[4] Canadian Centre for Language Benchmarks. Relating Canadian Language Benchmarks to Essential Skills: A Comparative Framework. 2015, p3

Regulatory Affairs Associate (Bio-health) ES/CLB Profile

Essential Skills	Equivalent CLB Level	ES Level				
Reading	Reading: 9–10	1	2	3	4	5
Document Use	Reading: 9–10 Writing: 7–8	1	2	3	4	5
Writing	Writing: 7–8	1	2	3	4	5
Oral Expression	Speaking: 9–10 Listening: 9–10	1	2	3	4	
Numeracy	n/a	1	2	3	4	5
Thinking Skills – Problem Solving	n/a	1	2	3	4	
Thinking Skills – Decision Making	n/a	1	2	3	4	
Thinking Skills – Job/Task Planning and Organizing	n/a	1	2	3	4	
Thinking Skills – Significant Use of Memory	n/a	Types 1,2,3				
Thinking Skills – Finding Information	n/a	1	2	3	4	
Digital Skills	n/a	1	2	3	4	5
Working with Others	n/a	See Below				
Continuous Learning	n/a	See Below				

Explanation of the Essential Skills and the Canadian Language Benchmark for Regulatory Affairs Associate (Bio-health)

Reading: ES 5 CLB: 11–12

Regulatory Affairs Associates read and interpret a wide array of complex scientific, technical, legal, and regulatory documentation in the course of their duties. They must synthesize information from various sources and use this information to inform the creation of regulatory reports and filings on behalf of their organization.

Document Use: ES 4 CLB: Reading: 11–12, Writing: 9–10

Regulatory Affairs Associates access and interpret information from a variety of electronic and paper-based sources. Information may be textual, graphical, tabular, and/or numerical in nature. They must be able to interpret legislation and regulations in order to understand the potential impacts to their organization's regulated activities, and will also use this information to inform the creation of regulatory reports and filings on behalf of their organization.

Writing: ES 4 CLB: 9–10

In addition to routine internal and external correspondence (emails, memos, etc.) Regulatory Affairs Associates write formal reports and submissions to regulatory bodies (Health Canada, Agriculture Canada, Environment and Climate Change Canada, etc.) on behalf of their organization. They also take part in developing internal documents, reports, and briefings for management to use in making strategic and tactical decisions for the business.

Oral Expression: ES 4 CLB: Speaking: 11–12, Listening: 11–12

Regulatory Affairs Associates communicate orally with internal and external stakeholders on matters of importance with respect to regulatory compliance. They translate legal and regulatory language for non-technical audiences in order to ensure understanding and compliance. Oral communication may be directive (e.g., explaining a procedure to ensure regulatory compliance) or informative. They may be involved in, or asked to facilitate, group discussions related to regulatory matters with other regulatory affairs personnel and

management and technical staff on matters related to changing regulations and their impact on the organization's commercialization efforts.

Numeracy: ES 2 (Money Math: 2, Scheduling, Budgeting and Accounting: n/a, Measurements: n/a, Data Analysis: 2)

Regulatory Affairs Associates support the organization's marketing and commercialization strategies and requires an intermediate level of skill with regards to budgets and accounting in order to understand the business implications of regulatory activities and to contribute meaningfully to discussions on regulatory processes. This can include multi-variate cost/benefit/risk analysis, using standardized formulae to support decisions. They must access data and use basic data analysis protocols in order to include relevant information in corporate regulatory filings.

Thinking Skills:

Thinking skills are subdivided into five domains:

- Thinking Skills — Problem Solving
- Thinking Skills — Decision Making
- Thinking Skills — Job/Task Planning and Organizing
- Thinking Skills — Finding Information
- Thinking Skills — Significant Use of Memory

- **Thinking Skills — Problem Solving: ES 3**

Regulatory Affairs Associates solve problems and determine best solutions related to regulatory compliance, taking into account a range of factors. The necessary information for problem solving is knowable and there are generally historical precedents that may be used to inform future action.

- Thinking Skills — Decision Making: ES 3

Regulatory Affairs Associates make decisions on courses of action for regulatory compliance that can have significant impact on the future financial well-being of their organization. Decisions are made in a climate of uncertainty, and often the results of these decisions are not immediately apparent and can only be reversed with difficulty in the future.

- Thinking Skills — Job/Task Planning and Organizing: ES 3

Regulatory Affairs Associates plan their own work and have discretion over how they will perform their tasks, within a framework of acceptable practice that is determined by their profession and by the organization in which they work. As professionals they are expected to be able to use judgement to set and manage their own priorities and task sequencing, although these may be overridden by more senior management. They work in a fluid environment and are expected to react dynamically to disruptions while remaining on schedule. They may be part of a team and will need to coordinate their work with others.

- Thinking Skills — Finding Information: ES 3

Regulatory Affairs Associates use a variety of data sources including regulatory databases (domestic and international) recent regulatory decisions, scientific reports, research data, and company records in order to design effective regulatory compliance strategies. Some information is in known locations, but they may be required to expand their information search to non-standard sources in order to uncover all of the information they need to accomplish their task and achieve the desired results.

- Thinking Skills — Significant Use of Memory: Types 1, 2, 3

Regulatory Affairs Associates must memorize, retain, and use information through one or all of the following methods:

- Purposeful memorization of procedures, codes, parts numbers, memorization through repetition (Type 1)
- Remembering information for brief periods, e.g., minutes or hours (Type 2)
- Unique events in which learning occurs from exposure (Type 3)

Digital Skills: ES 3

Regulatory Affairs Associates utilize standard office productivity software tools (Word processing, spreadsheets, presentations, etc.), electronic communication tools (email, text, instant messaging, video conferencing, etc.), and a variety of data retrieval and analysis tools and technologies in the performance of their duties.

Working with Others: Work Contexts 2, 3 & 4

The following work contexts and functions are relevant to the Regulatory Affairs Associate role:

- Works independently (Work Context 2)
- Works jointly with a partner or helper (Work Context 3)
- Works as a member of a team (Work Context 4)

They may also be involved in supervisory or leadership activities, as follows: Functions 1–5

- Participate in formal discussions about work processes or product improvement (S/L Function 1)
- Have opportunities to make suggestions on improving work processes (S/L Function 2)
- Monitor the work performance of others (S/L Function 3)
- Inform other workers or demonstrate to them how tasks are to be performed (S/L Function 4)
- orient new employees (S/L Function 5)

Continuous Learning: Types of Learning 1, 2, 3 How Learning Occurs: 1, 2, 3, 4, 5, 6

Type of learning may include:

- Training in job-related health and safety (Type 1)
- Obtaining and updating credentials (Type 2)
- Learning about new equipment, procedures, products, and services (Type 3)

The learning may occur:

- As part of regular work activity (Context 1)
- From coworkers (Context 2)
- Through training offered in the workplace (Context 3)
- Through other forms of self-study (Context 4):
    - At work
    - On worker's own time
    - Using materials available through work
    - Using materials obtained through a professional association or union

    - Using materials obtained through worker's own initiative
- Through offsite training (Context 5):
    - During working hours at no cost to the workers
    - Partially subsidized
- With costs paid by the worker (Context 6)

4 REFERENCES

Gathering the data

The development of the National Occupational Standards started with a review of existing information for the role. This review process included: referencing books, job postings, websites, articles, and BioTalent Canada's existing skills profiles to create the first draft. After several iterations via written feedback, focus groups and a national survey with subject matter experts, the National Standards were developed. The following are sources consulted during the creation of the Regulatory Affairs Associate - Bio-health profile:

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During the research period, several job posting boards were reviewed for this profile.

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