

Stage 1 Business Analysis

California Department of Technology, SIMM 19A.3 (Ver. 3.0.8, 02/01/2022)

1.1 General Information

1. Agency or State entity Name: XXXX - Other

If Agency/State entity is not in the list, enter here with the organization code.

1115 - Department of Cannabis Control

- 2. Proposal Name and Acronym: Laboratory Information Management System Replacement (LIMSR)
- 3. Proposal Description: (Provide a brief description of your proposal in 500 characters or less.)

The Department of Cannabis Control (Department) seeks to replace its current laboratory information management system (LIMS) with a product that is suitable for testing cannabis. Currently, the Department must utilize a LIMS that is owned by the California Department of Public Health (CDPH). The current LIMS is more appropriate for laboratory activities associated with public-health testing activities (e.g. blood testing and other human products). The Department requires a LIMS replacement that is appropriate for the testing of cannabis products. This will also assist the Department in making its lab operations independent of CDPH.

- 4. Proposed Project Execution Start Date: 2/1/2023
- 5. S1BA Version Number: Version 1

1.2 Submittal Information

1. Contact Information

Contact Name: Sean O'Connor

Contact Email: Sean.O'Connor@cannabis.ca.gov

Contact Phone: 916-282-0384

2. Submission Type: New Submission

If Withdraw, select Reason: Choose an item.

If Other, specify reason here:

Sections Changed, if this is a Submission Update: (List all sections changed.)

Click or tap here to enter text.

Summary of Changes: (Summarize updates made.)

Click or tap here to enter text.

- 3. Attach **Project Approval Executive Transmittal** to your email submission.
- 4. Attach <u>Stage 1 Project Reportability Assessment</u> to your email submission.

1.3 Business Sponsorship

1. Executive Champion (Sponsor)

Title: Chief Deputy Director

Name: Rasha Salama

Business Program Area: Executive Office

2. Business Owner

Title: Research Scientist Supervisor II

Name: Gordon Vrdoljak

Business Program Area: Laboratory Branch

3. Product Owner

Title: Research Scientist IV

Name: Yun Wang

Business Program Area: Laboratory Branch

TIP: Copy and paste or click the + button in the lower right corner on any section to add additional Executive Champions, Business Owners, or Product Owners with their related Business Program Areas as needed.

1.4 Stakeholder Assessment

The Stakeholder Assessment is designed to give the project team an overview of communication channels that the state entity needs to manage throughout the project. More stakeholders may result in increased complexity to a project.

1. Indicate which of the following are interested in this proposal and/or the outcome of the project. (Select 'Yes' or 'No' for each.)

State Entity Only: Yes Other Departments/State Entities: No Public: No Federal Entities: No Governor's Office: No Legislature: No Media: No Local Entities: No Special Interest Groups: No Other: No

2. Describe how each group marked 'Yes' will be involved in the planning process.

The Department's Laboratory Branch staff and subject matter experts will partner with the Department's IT Services Division staff and management to conduct all planning activities, including market research, procurement activities, and implementation strategies.

1.5 Business Program

- 1. Business Program Name: Laboratory Branch
- 2. Program Background and Context: (Provide a brief overview of the entity's business program(s) current operations.)

The Laboratory Branch is a branch of the Laboratory Division in the Department. The Laboratory Branch provides laboratory testing of cannabis product samples for surveillance, active investigations, support of licensing activities, review of remediation plans for failed cannabis products, laboratory support of Emergency outbreak response, and research into the safety of cannabis products and ingredients used in those products. The Laboratory Branch has 10 active staff consisting mainly of Research Scientists with background in microbiology and chemistry. Cannabis samples are handled under California and Drug Enforcement Agency (DEA) regulatory requirements. Samples are received, witnessed, logged into inventory, tested for any requested analysis, and peer reviewed reports released to the Department Compliance and Enforcement teams as part of investigations and regulatory actions. The Laboratory Branch has a DEA registration and is ISO 17025 accredited. Notable investigations include: Aspergillus testing which initiated the Department's first recall of an unsafe cannabis product; identification of the ingredient that was the major factor implicated in the EVALI outbreak which caused 2,807 hospitalizations and 68 deaths; and product testing to aid in enforcement against the cannabis illicit market.

3. How will this proposed project impact the product or services supported by the state entity?

A new LIMS will increase the effectiveness of testing as the new LIMS will be geared towards cannabis product testing. The new LIMS will enable the Laboratory Branch to be independent of CDPH's system, which is utilized via an interagency agreement. DCC will be able to configure the system in a manner that is geared towards cannabis sample collection, processing, and reporting – the system is currently designed for blood testing and other human products which makes it inefficient for use by the cannabis testing branch. Additionally the existing system is owned and operated by CDPH.

- 4. Business Program Name: Other Department Divisions (e.g. Enforcement, Executive, etc.)
- 5. Program Background and Context: (Provide a brief overview of the entity's business program(s) current operations.)

The Department is the California state agency that licenses and regulates cannabis businesses. The Department regulates the:

- Growing of cannabis plants
- Manufacture of cannabis products
- Transportation and tracking of cannabis goods throughout the state
- Sale of cannabis goods
- Events where cannabis is sold or used
- Labeling of goods sold at retail

All commercial activity must take place between licensed operators.

6. How will this proposed project impact the product or services supported by the state entity?

This project will result in a replacement LIMS that will provide result reports to the other divisions within the Department. The other Divisions within the Department can refer to lab results within the context of complaint investigations, policy development, and other Departmental regulatory activities. A key responsibility of the Department's regulatory functions is compliance and enforcement. All cannabis and cannabis products must be tested and meet certain regulatory requirements prior to sale. The LIMS will be utilized by the Laboratory Branch to capture sample data as a result of an inspection or investigation to ensure products are fit for consumption.

TIP: Copy and paste or click the + button in the lower right corner to add Business Programs, with background and context and impact descriptions as needed.

1.6 Project Justification

1. Strategic Business Alignment

Enterprise Architect

Title: Chief Infrastructure and Enterprise Services

Name: Donovan Dutt

Strategic Plan Last Updated? N/A - Initial Strategic Plan in Progress

Strategic Business Goal: N/A

Alignment: N/A

TIP: Copy and paste or click the + button in the lower right corner to add Strategic Business Goals and Alignments as needed.

Mandate(s): None

Bill Number/Code, if applicable: Click or tap here to enter text.

Add the Bill language that includes system-relevant requirements:

Click or tap here to enter text.

TIP: Copy and paste or click the + button in the lower right corner to add Bill Numbers/Codes and relevant language as needed.

2. Business Driver(s)

Financial Benefit: No

Increased Revenue: No

Cost Savings: No

Cost Avoidance: No

Cost Recovery: No

Will the state incur a financial penalty or sanction if this proposal is not implemented? No

If the answer to the above question is "Yes," please explain:

Click or tap here to enter text.

Improvement

Better Services to the People of California: Yes

Efficiencies to Program Operations: Yes

Improved Equity, Diversity, and/or Inclusivity: No

Improved Health and/or Human Safety: Yes

Improved Information Security: Yes

Improved Business Continuity: Yes Improved Technology Recovery: Yes Technology Refresh: Yes Technology End of Life: No

1.7 Business Outcomes Desired

Executive Summary of the Business Problem or Opportunity:

The Laboratory Branch currently utilizes a LIMS that is not optimized for cannabis testing. Currently, the system is configured for testing blood samples and other human products. As a result, each time a cannabis sample is entered or a new report is needed, the Laboratory Branch staff must complete additional manual data entry, which creates inefficiency in the process. A replacement LIMS with a cannabis testing focus will offer opportunities for substantial improvements.

Objective ID: 1

Objective: Reduce manual data entry required of staff to input results.

Metric: Percentage of results that require manual staff input.

Baseline: 80%

Target Result: 30%

Objective ID: 2

Objective: Decrease the amount of time needed to add a new test type.

Metric: Time (in weeks) to create a new test type in the system.

Baseline: 8 weeks

Target Result: 1 week

Objective ID: 3

Objective: Decrease the amount of time needed to add a new report.

Metric: Time (in weeks) to create a new report in the system.

Baseline: 4 weeks

Target Result: 1 week

Objective ID: 4

Objective: Decrease the turnaround time for releasing official report data

Metric: Time (in days) from receipt of sample results to releasing official report data.

Baseline: 3 days

Target Result: 1 day

TIP: Copy and paste or click the + button in the lower right corner to add Objectives as needed. Please number for reference.

TIP: Objectives should identify WHAT needs to be achieved or solved. Each objective should identify HOW the problem statement can be solved and must have a target result that is specific, measurable, attainable, realistic, and time-bound. Objective must cover the specific. Metric and Baseline must detail how the objective is measurable. Target Result needs to support the attainable, realistic, and time-bound requirements.

1.8 Project Management

1. Project Management Risk Score: 0.5

(Attach a completed <u>Statewide Information Management Manual (SIMM) Section 45 Appendix A</u> <u>Project Management Risk Assessment Template</u> to the email submission.)

2. Project Approval Lifecycle Completion and Project Execution Capacity Assessment

Does the proposal development or project execution anticipate sharing resources (state staff, vendors, consultants, or financial) with other priorities within the Agency/state entity (projects, PALs, or programmatic/technology workload)?

Answer: Yes

Does the Agency/state entity anticipate this proposal will result in the creation of new business processes or changes to existing business processes?

Answer (No, New, Existing, or Both): No

1.9 Initial Complexity Assessment

1. Business Complexity Score: 0.9

(Attach a completed <u>SIMM Section 45 Appendix C</u> to the email submission.)

2. Noncompliance Issues: (Indicate if your current operations include noncompliance issues and provide a narrative explaining how the business process is noncompliant.)

Programmatic regulations: No

HIPAA/CIIS/FTI/PII/PCI: No

Security: No

ADA: No

Other: No

Not Applicable: No

Noncompliance Description:

Click or tap here to enter text.

3. Additional Assessment Criteria

If there is an existing Privacy Threshold Assessment/Privacy Information Assessment, include it as an attachment to your email submission.

How many locations and total users is the project anticipated to affect?

Number of locations: One laboratory.

Estimated Number of Transactions/Business Events (per cycle): 1,000 – 3,000 tests per year.

Approximate number of internal end-users: 20 users

Approximate number of external end-users: None

1.10 Funding

Planning

1. Does the Agency/state entity anticipate requesting additional resources through a budget action to *complete planning* through the project approval lifecycle framework? No

If Yes, when will a budget action be submitted to your Agency/DOF for planning dollars?

Click or tap to enter a date.

2. Please provide the Funding Source(s) and dates funds for planning will be made available:

The Department will fund this project's planning activities from its operational resources.

Project Implementation Funding

1. Has the funding source(s) been identified for *project implementation*? Yes

If known, please provide the Funding Source(s) and dates funds for implementation will be made available:

Funds are available currently within the approved budget of the Department. The Department will fund this project from its operational resources.

Will a budget action be submitted to your Agency/DOF? No

If "Yes" is selected, specify when this BCP will be submitted: Click or tap here to enter text.

2. Please provide a rough order of magnitude (ROM) estimate as to the total cost of the project: Less than \$10 Million

End of agency/state entity document.

Please ensure ADA compliance before submitting this document to CDT.

When ready, submit Stage 1 and all attachments in an email to ProjectOversight@state.ca.gov.

Department of Technology Use Only

Original "New Submission" Date: 12/13/2022

Form Received Date: 12/13/2022

Form Accepted Date: 12/13/2022

Form Status: Completed

Form Status Date: 12/13/2022

Form Disposition: Approved

If Other, specify: Click or tap here to enter text.

Form Disposition Date: 12/13/2022

Department of Technology Project Number (0000-000): 1115-002