Stage 1 Business Analysis

California Department of Technology, SIMM 19A.3 (Ver. 3.0.9, 02/01/2022)

1.1 General Information

1. **Agency or State entity Name: 4265 - Public Health, Department of -**

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

   Click or tap here to enter text.

2. **Proposal Name and Acronym: Animal Testing Methods Web Portal**

3. **Proposal Description: (Provide a brief description of your proposal in 500 characters or less.)**

   The Reporting of Animal Testing Methods (AB 357) project creates a system for submitting, managing, and querying animal testing reports. Manufacturers and contract testing facilities will be able to submit required testing reports. This system will also allow the Center for Laboratory Sciences to evaluate reports, redacting proprietary information, and to publish the reports on a public-facing web page. This project is envisioned to leverage components of the Future of Public Health (FoPH) enterprise licensing system to enhance the services that can be provided, and to reduce project cost.

   Proposed Project Execution Start Date: 7/1/2024

4. **S1BA Version Number: Version 1**

1.2 Submittal Information

1. **Contact Information**

   Contact Name: Tracy Langlands

   Contact Email: tracy.langlands@cdph.ca.gov

   Contact Phone: (916)716-2704

2. **Submission Type: New Submission**

   If withdraw, select Reason: Choose an item.

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

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 Stage 1 Project Reportability Assessment** to your email submission.

1.3 Business Sponsorship

1. **Executive Champion (Sponsor)**

   Title: Deputy Director, Center for Laboratory Sciences

   Name: Anthony Tran

   Business Program Area: Center for Laboratory Sciences

2. **Business Owner**

   Title: Public Health Microbiologist, Supervisor

   Name: Joselita Joaquin

   Business Program Area: CDPH Richmond Campus Public Health Laboratory Animal Science

3. **Product Owner**

   Title: Public Health Microbiologist, Supervisor

   Name: Joselita Joaquin

   Business Program Area: CDPH Richmond Campus Public Health Laboratory Animal Science

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: No

   Other Departments/State Entities: Yes

   Public: Yes

   Federal Entities: No

   Governor's Office: No

   Legislature: No

   Media: No

   Local Entities: No

   Special Interest Groups: Yes

   Other: No

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

Other Departments:

Several organization units in CDPH will be involved in planning and will be impacted by implementing a Reporting of Animal Testing Methods system.

Enterprise Project Management Office (ePMO) - The ePMO will oversee and facilitate all aspects of project planning, and project execution.

Enterprise Architecture Office (EAO) - Enterprise architects are involved in the architecture analysis and design that precedes project planning, and in the architectural aspects of the Project Approval Lifecycle (PAL). EAO will oversee architectural aspects of the project through project execution.

Enterprise Platform Services Branch - The Enterprise Platform Services Branch will be involved during project planning and especially during project execution when DevOps teams will develop the new platform application.

Technology Operations - Technology operations will be involved in project planning as it relates to mainframe operations, cloud architecture, security architecture, and maintenance and operations planning. During project execution, Technology Operations will oversee implementation and operation of infrastructure components.

Center for Laboratory Sciences - The Center for Laboratory Sciences will be involved in the architecture analysis, project planning, project execution, and post-launch phases. Architecture analysis efforts focus on developing an understanding of the business and information architectures that drive program operations and developing strategies for their modernization. Project planning formalizes this work as part of the PAL process to produce project and procurement strategies to successfully implement the system.

Future of Public Health (FoPH) - FoPH is a major modernization program containing 9 initiatives. Initiative 2 focuses on licensing and surveillance. Through FoPH, a licensing framework is being

created that will be leveraged by the Reporting of Animal Testing Methods system. Example frameworks include user portal, document management, public reporting, and provider communication.

Public

The Public will not be involved in the planning process; however, they will benefit from using the web portal as they can request in real-time information regarding animal testing reports that currently need to be requested through Public Records Act requests.

Special Interest Groups

A number of special interest groups provided support for AB 357 when it was under consideration: Humane Society of the United States; American Society for the Prevention of Cruelty to Animals; Animal Legal Defense Fund; Cruelty Free International; GATC Health Corp.; Humane Society Veterinary Medical Association; Marin Humane Society; National Anti-Vivisection Society; Physicians Committee for Responsible Medicine Rise for Animals; San Diego Humane Society; and Social Compassion in Legislation. One or more of these groups may be involved in the evaluation of requirements for reporting information on the CDPH public web site.

1.5 Business Program

1. **Business Program Name:** Center for Laboratory Sciences (CLS)

2. **Program Background and Context:** (Provide a brief overview of the entity's business program(s) current operations.)

The Operations Branch resides under the new Center for Laboratory Sciences (CLS) Branch and operates the California Animal Laboratory Use and Approval Program, which resides in the Public Health Microbiologist (PHM) Training and Animal Science Section. CLS provides laboratory testing services, technical consultation, and leadership for the state Public Health Laboratory system to protect Californians from the threat of infectious and environmental diseases. The Center includes the Operations Branch, Laboratory Field Services (LFS), Drinking Water and Radiation Laboratory, Environmental Health Laboratory, Food and Drug Laboratory, Infant Botulism Treatment and Prevention Program, Microbial Diseases Laboratory, and Viral and Rickettsial Disease Laboratory. The Center provides laboratory testing services to support public health surveillance programs; research for disease diagnosis, characterization, investigation, and control; and subject matter expertise to inform effective decision-making.

USDA regulates all warm-blooded animals except birds, rats (genus Rattus) or mice (genus Mus) bred for use in research. The California Animal Laboratory Use and Approval Program processes applications for certification only for laboratories which use rats, mice, and/or birds, and do not receive federal funds for animal use activities. Laboratories which are subject to federal regulation (USDA-APHIS or NIH-OLAW) are exempt from state approval, as well as animal husbandry activities, private veterinary practice, and primary or secondary schools. Applicants must apply and annually renew their Certificate of Approval to Keep and Use Laboratory Animals. Changes in location, mailing address, responsible individuals, or purpose of animal use should be reported promptly to the Department. Application and renewal fees are authorized but are currently waived for all applicants.

The Department does not conduct a routine inspection. However, inspection for investigation purpose may be conducted as a result of complaints alleging improper or unapproved animal use. The program currently processes and certifies an average of 150 applications a year. Media and public requests for these documents through the Public Record Act (PRA) site and the program uses CDPH GovQA to submit responsive documents, which are redacted by the program and reviewed by the Office of Legal Services (OLS) prior to release. Media PRA requests are delivered through the Office of Public Affairs (OPA). The turnaround time for processing redactions and review of PRA requests depends on the date range, volume, and complexity of the documents. In addition, the program works on various legislative analyses related to animals used in research. It has responded to bills requesting transparency in animal research.

AB 357 requires a manufacturer or contract testing facility that uses traditional animal test methods to report specified information to the State Department of Public Health. It requires the department to make that information publicly available on its internet website, which supports transparency in animal research. This bill covers animal test methods for all vertebrate nonhuman animals. The USDA-APHIS public search portal currently lists more than 900 registered California facilities, which use different types of vertebrate animals and may have multiple types of animal test methods. AB 357 will create a new type of public service, which will have a tremendous impact to the current program. It will require new workflow, redaction methods and approval, and may lead to heavy workload on redaction of new types of documents.

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

Reporting of Animal Testing Methods creates a new public service. AB 357 mandates manufacturers and contract testing facilities use a traditional animal test method pursuant to prescribed standards, or an alternate test method that does not use animals and which has been identified and accepted by a federal agency or program. Manufacturers and contract testing facilities that use traditional animal test methods must report the information to CDPH, and CDPH must make this information available on its public web site. The current program only processes a one-page application for submitters that use only rats, mice and birds. The application may be downloaded from the program website but submission and mailing of certificates are all via hardcopy documents and US mail. There is no online portal or electronic document option for submission, query, or receipt of certification. Current PRA activities require the program to scan and upload documents, share or provide access to those documents to personnel performing the redaction and review, and upload or share access of the final redacted documents to the CDPH GovQA site or OPA office.

AB 357 requires submission of animal test methods for all types of vertebrate nonhuman animals. This would require redaction and review of new types of documents with unknown volume and complexity. Redaction processes and procedures must be developed and staff trained to remove any protected information and comply with government rules, such as FoIA (Freedom of Information Act) and PRA. The online portal will allow submission of animal test methods from all submitters that use vertebrate nonhuman animals. It will also allow the program to have immediate access to the submitted documents and start the redaction process. The turnaround time to perform redaction, review, and final approval to release these documents would depend on the number of submitters, number of animal test methods, and the volume and complexity of each test method.

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: Senior Enterprise Architect

Name: Craig Stone

Strategic Plan Last Updated? CDPH Strategic Map 2019 - 2022

Strategic Business Goal: Promote Health and Wellness – Elevate Public Awareness

Alignment: The Animal Testing Methods Web Portal project elevates public awareness of animal testing practices in manufacturing, and the adherence of manufacturers to using alternative testing methods that minimize the number of animals used, and that reduce the level of pain, suffering, and stress of an animal used for testing.

Strategic Business Goal: Enhance Services through Agile Operations: Tailor Practices to Meet Needs of Communities

Alignment: The Animal Testing Methods Web Portal project creates public facing methods for delivering animal testing information to interested communities. This shifts operations from only providing information via public record act requests to providing to the public real-time animal testing information.

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

Mandate(s): State

Bill Number/Code, if applicable: AB 357

AB 357 prohibits manufacturers and contract testing facilities from using traditional animal test methods, as defined, within this state for which an appropriate alternative test method or strategy exists, or a waiver has been granted by the agency responsible for regulating the specific product or activity for which the test is being conducted. If an appropriate alternative test method or strategy is unavailable, the bill would require a testing facility to use a traditional animal test method pursuant to prescribed standards, including using the fewest number of animals possible. The bill would define alternative test method or strategy as a test method that does not use animals, provides information of equivalent or better scientific quality and relevance compared to traditional animal test methods, and has been identified and accepted for use by a federal agency or program, as specified. The bill would except from these provisions traditional animal tests performed for the purpose of medical

research, as defined to not include testing done to assess the safety or efficacy of chemicals, ingredients, drugs, medical devices, vaccines, product formulations, or products, defined, and make conforming changes.

AB 357, starting January 1, 2027, and annually thereafter, requires a manufacturer or contract testing facility that uses traditional animal test methods to report specified information to the Attorney General, State Department of Public Health, and would require the Attorney General department to make that information publicly available on its internet website. The bill would require the department to ensure that information made available to the public does not include personally identifiable information or proprietary information.

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:

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: No

Improved Information Security: No

Improved Business Continuity: No

Improved Technology Recovery: No

Technology Refresh: No

Technology End of Life: No

1.7 Business Outcomes Desired

Executive Summary of the Business Problem or Opportunity:

AB 357 requires CDPH to establish a portal to compile and disclose data from manufacturers or contract testing facilities regarding animal usage, application of traditional testing methods, application of alternate testing methods, and waivers.

By January 1, 2027, manufacturers or contract testing facilities that use traditional animal testing procedures are required to annually report to CDPH, unless they are exempt, the following data: 1) the number and species of animals used, 2) the number and type of alternative test methods or strategies used, 3) the number of waivers used, and 4) the rationale for using traditional animal tests, alternative test methods or strategies, and waivers. CDPH would be required to create a portal to receive the information, and to make it publicly available on the internet, while excluding any personally identifiable or proprietary data. The online portal will ensure the public has access to information on the usage of traditional animal test methods in California. CDPH will need to review the technical data and redact the personal identification information or propriety data.

CLS will be supporting the Department's strategic goal of elevating public awareness by making animal test methods publicly available to educate consumers and aid the public in making decisions that promote health and wellness. This helps increase public trust and provides the public with better services by creating transparency on animal testing methods used by manufacturers and testing facilities in California. CLS intends to improve access, tracking, and sharing of information by providing the public access to animal testing reports via a web portal. Public access to this information will help increase awareness and educate the public on California test facilities and the animal test methods used in those facilities. The public will be informed and equipped to make better decisions as consumers. There have been several bills in the past that demand transparency in animal research, which has great support from different animal rights groups. This new service will help create transparency in animal research through public access to the redacted animal test methods submitted by the manufacturers or contract testing facilities.

Through the new CDPH online portal, animal test methods would eventually be redacted, shared, and updated regularly. This will reduce the need for the public to make individual and separate requests through the CDPH PRA site and reduce the need for CDPH staff to process and respond to each request through GovQA. Overall, this will help reduce future PRA requests related to AB 357 from getting processed through the CDPH PRA site and GovQA. Instead, the public would search and view available redacted animal test methods online through the new web portal, as they are made available.

As AB 357 requires the Department to publish animal testing data information that does not include personally identifiable information or proprietary information. The general procedure for this preparation is to evaluate each page of a report identifying and redacting confidential information. A redacted document then needs to undergo managerial review and then final review and approval by the Office of Legal Services.

Objective ID: 1

Objective: Improve public access to animal testing data.

Metric: Percentage of animal testing organizations submitting animal testing reports.

Baseline: 0% - Animal testing reports are not currently being collected.

Target Result: 80% - Assumes less than 100% compliance within the first year of implementation.

Objective ID: 2

Objective: Ensure personal and confidential data is redacted from animal testing reports.

Metric: Percentage of animal testing reports collected to be published on the portal after they have been redacted.

Baseline: 0% - Animal test reports are not currently being collected.

Target Result: 100% within the first year of implementation.

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:** 0.1

   (Attach a completed Statewide Information Management Manual (SIMM) Section 45 Appendix A Project Management Risk Assessment Template 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)**:** Both New and Existing Processes

1.9 Initial Complexity Assessment

1. **Business Complexity Score:** 1.2

   (Attach a completed SIMM Section 45 Appendix C 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: Yes

   Noncompliance Description:

   N/A

3. **Additional Assessment Criteria**

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

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

      Number of locations: 1

   Estimated Number of Transactions/Business Events (per cycle): 1,500

   Approximate number of internal end-users: 50

   Approximate number of external end-users:

      Manufacturers and Contract Testing Facilities: Approximately 930

      Public: 1,500 / year

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? Yes

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

   10/12/2023

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

The General Fund is the identified funding source with an anticipated date of 7/1/24 availability.

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:

The General Fund is the identified funding source with an anticipated date of 7/1/24 availability.

Will a budget action be submitted to your Agency/DOF? Yes

If "Yes" is selected, specify when this BCP will be submitted: 10-12-2023

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: 5/28/2024

Form Received Date: 5/28/2024

Form Accepted Date: 5/28/2024

Form Status: Completed

Form Status Date: 5/28/2024

Form Disposition: Approved

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

Form Disposition Date: 5/28/2024

Department of Technology Project Number (0000-000): 4265-094