STATE OF CALIFORNIA
Budget Change Proposal - Cover Sheet
DF-46 (REV 07/23)

Fiscal Year	Business Unit Number	Department
2024-25	4265	Department of Public Health

Hyperion Budget Request Name	Relevant Program or Subprogram
4265-319-BCP-2024-MR	4045068 - Laboratory Sciences

Budget Request Title
Reporting of Animal Testing Methods (AB 357)

Budget Request Summary
The California Department of Public Health requests $688,000 General Fund in 2024-25, $568,000 in 2025-26, and $257,000 and 1.0 position in 2026-27 and ongoing to create an online portal to receive animal test method information from mandated reporting entities, make such information publicly available, and comply with the reporting mandate of Section 1834.9 of the Civil Code, as revised by Assembly Bill (AB) 357.

Requires Legislation (submit required legislation with the BCP)	Code Section(s) to be Added/Amended/Repealed
☐ Trailer Bill Language ☐ Budget Bill Language ☒ N/A	N/A

Does this BCP contain information technology (IT) components? ☒ Yes ☐ No *If yes, departmental Chief Information Officer must sign.*	Department CIO John Roussel	Date 10/12/2023

For IT requests, specify the project number, the most recent project approval document (FSR, SPR, S1BA, S2AA, S3SD, S4PRA), the approval date, and the total project cost.

Project No.N/A **Project Approval Document:** N/A

Approval Date: N/A **Total Project Cost:** N/A

If proposal affects another department, does other department concur with proposal? ☐ Yes ☐ No
Attach comments of affected department, signed and dated by the department director or designee.

Prepared By	Date	Reviewed By	Date
Anthony Tran	1/3/2024	Phuong La	1/24/2024
Department Director	**Date**	**Agency Secretary**	**Date**
Susan Fanelli	2/8/2024	Julie Souliere	2/28/2024

Department of Finance Use Only

Additional Review: ☐ Capital Outlay ☒ ITCU ☐ FSCU ☐ OSAE ☒ Dept. of Technology

Principal Program Budget Analyst	Date submitted to the Legislature
Nina Hoang	5/14/2024

A. Problem Statement

The Department of Public Health's (CDPH) Laboratory Central Services (LCS) Laboratory Animal Use Approval Program (LAUAP) requires that individuals, corporations, or institutions that use live, warm-blooded animals for education, research, testing, or diagnostic purposes apply to the Department for approval to conduct such activities, in order to enforce the humane care and treatment of the animals kept and/or used.

Existing law prohibits manufacturers and contract testing facilities that make or test chemicals, products, product ingredients, and product formulations from using traditional animal test methods if a scientifically validated alternative method exists. The alternative method must be recommended by the Inter-Agency Coordinating Committee on the Validation of Alternative Methods (IACCVAM). In recent years, effective non-animal test methods, such as human-cell testing, bioinformatics, and computer modeling, have become increasingly viable. These technologies enable entities to achieve their research goals effectively without the use of animal testing.

In recognition of these scientific advancements, Assembly Bill (AB) 357 (Chapter 430, Statutes of 2023) was chaptered on October 8, 2023, and has amended Section 1834.9 of the Civil Code to prohibit manufacturing and contract testing facilities from using traditional animal testing methods if an alternative testing method or strategy exists, or a waiver by the federal regulatory agency overseeing the product or activity being tested has been granted. In cases where no other testing method or strategy is feasible, the revised law mandates that entities using traditional animal testing methods utilize a method that employs the fewest animals possible, and minimizes the pain, suffering, and distress experienced by the animal subjected to testing.

The revised law now requires manufacturers and contract testing facilities using traditional animal testing methods to report specified metrics to CDPH annually, unless they are exempt. The revised law requires CDPH LCS to create an online portal to receive the mandated information reported to the Department and make it publicly available on the internet while excluding personally identifiable or proprietary data.

CDPH requires additional resources to comply with AB 357 and the mandates of Section 1834.9 of the Civil Code, effective January 1, 2027.

Resource History
(Dollars in thousands)

Lab Central Services Section	**2019-20**	**2020-21**	**2021-22**	**2022-23**	**2023-24***
Authorized Expenditures	$4,153	$4,269	$4,198	$4,191	$4,187
Actual Expenditures	$3,124	$3,668	$3,830	$3,885	$4,187
Authorized Positions	24	24	24	24	24
Filled Positions	22	20	22	22	20
Vacancies	2	4	2	2	4

* Figures are projections based on estimates

B. Justification

LCS currently approves 100 private laboratories holding valid licenses and registration under the program to conduct research, testing, or training for scientists and health care providers. Currently, the program requires facilities to provide; 1) the number and species of animals utilized in the preceding year, 2) the reasons for which the animals were utilized, and 3) the number of animals experiencing pain or distress from animal use activities.

Starting January 1, 2027, the revised law requires manufacturers and/or contract testing facilities using traditional animal testing procedures, unless exempt, to annually report the following data to CDPH:

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.
4) The purpose for using traditional animal tests, alternative test methods or strategies, and waivers.

This revised law will require CDPH to create a portal to receive the above information, make it publicly available on the internet, and ensure that personally identifiable or proprietary data is kept confidential and is not disclosed. CDPH does not currently have funding to support the information technology project and the ongoing operations required to maintain compliance. To support these activities, CDPH requires:

1) $688,000 General Fund in 2024-25 and $568,000 in 2025-26 to develop the online portal.
2) One position and $257,000 General Fund in 2026-27 and ongoing to support the ongoing operations of the online portal.

CDPH requests the following position beginning 2026-27:

1.0 Associate Governmental Program Analyst. This role is crucial to support accuracy and confidentiality of data reported to CDPH. This critical administrative position will:

- Review self-reported data by mandated reporting entities, identify personal and proprietary information to be withheld from public disclosure, and verify that all shared data complies with applicable laws and regulations.
- Develop, implement, and maintain new policies and procedures for the implementation and maintenance of the online portal.
- Collaborate with CDPH information technology staff on data compliance and security issues related to the online portal.
- Respond to communication from laboratories to provide information, updates, and customer service.
- Partner with specialists to advise on sensitive issues and inquiries.
- Maintain an updated online portal in alignment with policies, procedures, and information technology requirements.

C. Departmentwide and Statewide Considerations

AB 357 requires California research laboratories currently conducting traditional animal testing unrelated to medical research to assess and eventually adopt non-animal testing methods. This may lead to higher research and operations costs for entities using animal testing.

D. Outcomes and Accountability

CDPH currently approves 100 private licensed and registered under the program to conduct research, testing, or training for scientists and health care providers. AB 357 will require these entities to report additional data to CDPH.

E. Implementation Plan

CDPH is required by statute to complete the IT Planning: Project Approval Lifecycle (PAL) process to ensure that IT projects are thoroughly reviewed by the California Department of Technology to inform effective implementation of the project. The estimated timeline for this process, subject to change, is:

1) April 2024-June 2025: Planning and development of online portal.
2) July 2025-July 2026: Design, development, and implementation of the online portal.
3) February 1, 2026: Online portal goes live.
4) July-December 2024: Hire and train new staff.

F. Supplemental Information

Attachment A: BCP Fiscal Detail Sheet

Attachment B: Workload Analysis

Attachment C: Current Org Charts

Attachment D: Proposed Org Charts

BCP Fiscal Detail Sheet

BCP Title: Reporting of Animal Testing Methods (AB 357)

BR Name: 4265-319-BCP-2024-MR

Budget Request Summary

Personal Services

Personal Services	FY24 Current Year	FY24 Budget r	FY24 BY+1	FY24 BY+2	FY24 BY+3	FY24 BY+4
Positions - Permanent	0.0	0.0	0.0	1.0	1.0	1.0
Total Positions	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**1.0**
Salaries and Wages Earnings - Permanent	0 Yea	0	0	76	76	76
Total Salaries and Wages	**$0**	**$0**	**$0**	**$76**	**$76**	**$76**
Total Staff Benefits	0	0	0	45	45	45
Total Personal Services	**$0**	**$0**	**$0**	**$121**	**$121**	**$121**

Operating Expenses and Equipment

Operating Expenses and Equipment	FY24 Current Year	FY24 Budget Year	FY24 BY+1	FY24 BY+2	FY24 BY+3	FY24 BY+4
5301 - General Expense	0	0	0	16	16	16
5302 - Printing	0	0	0	2	2	2
5320 - Travel: Out-of-State	0	0	0	8	8	8
5322 - Training	0	0	0	1	1	1
5340 - Consulting and Professional Services - Interdepartmental	0	688	568	95	95	95
5342 - Departmental Services	0	0	0	14	14	14
Total Operating Expenses and Equipment	**$0**	**$688**	**$568**	**$136**	**$136**	**$136**

Total Budget Request

Total Budget Request	FY24 Current Year	FY24 Budget Year	FY24 BY+1	FY24 BY+2	FY24 BY+3	FY24 BY+4
Total Budget Request	**$0**	**$688**	**$568**	**$257**	**$257**	**$257**

Fund Summary

Fund Source

Fund Source	FY24 Current Year	FY24 Budget Year	FY24 BY+1	FY24 BY+2	FY24 BY+3	FY24 BY+4
State Operations - 0001 - General Fund	0	688	568	257	257	257
Total State Operations Expenditures	**$0**	**$688**	**$568**	**$257**	**$257**	**$257**
Total All Funds	**$0**	**$688**	**$568**	**$257**	**$257**	**$257**

Program Summary

Program Funding

Program Funding	FY24 Current Year	FY24 Budget Year	FY24 BY+1	FY24 BY+2	FY24 BY+3	FY24 BY+4
4045068 - Laboratory Sciences	0	688	568	257	257	257
Total All Programs	**$0**	**$688**	**$568**	**$257**	**$257**	**$257**

Personal Services Details

Positions

Positions	FY24 Current Year	FY24 Budget Year	FY24 BY+1	FY24 BY+2	FY24 BY+3	FY24 BY+4
5393 - Assoc Govtl Program Analyst (Eff. 07-01-2026)	0.0	0.0	0.0	1.0	1.0	1.0
Total Positions	**0.0**	**0.0**	**0.0**	**1.0**	**1.0**	**1.0**

Salaries and Wages

Salaries and Wages	FY24 Current Year	FY24 Budget Year	FY24 BY+1	FY24 BY+2	FY24 BY+3	FY24 BY+4
5393 - Assoc Govtl Program Analyst (Eff. 07-01-2026)	0	0	0	76	76	76
Total Salaries and Wages	**$0**	**$0**	**$0**	**$76**	**$76**	**$76**

Staff Benefits

Staff Benefits	FY24 Current Year	FY24 Budget Year	FY24 BY+1	FY24 BY+2	FY24 BY+3	FY24 BY+4
5150900 - Staff Benefits - Other	0	0	0	45	45	45
Total Staff Benefits	**$0**	**$0**	**$0**	**$45**	**$45**	**$45**

Total Personal Services

Total Personal Services	FY24 Current Year	FY24 Budget Year	FY24 BY+1	FY24 BY+2	FY24 BY+3	FY24 BY+4
Total Personal Services	**$0**	**$0**	**$0**	**$121**	**$121**	**$121**

Center for Laboratory Sciences
Operations Branch, Laboratory Central Services
PHM Training Program & Laboratory Animal Services Section
Associate Governmental Program Analyst
1.0 Position

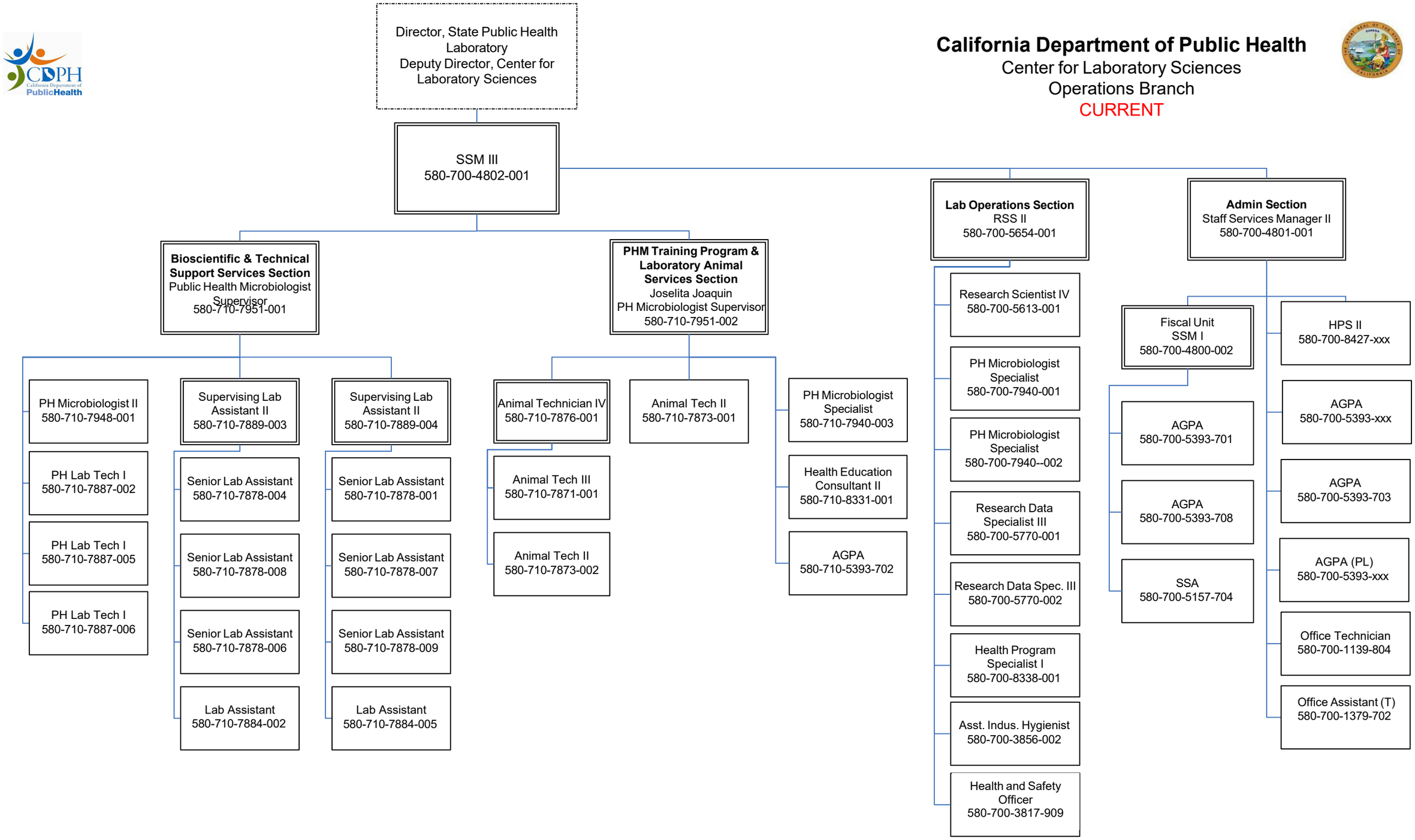
Activity	Number of Items	Hours per Item	Total Annual Hours
Review self-reported data by mandated reporting entities, identifying personal and proprietary information to be withheld from public disclosure, and collaborate with legal experts to ensure that all shared data complies with applicable law and regulations.	100	3	300
Develop, implement, and maintain new policies and procedures for the implementation and maintenance of the online portal.	15	40	600
Collaborate with CDPH information technology staff on data compliance and security issues related to the online portal.	12	5	60
Respond to communication from laboratories to provide information, updates, and overall customer service.	1,200	0.5	600
Coordinate with internal staff specialists to obtain expertise and advice on sensitive issues and inquiries.	200	1	200
Ensure that the new online portal is maintained and kept up-to-date in-line with developed policies and procedures, collaborating with internal information technology staff.	40	1	40
Total hours for workload projected for this classification			**1,800**
1,800 hours = 1 Position			
Actual number of Positions requested			**1.0**

California Department of Public Health

Center for Laboratory Sciences

Operations Branch

CURRENT



California Department of Public Health

Center for Laboratory Sciences
Operations Branch
PROPOSED

