



California Environmental Protection Agency
Department of Pesticide Regulation
Pesticide Program Division
Pesticide Registration Branch



Product Registration Data Management System (PRDMS)

Feasibility Study Report (FSR)

June 2014

Prepared by:



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Section 1.0

Executive Project Approval Transmittal

Information Technology Project Request

Feasibility Study Report
Executive Approval Transmittal



Department Name		
California Environmental Protection Agency, Department of Pesticide Regulation		
Project Title (maximum of 75 characters)		
Product Registration Data Management System		
Project Acronym	Department Priority	Agency Priority
PRDMS	1	N/A

I am submitting the attached Feasibility Study Report (FSR) in support of our request for the California Technology Agency's approval to undertake this project.

I certify that the FSR was prepared in accordance with State Administrative Manual Sections 4920-4930.1 and that the proposed project is consistent with our information technology strategy as expressed in our current Agency Information Management Strategy (AIMS).

I have reviewed and agree with the information in the attached Feasibility Study Report.

I also certify that the acquisition of the applicable information technology (IT) product(s) or service(s) required by my department that are subject to Government Code 11135 applying Section 508 of the Rehabilitation Act of 1973 as amended meets the requirements or qualifies for one or more exceptions (see following page).

APPROVAL SIGNATURES		
Chief Information Officer		Date Signed
Printed name:	Larry Wasson	7/2/2014
Budget Officer		Date Signed
Printed name:	Leslie Ford	07.01.2014
Department Director		Date Signed
Printed name:	Brian R. Leahy	7.03.2014
Agency Chief Information Officer		Date Signed
Printed name:	Sergio Gutierrez	7/9/14
Agency Secretary		Date Signed
Printed name:	Matt Rodriguez	7/9/14

**Feasibility Study Report
Executive Approval Transmittal**

IT Accessibility Certification

Yes or No

Yes	The Proposed Project Meets Government Code 11135 / Section 508 Requirements and no exceptions apply.
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Exceptions Not Requiring Alternative Means of Access

Yes or No	Accessibility Exception Justification
No	The IT project meets the definition of a national security system.
No	The IT project will be located in spaces frequented only by service personnel for maintenance, repair, or occasional monitoring of equipment (i.e., "Back Office Exception.")
No	The IT acquisition is acquired by a contractor incidental to a contract.

Exceptions Requiring Alternative Means of Access for Persons with Disabilities

Yes or No	Accessibility Exception Justification
No	Meeting the accessibility requirements would constitute an "undue burden" (i.e., a significant difficulty or expense considering all agency resources).
No	No commercial solution is available to meet the requirements for the IT project that provides for accessibility.

Exceptions Requiring Alternative Means of Access for Persons with Disabilities

Yes or No	Accessibility Exception Justification
No	No solution is available to meet the requirements for the IT project that does not require a fundamental alteration in the nature of the product or its components.

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Section 2.0

**Information Technology:
Project Summary Package**

INFORMATION TECHNOLOGY PROJECT SUMMARY PACKAGE
SECTION A: EXECUTIVE SUMMARY

1. Submittal Date	6/30/2014
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	FSR	SPR	PSP Only	Other:
2. Type of Document	X			
Project Number				

		Estimated Project Dates	
3. Project Title	Product Registration Data Management System	Start	End
Project Acronym	PRDMS	7/1/2015	6/30/2017

4. Submitting Department	California Department of Pesticide Regulation
5. Reporting Agency	California Environmental Protection Agency

6. Project Objectives
<p>The intent of the PRDMS project is to implement an integrated system to enable effective and efficient administration of DPR's pesticide product registration program by providing necessary program information; linking program activities with outcomes; providing workflow management; integrating the existing numerous data repositories to a single-point data capture; and helping streamline DPR's current manual and duplicated processes. The PRDMS project will entail a custom developed information system. Objectives of PRDMS are to:</p> <ul style="list-style-type: none"> • Improve data collection and integration, and develop validation processes to ensure accuracy, quality and completeness of submissions • Provide access to electronic product labels anytime and anywhere through the internet/intranet • Establish measurable process performance targets and accountability as a best practice • Improve registration, communication and staff coordination processes • Centralize (electronically) company profile information, pesticide label data, scientific studies data, and supporting documents • Improve training and provide intelligent work tools for employees

8. Major Milestones	Est Complete Date
Procurement complete	07/01/2015
Project Planning and Req't Confirmed	12/31/2015
Architecture and Design Specifications	04/30/2016
Data Conversion	02/28/2017
System Development	05/31/2017
User acceptance testing	05/31/2017
Pilot and Implementation	06/30/2017
Post Implementation	12/31/2017
PIER	06/30/2018
Key Deliverables	
Executed contract	07/01/2015
Proj. plans dev, bus. req'ts confirmed	12/31/2015
Data conversion systems developed	02/28/2017
User acceptance test results	05/31/2017
PRDMS full production	06/30/2017
Post Implementation Support, Closeout	12/31/2017

7. Proposed Solution
Utilize a system integrator (vendor), selected through a competitive procurement, to work in partnership with DPR staff to develop a custom developed solution that contains some components of COTS, where applicable and available, that meets DPR's business needs.

INFORMATION TECHNOLOGY PROJECT SUMMARY PACKAGE
SECTION B: PROJECT CONTACTS

Project #	3930-012
Doc. Type	Feasibility Study Report (FSR)

Executive Contacts								
	First Name	Last Name	Area Code	Phone #	Ext.	Area Code	Fax #	E-mail
Agency Secretary	Matt	Rodriquez	916	323-2514		916	324-0908	matthew.rodriquez@calepa.ca.gov
Dept. Director	Brian R.	Leahy	916	445-4000		916	324-1452	brian.leahy@cdpr.ca.gov
Budget Officer	Leslie	Ford	916	445-1522		916	445-6845	leslie.ford@cdpr.ca.gov
CIO	Larry	Wasson	916	324-5887		916	445-4115	larry.wasson@cdpr.ca.gov
Proj. Sponsor	Chuck	Andrews	916	445-3984		916	324-1452	chuck.andrews@cdpr.ca.gov

Direct Contacts								
	First Name	Last Name	Area Code	Phone #	Ext.	Area Code	Fax #	E-mail
Doc. prepared by	Lisa	Voeller	916	492-5133		916	441-1110	lisa.voeller@crowehorwath.com
Primary contact	Larry	Wasson	916	324-5887		916	445-4115	larry.wasson@cdpr.ca.gov
Project Manager	Michael	Wanser	916	341-7311		916	445-4115	mike.wanser@cdpr.ca.gov

INFORMATION TECHNOLOGY PROJECT SUMMARY
SECTION C: PROJECT RELEVANCE TO STATE AND/OR DEPARTMENTAL PLANS

1.	What is the date of your current Operational Recovery Plan (ORP)?	Date	10/07/2013
2.	What is the date of your current Agency Information Management Strategy (AIMS)?	Date	August, 2007
3.	For the proposed project, provide the page reference in your current AIMS and/or strategic business plan.	Doc.	Strategic Business Plan
		Page #	Goal 5 – Pg 16

Project #	3930-012
Doc. Type	Feasibility Study Report (FSR)

4.	Is the project reportable to control agencies?	Yes	No
		X	
	If YES, CHECK all that apply:		
	X	a) The project involves a budget action.	
		b) A new system development or acquisition that is specifically required by legislative mandate or is subject to special legislative review as specified in budget control language or other legislation.	
X	c) The estimated total development and acquisition cost exceeds the departmental cost threshold and the project does not meet the criteria of a desktop and mobile computing commodity expenditure (see SAM 4989 – 4989.3).		
	d) The project meets a condition previously imposed by the Technology Agency.		

INFORMATION TECHNOLOGY PROJECT SUMMARY PACKAGE
SECTION D: BUDGET INFORMATION

Project #	3930-012
Doc. Type	Feasibility Study Report (FSR)

Budget Augmentation Required?			
No			
Yes	X	If YES, indicate fiscal year(s) and associated amount:	
		FY	2015/16
		FY	2016/17
		FY	2017/18
		FY	2018/19
		\$1,957,567	\$1,961,047
		\$400,465	\$162,980

PROJECT COSTS

1.	Fiscal Year	2015/16	2016/17	2017/18	2018/19	TOTAL
2.	One-Time Cost	\$ 2,639,298	\$ 2,642,778	\$ 0	\$ 0	\$ 5,282,076
3.	Continuing Costs	\$ 0	\$ 0	\$ 496,656	\$ 259,171	\$ 755,828
4.	TOTAL PROJECT BUDGET	\$ 2,639,298	\$ 2,642,778	\$ 496,656	\$ 259,171	\$ 6,037,904

PROJECT FINANCIAL BENEFITS

5.	Cost Savings/Avoidances	\$0	\$0	\$0	\$0	\$0
6.	Revenue Increase	\$0	\$0	\$0	\$0	\$0

**INFORMATION TECHNOLOGY PROJECT SUMMARY PACKAGE
SECTION E: VENDOR PROJECT BUDGET**

Vendor Cost for FSR Development (if applicable)	\$122,000
Vendor Name	The Highlands Consulting Group / Crowe Horwath

Project #	3930-012
Doc. Type	Feasibility Study Report (FSR)

VENDOR PROJECT BUDGET

1.	Fiscal Year	2015/16	2016/17	2017/18	2018/19	TOTAL
2.	Primary Vendor Budget	\$ 1,455,736	\$ 1,455,736	\$ 237,485	\$ 0	\$ 3,148,957
3.	Independent Oversight Budget	\$ 112,560	\$ 112,560	\$ 0	\$ 0	\$ 225,120
4.	IV&V Budget	\$ 265,000	\$ 265,000	\$ 0	\$ 0	\$ 530,000
5.	Other Budget	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0
6.	TOTAL VENDOR BUDGET	\$ 1,782,536	\$ 1,782,536	\$ 237,485	\$ 0	\$ 3,904,078

------(Applies to SPR only)-----

PRIMARY VENDOR HISTORY SPECIFIC TO THIS PROJECT

7.	Primary Vendor	
8.	Contract Start Date	
9.	Contract End Date (projected)	
10.	Amount	\$

PRIMARY VENDOR CONTACTS

	Vendor	First Name	Last Name	Area Code	Phone #	Ext.	Area Code	Fax #	E-mail
11.									
12.									
13.									

**INFORMATION TECHNOLOGY PROJECT SUMMARY PACKAGE
SECTION F: RISK ASSESSMENT INFORMATION**

Project #	3930-012
Doc. Type	Feasibility Study Report (FSR)

RISK ASSESSMENT

	Yes	No
Has a Risk Management Plan been developed for this project?	X	

General Comment(s)
<p>Refer to Section 7, Risk Register, for general and specific comments.</p> <p>The DPR understands that risk management planning is a vital component of ensuring project success. A disciplined approach to risk management includes developing a risk management plan that identifies and documents potential risk (risk identification, identifies the ways in which they can be minimized (risk mitigation planning), and includes policies and procedures to monitor and resolve risks that arise (track and control). The risk management plan will be revised when the DPR's PRDMS project managers are positioned, again after the contract is awarded, and throughout the project. The project managers will develop policies and procedures that the project will follow to identify, assess, rank, prioritize, mitigate, and monitor each project risk.</p> <p>In general, the mitigation approach for potential changes in scope includes a clear definition of business objectives in the request for proposal and a strong change management process. The mitigation approach for potential resistance to change by staff is to involve them throughout the process and to communicate frequently with staff about project progress.</p> <p>The project managers and the project team will update the risk management plan as the project progresses.</p>



Section 3.0
Business Case

3.0 Business Case

The California Department of Pesticide Regulation (DPR) is committed to protecting human health and the environment by regulating pesticide sales and use. Any pesticide product for sale, distributed, or used in California is required to be registered with DPR¹; the Pesticide Registration Branch (PRB) is responsible for processing all new product registrations, amendments, renewals, and inactivations.

In 2013, PRB initiated the Registration Program Reengineering Project (RP²). The RP² project conducted detailed business process analyses and process reengineering of its core business processes. As a result of the effort, RP² identified and documented a new system which will provide comprehensive data capture, analysis, and management capability to support pesticide registrations, amendments, renewals, and other critical PRB activities.

This section describes the business areas evaluated for this Feasibility Study Report (FSR). This section also presents the problems and/or opportunities associated with the business areas, the extent that opportunities can be realized, and the characteristics of the proposed solution. The remainder of this section is organized as follows:

- 3.1 Business Drivers
- 3.2 Statutes or Legislation
- 3.3 Program Background and Context
- 3.4 Business Problem or Opportunity Summary
- 3.5 Business Problems or Opportunities and Solution Objectives Table
- 3.6 Strategic Business Alignment

The RP² project executive sponsors, business process owners, and key stakeholders who have a vested interest in the outcome of the project are listed in **Exhibit 3.0**, on the following page.

¹ A product requires registration in California if: (1) The U.S. Environmental Protection Agency (U.S. EPA), Office of Pesticide Programs, requires registration of the product (excluding Plant Incorporated Protectants) and the product is sold, distributed, or used in California; (2) California law requires registration of the product even if U.S. EPA does not (e.g., spray adjuvants, structural pest control devices, certain FIFRA 25(b) products).

Exhibit 3.0 Business Sponsor and Key Stakeholders

Title	First Name	Last Name	Business Program Area	External
DPR Executive Sponsors and Project Director				
Associate Director	Charles	Andrews	Pesticide Programs Division	
Assistant Director	Marylou	Verder-Carlos	Pesticide Programs Division	
Assistant Director	Anise	Severns	Administrative Services Division	
Chief Information Officer and Project Director	Larry	Wasson	Office of Technology Services	
DPR Business Process Owners				
PRB Branch Chief	Ann	Prichard	Pesticide Registration Branch	
IT Manager	Michael	Wanser	Information Technology Branch, Application Development & Database Administration	
Key Stakeholders				
Branch Chief	George	Farnsworth	Enforcement Branch	
Branch Chief	David	Duncan	Environmental Monitoring Branch	
Branch Chief	Nan	Gorder	Pest Management and Licensing Branch	
Branch Chief	Gary	Patterson	Medical Toxicology Branch	
Branch Chief	Donna	Marciano	Product Compliance Branch	
Branch Chief	Lisa	Ross	Worker Health and Safety Branch	
PRB Employees	Various	Various	Employees working with PRB core processes	
Registrants	Various	Various	Business entity registering a pesticide product for sale in California (e.g., pesticide product manufacturers Bayer, DuPont, BASF, Dow Chemical, etc.)	X
Applicants	Various	Various	Researcher, manufacturer, grower group, and other stakeholders	X
U.S. EPA	Various	Various	Office of Pesticide Programs	X
Other State Agencies	Various	Various	Pesticide intersections with various agency's responsibilities	X
Public	Various	Various	Environmental groups, schools, UC IPM, and others	X
County Agricultural Commissioners	Various	Various	All aspects of county pesticide enforcement	X

3.1 Business Drivers

The RP² project is expected to benefit the PRB and its stakeholders by providing for an integrated business process and technology-based solution that supports and enhances the core pesticide registration business processes. **Exhibit 3.1**, below, identifies the key business drivers for this RP² project.

Exhibit 3.1 Business Drivers

Category	Driver	Description
Financial Benefit	<ul style="list-style-type: none"> • Increased Revenues • Cost Avoidance (Cost Containment) • Cost Savings 	California receives revenue from product sales; therefore, expediting the review process speeds products to market and realizes revenue for registrants and California's economy sooner. In addition, an efficient review process helps ensure products are available to protect crops during their growing season which could result in reduced crop loss.
Mandates	<ul style="list-style-type: none"> • State Mandate • Legislation 	Section 3.2 lists new mandates impacting PRB's workload. In addition, PRB has mandated evaluation timeframes under Title 3, Section 6151 of the California Code of Regulations. PRB expects the proposed solution will support them in meeting these evaluation timeframe mandates.
Improvement	<ul style="list-style-type: none"> • Better Services to Citizens • Efficiencies to Program Operations • Technology Refresh 	Process improvements that ensure a consistent review process and reduce the overall submission processing time helps DPR achieve its mission of protecting people and the environment. In addition to internal improvements, by enabling applicants and registrants to submit, pay, and track submissions online leads to a self-service government. Citizens benefit with access to current electronic product labels and greater regulatory transparency.

3.2 Statutes or Legislation

Statutes and/or legislation impact the business processes and solution. **Exhibit 3.2**, on the following page, identifies existing statutes as well as new legislation that affect PRB and the proposed solution.

Exhibit 3.2 Statutes or Legislation Affecting Business Solutions

1	<p>Statutes or Legislation: <input checked="" type="checkbox"/> New statutes or potential legislation <input type="checkbox"/> Not applicable <input type="checkbox"/> Changes to existing legislation</p>
<p>Bill Number: Chapter 584, Statutes of 2013 (AB 304, Williams) Legal Code: Sections 14022, 14023, and 14024 of the Food and Agricultural Code Additional Information: Pesticides: toxic air contaminant: control measures. Requires the Department of Pesticide Regulation to complete Toxic Air Contaminant risk mitigations within 2 years of problem being identified. This bill was enrolled and presented to the Governor September 19, 2013.</p>	
2	<p>Statutes or Legislation: <input checked="" type="checkbox"/> New statutes or potential legislation <input type="checkbox"/> Not applicable <input type="checkbox"/> Changes to existing legislation <input type="checkbox"/> Existing statute</p>
<p>Bill Number: Chapter 20, Statutes of 2013 (AB 101 / SB 95) Legal Code: Section 2.00 of the Budget Act of 2013 Additional Information: Requires the Department of Pesticide Regulation to conduct a minimum of five risk assessments per year. This budget bill passed September 12, 2013 and takes effect immediately.</p>	
3	<p>Statutes or Legislation: <input type="checkbox"/> New statutes or potential legislation <input type="checkbox"/> Not applicable <input type="checkbox"/> Changes to existing legislation <input checked="" type="checkbox"/> Existing statute</p>
<p>Bill Number: Chapter 612, Statutes of 2005 (AB 101) Legal Code: Sections 12811.5 of the Food and Agricultural Code Additional Information: Allows DPR to consider all data it has on file, regardless of the source of the data. Previously, DPR was prohibited from considering data submitted by one company to support another company's application to register or amend a pesticide product, without a letter of authorization from the data owner.</p>	
4	<p>Statutes or Legislation: <input type="checkbox"/> New statutes or potential legislation <input type="checkbox"/> Not applicable <input type="checkbox"/> Changes to existing legislation <input checked="" type="checkbox"/> Existing statute</p>
<p>Bill Number: Not Applicable Legal Code: Code of Regulation, Title 3, Division 6, Chapter 2, Article 1. Section 6151 Additional Information: Requires DPR to evaluate regular product registration submissions within 60 days of receipt, and new Active Ingredient submissions within 120 days.</p>	

3.3 Program Background and Context

As part of DPR's regulation of pesticide sales and use in California, PRB is responsible for the evaluation and registration of pesticides and certain devices. The PRB also processes exemptions from registration, tracks adverse effects, issues research authorizations, and coordinates reevaluations, and human health risk assessments and mitigations.

A PRB priority is efficient, effective and consistent service delivery with registrants and other stakeholders. As part of this RP² effort, DPR leadership and staff have defined the following Vision Statement: *To better serve our stakeholders, PRB leadership and staff are committed to an electronic, customer service focused, pesticide product registration program promoting effectiveness, efficiency, and quality.*

The PRB has five core registration program business processes:

- Register, amend, and renew pesticide products/devices
- Manage pesticide product label data, pesticide product labels, and scientific data
- Issue Research Authorizations (RAs)
- Receive and track adverse effects and make determinations
- Coordinate pesticide product(s) reevaluation, risk assessment, and mitigation programs.

PRB, as the primary liaison with pesticide product registrants, corresponds with registrants regarding data requirements, health effects of pesticide determinations, labeling requirements, and final actions on registrations. PRB, with assistance of evaluation scientists within other DPR branches (i.e., Environmental Monitoring, Medical Toxicology, Worker Health and Safety, and Enforcement Branches), conducts a thorough evaluation to determine whether the pesticide product endangers human health or the environment, and is effective for its intended use. PRB also prepares public notices, manages submitted data, oversees data call-ins on environmental fate and acute and chronic toxicology, coordinates the reevaluation process, and maintains label files and the Registration Resource Center. It also receives and tracks registration and renewal fees and penalties, and provides information on registered pesticides and label instructions to pesticide enforcement agencies (e.g., other DPR branches, County Agricultural Commissioners, other State agencies) and the public.

In addition, PRB receives and processes additional data. For example, PRB assists the U.S. EPA in performing IR-4 reviews, analyzing residue studies for minor crops. PRB provides the evaluation reports to U.S. EPA using U.S. EPA's report format, processing about four to six reports a year. Additionally, PRB regularly logs correspondence with registrants and other stakeholders, including incoming public comments, letters of support from grower groups, outgoing correspondence regarding pesticide determinations (whether or not a product requires registration as a pesticide), public information requests, and other miscellaneous announcements.

Section 4, *Baseline Analysis*, following this section, provides a more descriptive overview of the core business processes. Section 4 also provides the technical environment utilized by DPR in performing their operations.

3.4 Business Problem or Opportunity Summary

California has one of the most comprehensive and rigorous state pesticide regulation and enforcement programs. DPR's mission is to "*protect human health and the environment by regulating pesticide sales and use, and by fostering reduced-risk pest management.*" DPR regulates pesticides with its comprehensive program that encompasses not only the evaluation process of registering pesticide products, but also enforcement of pesticide sales and use, prevention of environmental contamination, licensing of applicators, and protection of workers, consumers, endangered species, and the environment.

To effectively fulfill DPR's mission, there is a critical need for PRB to improve its business processes and supporting technology to support meeting State Mandates as well as provide access to critical product and management information. The PRB plans to reduce manual processes and implement an integrated solution to better serve employees, registrants, applicants, and other stakeholders.

Faced with business issues arising from a paper-intensive registration process (details further described below), DPR performed the *Pesticide Product Registration Business Process Assessment and Design* effort as part of RP² to evaluate the current PRB operations. During this effort, the project team analyzed the current operations of the PRB, and opportunities for improvement. Included in the process assessment efforts were research and information gathering, participation in approximately 20 team meetings and one-on-one interviews, and walk-throughs of the core business processes. The project team gathered key performance metrics for developing the baseline as well as to help build the case for change. As a result, the project team documented the current business processes, identified issues and improvement opportunities, developed a future state for improved business processes, and identified regulatory and policy implications.

The RP² project identified several problems and/or opportunities. These problems and/or opportunities are:

1. Paper-based, manual-intensive registration processes result in cumbersome processing, bottlenecks and inefficiencies
2. Hardcopy product labels limit the ability to efficiently evaluate pesticide product labels and impact stakeholders in the field needing the information
3. Registrants submit incomplete registration and label amendment submissions
4. Inconsistent work practices and lack of standardized process execution
5. Disparate, standalone systems limit visibility of workload per station and staff and no single data source exists to register products
6. Staff are not consistently trained or need more ongoing training

7. Lack of Communication
8. Lack of Performance Measures and Accountability
9. Lack of Rewards, Recognition and Feedback Linked to Process Performance

Each of these business problems are described in detail below. Subsection 3.5, following this subsection, lists how each business problem will be addressed by a business solution objective.

BP-1 Paper-based, manual-intensive registration processes result in cumbersome processing, bottlenecks and inefficiencies

PRB's current processes rely on paper-based submission of fees, registration applications, product renewals, scientific data studies, product labels, and other supporting documents. These paper-based submissions are extremely inefficient for staff and significantly increase the time it takes to make a registration decision on pesticide products in California. In 2012, DPR received 1,762 new pesticide product registration submissions, of which 1,726 were regular product registrations and 36 were new pesticide product submissions containing a new active ingredient (AI). On average, it took 90 days to reach a final action for a 2012 regular product submission. For new active ingredient submissions received in 2010 that entered scientific evaluation, it took on average took 531 days from submission to proposed decision. These timeframes cause problems with manufacturers missing product sales during their pesticide season, as well as potentially resulting in use of other pesticides that pose greater unintended risks to human health and the environment.

Multiple issues exist in the paper-based, manually intensive processes. Below are illustrative challenges and examples:

- Tracking, managing, and storing large volumes of hardcopy documents is very cumbersome, time-consuming, and prone to lost or misplaced documentation. Documents and data studies may be lost or misplaced, resulting in increased processing time. As documents move through the registration process, many handoffs exist due to the current process of managing and tracking of all registration documents. PRB employees generally follow the document check-out and check-in policies for the documents, but occasionally employees share or loan documents to other employees, which results in lost and/or misplaced documents. In addition, hard-copy registration documents are stored in multiple places rather than in a centralized electronic location, which prevents quick access to needed registration product information. To note, the PRB paid approximately \$10,000 for storage space at the State Records Center for archived records in the past year. Annual storage costs increased almost \$800 between 2012 and 2013. PRB expects the annual storage costs to increase by the same rate each year.
- PRB currently cannot accept electronic payment of registration and renewal fees, and relies on a cumbersome, unsecured paper check processing process. Registrants must submit paper checks along with their registration submissions and renewal application forms. Checks arrive daily in the mail and reside in a processing location until staff can process the checks and submit them to DPR

Cashier. At times there may be up to a 15 day delay for check processing. In addition, paper checks are cumbersome for registrants to submit and for DPR to process, requiring multiple handoffs and audit separation of duties.

- PRB relies on 24 separate and disparate tracking systems and databases to log, index, manage, and track the work associated with PRB's core business processes. For example, with new product submissions, during the mail intake and indexing processes, employees from various PRB work units must manually log the mail received from registrants, enter key data elements from the registration application into DPR's Tracking database, and index key data from scientific studies submitted to support the application. Then after the product is licensed, staff code information from accepted hard-copy labels into DPR's Product Label database. Most of this activity is entered and tracked in separate database applications.
- In the current environment, scientific evaluation stations working on regular product registrations (excludes product registrations with new AIs) receive registration submissions sequentially after the previous station has completed its analysis of the submission. This sequential processing is due to hard copy submissions, along with the frequent need to reference additional studies that are archived off-site (requiring additional time for retrieval), all of which increases processing time. For example, in 2012, it took 48 days or more to complete a review in one station. Therefore, for submissions that required evaluation by two or more stations, the evaluation portion of the registration process is expected to take 96 days or more.
- The current registration system lacks a robust workflow and product status identification, making it difficult to track and account for conditionally registered products. Because conditionally registered products are not adequately tracked, and as a result may retain a conditional status for years, and may receive full registration in error. Conditional registration is intended to be a temporary status until a registrant completes certain specified data requirements. However, some conditionally registered products have been granted renewal of their conditional status for years without providing PRB with the additional data needed to grant or deny full registration status. In addition, conditionally registered products can be easily missed, overlooked, and improperly recorded in PRB's data systems as a result of human error, resulting in inconsistent tracking of the registration status (e.g., some products have full registration in the database but are conditional in the product file, or the reverse). Also, upon product renewal, a conditionally registered product may receive full registration in error when all conditions have not been satisfied (e.g., due to complex conditions, one condition may be partially met but not completely satisfied). This may result in a pesticide being sold and used when additional information may have resulted in a decision to deny registration due to safety, health, or other environmental concerns.

The lengthy registration and licensing process financially impacts registrants by delaying their ability to sell products in California until the registrant receives a product license from DPR. Through various pesticide manufacturer work groups and discussions with DPR, registrants identified this issue is their number one concern with the current registration process. The delays also impact DPR's revenue stream since Mill Assessment Fees cannot be assessed until products are licensed and sold. For consumer pesticide products, the market is often driven by registrants' ability to place products in "big box" stores like Wal-Mart and Home Depot. Such stores only accept new products two times per year. Missing one of these two deadlines can be devastating for a consumer product pesticide company as it will have to wait another six months to try and get its product into the marketplace.

California's farmers and growers are also impacted by these delays since they cannot use a new pesticide until it is approved by DPR. The lengthy new product registration process can result in growers missing a product application window, resulting in crop loss due to pests that would be better controlled with a product pending registration. This product registration delay also can cause farmers to forgo planting a crop altogether because the product would not be available during the application period. In addition, the farming community often complains that neighboring producers (in other states) have an unfair advantage due to those states' quick acceptance of U.S. EPA approved products.

Reducing the average pesticide registration processing time by 30 days, results in additional time that the newly registered product is available for sale. It is estimated that reducing the average registration time from 90 days to 60 days for a new product that contains an active ingredient found in other registered products, could potentially increase total pesticide sales during those 30 days by \$19.8 million. (Pesticide products, newly registered between Q4 2011 and Q3 2012, totaled 1,318 products. Of these 1,318 products, 722 reported sales between Q1 2012 and Q4 2012. The average monthly reported sales for these 722 products totaled \$19,776,901, or \$27,392 per product.²)

² The calculation excludes quarters without reported product sales. The pesticide product sales amounts come from the registrants', brokers', and dealers' quarterly report of pesticide sales.

BP-2 Hard-copy product labels limit the ability to evaluate pesticide products and impact stakeholders in the field needing the information

The current process for submitting and storing pesticide product labels and label data requires registrants to submit six hard-copy labels, one of which, after completion of the registration process, is stored in filing cabinets in PRB's offices in Sacramento. Registrants are required to submit additional hard copies of labels if any information on the label changes, including minor modifications. One copy of each amendment to a label is also stored in DPR's filing cabinets.

Physical submission and storage of labels present myriad problems for PRB, including limiting public access to critical label data. Timely access to pesticide labels is especially important to: (1) registrants who need the ability to view the latest labels for all products currently registered with DPR; (2) Poison Control Centers in California that need to reference the most accurate and up-to-date product labels in emergencies; and, (3) consumers, growers and product end-users who need access to labels in the field. In addition, access to California registered pesticide labels would be extremely useful to product compliance and enforcement personnel during field inspections to ensure products are registered and being used and applied in accordance with the latest label specifications.

In addition, hard-copy product label submissions present a significant bottleneck in the pesticide product registration and label amendment processes. All DPR staff identified that working with hardcopy labels was a major inefficiency in the current processes.

Hardcopy labels, particularly broad use agricultural labels may contain up to 100 pages of detailed technical information. Due to the lack of federal formatting standards the placement of information on the label is not standardized, and as a result, can take a long time to accurately code (index into the data structure). Because they are paper based, they are stored and accessed via a central repository. This makes distribution, technical evaluation and label comparison a much slower, cumbersome, and potentially less accurate process.

The manual process to code an approved product label data into the Product Label Database (PLD) generally takes less than a week. Due to seasonal fluctuations in the submission of new and amended products related to the agricultural industry, at times there can be an eight to twelve week backlog of labels waiting to be coded. Seasonal fluctuations impact the entire spectrum of the "registration process" and make requesting new positions or re-directing current staff difficult. Staff requires lengthy training to accurately interpret and code complex labels. The work cannot be conducted by untrained or temporary staff. When backlogs occur, issues arise when inspectors and other stakeholders need current product information. A typical example is a local county agricultural commissioner (CAC) that wishes to process a pesticide use permit (to apply pesticides) or submit pesticide use reports (PUR). If the PLD contains incomplete label data, the local CAC is unable to proceed with their responsibilities. Missing data can include critical information on whether use of the product is restricted, chemical formulation, and approved application sites. Complete PLD data is necessary to validate PUR reporting. Resolution of the backlog

issues and other problems relative to access of critical data requires a combination of new methodologies for submission/collection of discreet label data and the submission of standard format electronic labels.

As an example of the impact of hardcopy labels on stakeholders, the Worker Health and Safety Branch (WH&S) fields calls during pesticide related illness or exposure incidents ("episodes"), responding to approximately 70 episodes per year. An episode may affect one person to hundreds of people. WH&S personnel need to quickly access product label information and occasionally the Confidential Statement of Formulation (CSF), relaying the pesticide product information to first responders or hospital personnel (e.g., emergency room doctors). Medical professionals then use the information to determine the appropriate course of treatment. Currently, medical professionals must contact DPR during normal business hours; WH&S personnel then must physically go to the Registration Resource Center to retrieve the hardcopy label and CSF, as applicable. A particularly extreme example of this was during the Bhopal, India leak of methyl isocyanate (an insecticide), where thousands were killed and hundreds of thousands injured. DPR staff needed to rush to the building over the weekend to retrieve critical hard-copy data, including the CSF. While it is difficult to gauge the impact of "timely access" to data on this episode, it is important to note that pesticide use can take at any time, 24 hours a day, seven days a week, which highlights the value of electronic access to critical health and safety data.

A second example of the impact to stakeholders; Product Compliance Branch auditors make copies of the label(s) registered to, or associated with, the entity (i.e., registrant, broker, or dealer) selected for audit. The auditor uses the hard-copy label to compare against the product labels identified in the field. The auditor may also need to contact the PRB while in the field to confirm the validity of a site's amended label. Often, the auditor must return to the field with the additional label information given the label was unavailable electronically at the location at the time of the audit visit.

BP-3 Registrants submit incomplete registration and label amendment submissions

Registrants often submit incomplete new and amended product registration packages, which increase time lags in the registration process. DPR returns about 14 percent of registration submissions due to incomplete information. Registrants often submit packages that are missing information needed to properly evaluate requests. Submissions may be poorly organized, cite products not registered with DPR, omit cover letters describing proposed changes, contain labels that don't identify changes, or fail to provide supplemental documentation. Each of these issues makes the evaluation more lengthy and cumbersome. Regulatory Scientists must then contact registrants for more information or prepare a return package to send to the registrant.

In 2012, DPR returned 712 submissions to registrants who then had to resubmit revised packages and start the registration review process over again. Due to the high volume of applications, and PRB's policy of first-in, first-out processing, incomplete

application packages may sit in the queue on the Regulatory Scientist's desk for 30 to 90 days without any action, to then be found incomplete upon initial review.

Similar issues exist with label amendment submissions from registrants. Often, registrants do not provide adequate documentation to support the label amendment request or send multiple label amendments (sometimes with a single cover letter) without detailing what is being provided or requested.

For minor label amendments (i.e., changes not requiring scientific data for support), neither statute nor regulations require registrants to submit a label amendment application or cover letter. In cases where limited or no information is provided, the Regulatory Scientist spends additional time to research and verify what is being amended on the label and often must compare the proposed label to prior DPR-accepted labels to identify the changes. Without a cover letter or adequate documentation, the Regulatory Scientist must call registrants to ask why they are submitting the label or may need to request additional documentation, increasing delays in the processing time.

BP-4 Inconsistent work practices and lack of standardized process execution

From the employee survey, employees feel there are varying practices across PRB including inconsistencies in the way individuals perform their duties, conduct technical evaluations, and prepare and finalize submissions. Employees cite inconsistency in how processes are followed as one of the top three challenges they face in effectively and efficiently doing their jobs.

Anecdotally, employees cite differences in the way Regulatory Scientists execute the registration process, which leads to registrant frustration and processing delays. Similarly, employees note inconsistencies in the way supervisors or groups of Regulatory Scientists apply State regulations during the registration process. Examples include conditional letters not being forwarded consistently to Licensing, inconsistent application of amendment fees, and supervisors focusing on different factors when reviewing a completed package.

BP-5 Disparate, stand-alone systems limit visibility of workload per station and staff and no single data source exists to register products

Each of the five core business processes within PRB relies on numerous stand-alone systems and databases that are not fully integrated. This results in duplicate entry of similar and/or redundant information. Currently, DPR maintains 24 separate PRB systems including MS Access databases and complex macro-driven MS Excel spreadsheets. Each scientific evaluation workstation maintains its own stand-alone tracking system to log and assign submissions for scientific evaluation. Most workstations use MS Excel, MS Access, or paper logs to track incoming submissions, assignments, and other scientific evaluation process information. The Regulatory Scientists commonly go to the individual workstation to check the package status and identify the assigned evaluation staff. Use of stand-alone systems also limits visibility of workload per station, staff, and other information that can be used to effectively manage the registration process, workloads, and backlogs.

The manual entry of information and product data can lead to input errors causing other processing or reporting errors. For example, if a product is incorrectly entered in the Product Label database, then Pesticide Use Reports (PUR) will be rejected by the system. These errors then need to be investigated and corrected.

BP-6 Staff are not consistently trained or need more ongoing training

PRB employees desire more effective and consistent training. Employees indicated that they should be better trained and informed not only on their own processes, but about all steps in the registration process. Staff noted that the lack of regular refresher courses for Regulatory Scientists may be partially responsible for inconsistencies in the way staff implements processes and policy/regulatory changes. An example is the prevalence of incomplete AB 1011 (Assembly Bill 1011, Chapter 612, Statutes of 2005) searches that result in unnecessary routing of registration packages to evaluation stations.

Employees also cite inconsistencies in the way some senior and novice Regulatory Scientists process packages to be the result of past training practices where multiple trainers provided different or conflicting instructions to staff. PRB has recently consolidated training under a single trainer to address this issue.

In addition, there is limited/no training for supervisory or management staff that provide them with tools and techniques for organizational change management and managing employees' abilities to meet performance objectives.

Also, policy and procedure documentation may contain outdated material and is spread over various source documents. Procedures for Regulatory Scientists can be documented in policy procedure memos, branch memos (old), web documents, California Notices, various e-mails and the Regulatory Scientist Desk Manual (the Desk Manual is intended to be the final authority consolidating information from all other documentation sources). Intake through archiving procedures for support staff are documented in the Intake through Archiving manual and separate desk manuals for each station (i.e., intake, indexing, licensing). Evaluation Scientist stations do not have desk manuals. The resulting confusion about where to look for definitive guidance on policies, procedures and requirements contributes to inconsistencies in the way employees conduct their work.

BP-7 Lack of Communication

Employees reported lack of communication as one of the top challenges they face in performing their work effectively. They identified communication challenges between units within PRB, between PRB and other DPR branches, and between DPR and registrants.

Communication between PRB units:

- Employees placed heavy emphasis on fostering effective communication between Regulatory Scientists and Evaluation Scientists, and between all scientists and support staff. In particular, they believe better communication between Regulatory Scientists and Evaluation Scientists when conducting AB 1011 label searches, as well as quick discussions of possible label candidates

prior to routing of packages, could reduce unnecessary routing or misrouting of packages, which adds significant delays to the registration process.

In general, employees desire better communication between all areas within the Branch (intake, coding, technical and scientific evaluation, Registration Resource Center, etc.) Also, employees desire information about the functions, workload and responsibilities of each area. Such information would make each area more aware of how the other areas operate and how areas impact one another, which could foster cross-functional efficiencies and process improvements. For example, if Regulatory Scientists knew exactly what the coders look for and what they code for, the coding process could be more efficient, (i.e., fewer unnecessary packages forwarded to coding)

Communication between PRB and other DPR Branches:

- Employees desire improved communication between PRB and other DPR Branches. Better communication would allow employees within each Branch to know what other branches do, how they do it, and how each fits into the Department's mission. Improved communication between Registration, Enforcement, and Product Compliance Branches leads to better coordination of activities. Branch employees need to learn and understand the primary concerns of other Branches and the interdependency of processes between Branches. For example, if coders knew what information was available to pesticide applicators, they could better recognize and prevent errors that could show up in the PUR.

Communication between PRB and Registrants:

- While communication between registrants and Regulatory Scientists is frequent and usually productive, it is typically on a case-by-case basis. More proactive, continuous communication with registrants through additional workshops, pre-registration meetings and online informational videos could help registrants better understand PRB's processes. Also, this communication may result in more accurate submissions, and reduce returns and process delays.

BP-8 Lack of Performance Measures and Accountability

Currently in PRB, each core process lacks performance targets and standards to hold employees accountable. Also, given the numerous, disparate systems and databases, it is very difficult to obtain and provide quality management reports in a timely manner. Certain key information is currently not available, limiting management's ability to monitor process performance metrics.

Given the manual, paper intensive processes, it is difficult to isolate and manage the various workflows and workloads. Related to the common theme of inconsistent work practices, employees cited the need for improved accountability, as well as adherence to standards and accepted performance objectives and time frames. Employees observed inconsistencies in the way others perform similar work with little accountability for accuracy and timeliness of the work products. Supervisors report there is a general inability to track staff productivity, backlog, and workflow.

In addition, a lack of visibility in evaluation stations and inconsistencies in how Regulatory Scientists review labels and bridge data are cited as examples of lack of accountability across PRB. Although it is difficult to quantify the impact, it is reasonable to assume that these issues contribute to processing delays and reduced productivity from employees.

BP-9 Lack of Rewards, Recognition and Feedback Linked to Process Performance

Currently, there are limited performance goals and metrics in place for each core business process. As part of their annual Individual Development Plans, employees currently do not have specific, measurable performance targets that link to the overall process performance.

Some employees in PRB cite the lack of motivating rewards and recognition for high performers. Some employees desire management to actively solicit and encourage feedback and ideas to improve the registration process, procedures, and policies. Employees suggested a formal procedure for submitting improvement ideas. Also, employees requested that there be greater educational, training and special project opportunities for motivated employees to allow them to advance beyond their current position and responsibilities.

3.5 Business Problems or Opportunities and Solution Objectives Table

To fulfill DPR's mission, stakeholder needs, and address the nine key business issues, PRB developed seven business solution objectives. **Exhibit 3.3.1**, starting below, presents each of the seven solution objectives, associated descriptions, and maps how the solution objective addresses one or more of the business problems/opportunities.

Exhibit 3.3.1 RP² Solution Objectives

Business Solution Objective	Description	Business Problem Addressed
<p>B-1 Improve data collection and integration, and develop validation processes to ensure the accuracy, quality & completeness of registrants' submissions</p>	<p>Creating an electronic registration submission system that enforces robust data validation rules and imposes data format standards on registrants' data at the time of submission can improve the quality, accuracy and completeness of data received from registrants. Data validation rules and standards that are integrated into the system would automatically screen registration information, flag missing or incomplete data, and require registrants to correct deficiencies prior to submitting requests for registration actions.</p> <p>Ensuring that data submitted by registrants is accurate and complete, at the time of submittal, will decrease the current workload and processing time needed to identify deficiencies and reduce the need for registrant follow up to correct them. In addition, decreasing this workload will improve the efficiency and effectiveness of the registration process.</p>	<p>BP-1, BP-3, BP-4, BP-5</p>
<p>B-2 Provide access to electronic product labels anytime and anywhere through the Internet/ Intranet</p>	<p>Electronic labels will allow all PRB and DPR staff to view and electronically compare labels – including prior versions of labels – rather than having to visually review and compare two hard copy labels side-by-side. Electronic labels would eliminate lost or missing labels and allow multiple staff to view labels simultaneously from their respective workstations or worksites. Overall, electronic label submission would greatly increase productivity across PRB processes and make it easier for staff to track label amendments and history. Also, approved electronic labels made available and accessible, through the Internet, will allow registrants, government agencies, Poison Control Centers, growers, consumers, enforcement or compliance personnel in the field, and other stakeholders to search, view, print, and download the most accurate and up-to-date product labels, as well as historic product labels, registered in the State.</p>	<p>BP-1, BP-2</p>

Business Solution Objective	Description	Business Problem Addressed
<p>B-3 Increase throughput while decreasing the time & effort to process registration submissions</p>	<p>By developing a paperless, automated registration process, the burden of processing, tracking and archiving large volumes of paper documentation would be eliminated. Currently, a large number of person years (PYs) within the Branch manage hard-copy documents. With a paperless application submission process, these resources could be redirected to more high-value data management, analysis and evaluation activities that would help reduce backlog in these areas.</p> <p>As part of an electronic submission of data, registrants would be able to submit electronic versions of pesticide product labels. This would allow staff to perform electronic comparisons of labels, significantly speeding the current labor-intensive process, reducing errors and oversight, and establishing automated version control. An electronic data submission/application process would reduce the incidence of incomplete submissions and eliminate lost or misplaced hard-copy data. It would also allow evaluation stations to simultaneously evaluate a submission where possible, reducing the time needed to register products by minimizing sequential processing and redundant manual data entry across multiple systems.</p> <p>As part of this goal, PRB would also accept electronic payments for registration applications and license renewal fees. Electronic payments eliminate the manual workload to process paper checks within PRB and the Department, and would provide added fiscal safeguards.</p>	<p>BP-1, BP-3, BP-4, BP-5</p>
<p>B-4 Establish measurable process performance targets and accountability as a Best Practice</p>	<p>To help achieve its goal of effectively managing the pesticide registration process in California, the PRB must adopt streamlined and efficient processes that meet regulatory timelines. PRB needs to define and implement process performance targets and key performance indicators. Those indicators must be quantifiable measurements that allow PRB management to measure achievement of its performance targets as well as identify problem areas and process bottlenecks to more effectively reduce and handle exception processes and backlogs. The new system should provide key metrics regarding day-to-day work to more effectively manage business processes and workflow monitoring. Once performance metrics can be established, the PRB can quantify accountability.</p>	<p>BP-1, BP-4, BP-7</p>
<p>B-5 Improve registration, communication and staff coordination processes</p>	<p>A key component to the entire registration process is effective communication and coordination between PRB staff, Department staff and registrants. Improving communication and coordination through flexible and configurable workflow automation is a key goal for the Branch. Automated workflow would automatically route work and necessary data to employees and notify registrants on key events/activities/requests/updates.</p> <p>Automated workflow would enable PRB management and employees to better manage work assignments and workload. It would also allow employees and registrants to track the real-</p>	<p>BP-2, BP-3, BP-4, BP-6, BP-7</p>

Business Solution Objective	Description	Business Problem Addressed
	<p>time status of a product registration at any time during the process and track to whom it is assigned. Management would be able to capture valuable metrics by registrant and workload type. Management would also be able to measure employee productivity and resource capacity, identify bottlenecks in the process, and provide audit trails. An automated workflow also eliminates the need to physically route submissions between stations and branches. Registrants would be better informed about the status of their product registration(s) through automated messaging at key process steps such as submission confirmation, assignment, returns, recommendations, completions and alerts.</p>	
<p>B-6 Centralize (electronically) company profile information, pesticide label data, scientific studies data and supporting documents</p>	<p>A single, centralized product registration system to capture, track, process and archive new registration submissions, pesticide label data, scientific studies, and supporting documents would greatly improve efficiencies and facilitate data sharing across all five core processes. By consolidating the existing 24 systems and databases, a centralized system would provide numerous benefits, such as eliminating duplicate data entry in multiple stand-alone systems and eliminating the risk of data entry errors.</p> <p>In addition, a centralized registration system would allow PYs currently dedicated to logging, indexing, and keying registration submissions and scientific studies into separate systems to take on more analytical duties. It would also streamline the coding of pesticide label information. A consolidated system allows staff to view data simultaneously from their desktops, rather than having to physically check out the limited number of hard copies of scientific studies and product labels.</p> <p>Over time, as more and more registration data becomes stored electronically in a centralized system, the need to store hard-copy data offsite and retrieve it when needed would be greatly reduced. This would reduce off-site storage and retrieval costs for PRB and speed access to archived data studies, and ultimately reduce the time to process registrations.</p> <p>Also, a company and product management component of a new system will help improve the quality of company profile data, contacts and products. This information also will be helpful for future queries, public information requests, and other analyses (e.g., adverse effect, reevaluation, and risk assessment and mitigation evaluations).</p>	<p>BP-1, BP-2, BP-5, BP-7</p>
<p>B-7 Improve training and provide intelligent work tools for employees</p>	<p>PRB management recognizes that employees are knowledgeable, dedicated and hardworking. Management is also committed to provide meaningful training opportunities and create a work environment that is fulfilling and rewarding. PRB should explore methods to standardize training in order to address staff concerns that non-standardized training across units leads to inconsistent process execution. They should clarify existing policy guidelines and procedures and communicate clear</p>	<p>BP-4, BP-6, BP-7</p>

Business Solution Objective	Description	Business Problem Addressed
	<p>expectations that all employees must consistently follow Branch procedures when completing their work.</p> <p>In addition, PRB needs to explore ways to engage employees in training curriculum tailored to their specific professional objectives. Similarly, PRB should investigate methods to improve accountability and adhere to established standards and accepted performance objectives and time frames, and, in turn, provide recognition for high-performing employees.</p> <p>Management also must explore various options to establish better communication between PRB and other DPR Branches. Such communication will help inform employees about the functions, workloads and responsibilities of each area while fostering a greater appreciation for the impacts each area’s work has on the others.</p> <p>Furthermore, PRB should provide process support for staff through the implementation of automated, intelligent work tools and systems that incorporate PRB’s business rules and guide the user step-by step through each process. Based on the task being completed and specific user input, intelligent work tools (e.g., self-help) would lead employees through the process, prompting them with next steps and requesting required information at relevant points until the work is completed. Additionally, such systems can provide robust, context-sensitive help tools based on the task currently in process and provide links or access to relevant supporting documentation and resources such as California and Federal laws and regulations.</p>	

Exhibit 3.3.2, starting on the next page, identifies each problem and/or opportunity and presents the S-M-A-R-T (Specific, Measurable, Achievable, Realistic, Time) objective(s) that address the problem and/or opportunity. A SMART objective was developed by reviewing each business problem/opportunity and associated business objective(s), and one or more corresponding metric. A SMART objective may address one or more of the business problems identified and described in the preceding subsection.

Exhibit 3.3.2 S-M-A-R-T Objectives by Business Problem/Opportunity

Business Problem/Opportunity and SMART Objectives			
Problems and Opportunities			
BP-1	Paper-based, manual-intensive registration processes result in cumbersome processing, bottlenecks and inefficiencies		
SMART Objective(s)			
O-1	15% of registration submissions received electronically by end of the first year of implementation, June 2018		
	Metric	Baseline	Target
	% of registration submissions received electronically	0% registration submissions are currently submitted electronically	15% of registration submissions are submitted electronically by end of the first year of implementation
			Measurement Method
			Number and percentage of submissions received by method: internet, Electronic Data Interchange (EDI), paper
O-2	Regular registration submissions processed, on average, within 60 days by the end of the third year of implementation, June 2018		
	Metric	Baseline	Target
	Length of time to process a regular registration submission	90 days for regular submission	60 days for regular submission by end of the third year of implementation
			Measurement Method
			Length of time to process a registration submission, from date of submission to date of final decision
Problems and Opportunities			
BP-2	Hard-copy product labels limit the ability to evaluate pesticide products and impact stakeholders in the field needing the information		
SMART Objective(s)			
O-3	Provide 100% access to electronic product labels available ³ anytime and anywhere through the Internet/Intranet upon implementation, June 2017		
	Metric	Baseline	Target
	% of product labels received electronically	0% of product label submissions are captured electronically	15% of label submissions are submitted electronically by end of the first year of implementation
			Measurement Method
			Number and percentage of product labels received by method: electronic, EDI, paper
	Labels accessible online	0% of product labels are accessible and available online	100% of accepted labels submitted electronically are accessible and available online upon implementation
			Measurement Method
			Product labels accessible electronically

³ Note, only product labels that have been submitted and stored by the new system will be available online and electronically at the time of implementation. Over time, all labels will be available electronically.

Business Problem/Opportunity and SMART Objectives <i>(continued)</i>				
Problems and Opportunities				
BP-3	Registrants submit incomplete registration and label amendment submissions			
SMART Objective(s)				
O-4	Reduce incomplete submissions by 75 percent by end of the third year of implementation, June 2020			
	Metric	Baseline	Target	Measurement Method
	# of incomplete submissions	712 (14%) incomplete submissions in 2012 ⁴	Reduce incomplete submissions by 75% by end of the third year of implementation	Number of incomplete submission received
Problems and Opportunities				
BP-4	Inconsistent work practices and lack of standardized process execution			
SMART Objective(s)				
O-5	Establish 100% electronic workflows and standardized business rules for each core business process that is part of the proposed solution upon implementation, June 2017			
	Metric	Baseline	Target	Measurement Method
	% of electronic workflows and standardize business rules	0% workflows and business rules	100% electronic workflows and standardized business rules upon implementation	Workflow metrics and reports
Problems and Opportunities				
BP-5	Disparate, stand-alone systems limit visibility of workload per station and staff, and no single data source exists to register products			
SMART Objective(s)				
O-6	100% of active registrants/applicants profile and product information available and accessible to PRB staff by end of the first year of implementation, June 2018			
	Metric	Baseline	Target	Measurement Method
	Centralized data available and accessible online	Less than 20% of information available online	100% of information available to staff by end of the first year of implementation	Availability of information online
O-7	100% of key process metrics available real-time upon implementation, June 2017			
	Metric	Baseline	Target	Measurement Method
	Key process and management metrics available real-time	Minimal (5%) real time metrics available; historical data and reports are created several months later	100% of key process and management metrics available real-time upon implementation	Workload metrics and reports

⁴ Source: The current system lacks the ability to identify specific reasons for submission return.

Business Problem/Opportunity and SMART Objectives (continued)			
Problems and Opportunities			
BP-6	Staff are not consistently trained or need more ongoing training		
SMART Objective(s)			
O-8	Provide online tools and self-help by each major step in core business process upon implementation, June 2017		
	Metric	Baseline	Metric
	Online tools and self-help by each major step in core business process	Zero tools currently available linking to major workflow steps	Online tools and self-help available by major process upon implementation
			Measurement Method
			% of major process steps with links to online and critical information
Problems and Opportunities			
BP-7	Lack of Communication		
SMART Objective(s)			
O-9	Provide daily, weekly, and monthly key performance/status information/reports upon implementation, June 2017		
	Metric	Baseline	Target
	Number of daily, weekly and monthly performance/status information/reports	Limited performance/status information/reports currently available	100% of daily, weekly, monthly key performance/status information/reports available upon implementation
			Measurement Method
			# and availability of metric reports
Problems and Opportunities			
BP-8	Lack of Performance Measures and Accountability		
SMART Objective(s)			
O-10	Establish measurable process performance targets for each major activity within a core process by end of the third year of implementation, June 2020		
	Metric	Baseline	Target
	Key process measures and targets established for each major core process activity	Limited process targets established for interim process activities	All major process activities have a measurable process target(s) by end of the third year of implementation
			Measurement Method
			Days to complete each major process activity
Problems and Opportunities			
BP-9	Lack of Rewards, Recognition and Feedback Linked to Process Performance		
SMART Objective(s)			
O-11	100% of individual development plans link and align with process goals by end of the third year of implementation, June 2020		
	Metric	Baseline	Target
	Individual development plans and performance linked directly to process targets	0% of current Individual Development Plans linked to process metrics and performance	100% of Individual Development Plans link and cite personal goals that align with process goals, by end of the third year of implementation
			Measurement Method
			Count of Individual Development Plans complete with performance metrics aligned with business process metrics

3.6 Strategic Business Alignment

Exhibit 3.4, starting below, identifies DPR’s strategic business goals as defined in the Strategic Plan, dated February 2013. DPR’s 2013 Strategic Plan includes six strategic goals and 26 objectives. Exhibit 3.4 briefly describes how this RP² effort aligns with DPR’s broader strategic goals and objectives.

Exhibit 3.4 Strategic Business Goals and Alignment

Strategic Business Goals	Alignment
<p>DPR Strategic Plan Goal 1 – Protect People and the Environment</p>	<p>Goal 1 of DPR’s Strategic Plan focuses on assuring California’s environment is not adversely affected by pesticides and that all people are protected from unacceptable pesticide risks. The PRB plays a key role in assuring that pesticide products that are available for use in California do not pose an unacceptable risk. The proposed solution enables PRB to help the Department fulfill this goal by improving the evaluation process and disseminating information to other branches and external stakeholders that are responsible for product monitoring, enforcement, and emergency response activities.</p> <p>The RP² would address problems BP-1, 2, 4, 5, and 7 stated in Sections 3.4 and 3.5, which is in alignment with DPR’s Goal 1, and five associated objectives.</p>
<p>DPR Strategic Plan Goal 2 – Advance Reduced-Risk Pest Management Systems</p>	<p>Goal 2 of DPR’s Strategic Plan focuses on advancing the research, development and adoption of effective pest management systems that reduce risks to people and the environment. The current manual-intensive pesticide registration business processes result in inefficiencies and lack of communication amongst key stakeholders. The proposed solution provides for access to centralized data, allowing various stakeholders to access and utilize the pesticide product information to perform various evaluations and analyses.</p> <p>The RP² would address problems BP-1, 2, 4, and 5 stated in Sections 3.4 and 3.5, which is in alignment with DPR’s Goal 2, and three associated objectives.</p>
<p>DPR Strategic Plan Goal 3 – Enforce and Achieve Compliance</p>	<p>Goal 3 of DPR’s Strategic Plan focuses on maintaining and continuously improving strong and equitable compliance and enforcement programs to ensure people and the environment are not exposed to unacceptable pesticide risks. The proposed solution provides for the PRB to better perform registration activities; communicate requirements and status to registrants; disseminate information to stakeholders for enforcement; and readily provide access to pesticide registration data for ongoing data reviews.</p> <p>The RP² would address problems BP-2, 3, 6, and 7 stated in Sections 3.4 and 3.5, which is in alignment with DPR’s Goal 3, and three associated objectives.</p>

Strategic Business Goals	Alignment
<p>DPR Strategic Plan Goal 4 – Ensure Environmental Justice</p>	<p>Goal 4 of DPR’s Strategic Plan focuses on protecting all people in California, regardless of race, age, culture, income, or geographic location, from adverse environmental and health effects of pesticides. The RP² project will increase the PRB’s ability to communicate with internal and external stakeholders, providing vital information regarding pesticides. In part, stakeholders groups will still receive communications regarding registrations, reevaluations, and other critical activities, allowing stakeholders the opportunity to respond.</p> <p>The RP² would address problems BP-2 and BP-7 stated in Sections 3.4 and 3.5, which is in alignment with DPR’s Goal 4, especially related to maintaining transparency and effectiveness in public participation through the use of advisory committees, workshops, and other forums.</p>
<p>DPR Strategic Plan Goal 5 – Continuously Improve Performance, Accountability, and Organizational Effectiveness</p>	<p>Goal 5 of DPR’s Strategic Plan focuses on efficiently delivering programs by attracting and retaining a competent workforce, effective business processes, and use of current technology. As staff identified in the branch-wide survey, they desire increased and effective training, and consistency in processing submissions. The proposed solution promotes development and sustainment of highly skilled PRB staff that are valued and encouraged to grow professionally. The effort also supports DPR’s objectives to implement and maintain an effective information system to support the program and accurately capture data that may be used to forecast trends, account for performance, and assess the ability to meet future program needs.</p> <p>The RP² would address problems BP-1, 2, 4, 5, 6, 8, and 9 stated in Sections 3.4 and 3.5, which is in alignment with DPR’s Goal 5, and seven associated objectives.</p>
<p>DPR Strategic Plan Goal 6 – Communication and Outreach</p>	<p>Goal 6 of DPR’s Strategic Plan focuses on promoting an understanding and awareness of DPR programs, priorities, initiatives, and accomplishments through effective external communications, outreach, and public education. This proposed solution includes utilizing the DPR website and other media to convey pesticide information, including making key pesticide label information readily available to household, and institutional and agricultural pesticide product users, specifically regarding safe, appropriate, and effective use.</p> <p>The RP² would address problems BP-2 and 7 stated in Sections 3.4 and 3.5, which is in alignment with DPR’s Goal 6, and three associated objectives.</p>



Section 4.0

Baseline Analysis

4.0 Baseline Analysis

This section provides a general understanding of the business and technical environments that currently support the Pesticide Registration Branch's (PRB) five core business processes. This baseline analysis provides a foundation for assessing the merits of potential solutions.

The PRB conducted an extensive business process analyses and reengineering (BPR) project prior to initiating this Feasibility Study Report (FSR). The results of the reengineering effort are documented in the Business Process Assessment and Design (BPAD) document. This FSR section draws key information from the BPAD to document the current methods.

4.1 Current Method

The PRB currently maintains registrations for approximately 13,000 pesticide products containing 1,000 different active ingredients (AIs). PRB receives and processes approximately 5,000 registration submissions each year, as well as manages pesticide product license renewals and data storage for the existing products. PRB largely manages these processes manually, with some technology support.

The PRB conducts work in five core Registration Program business processes. These five core business processes are:

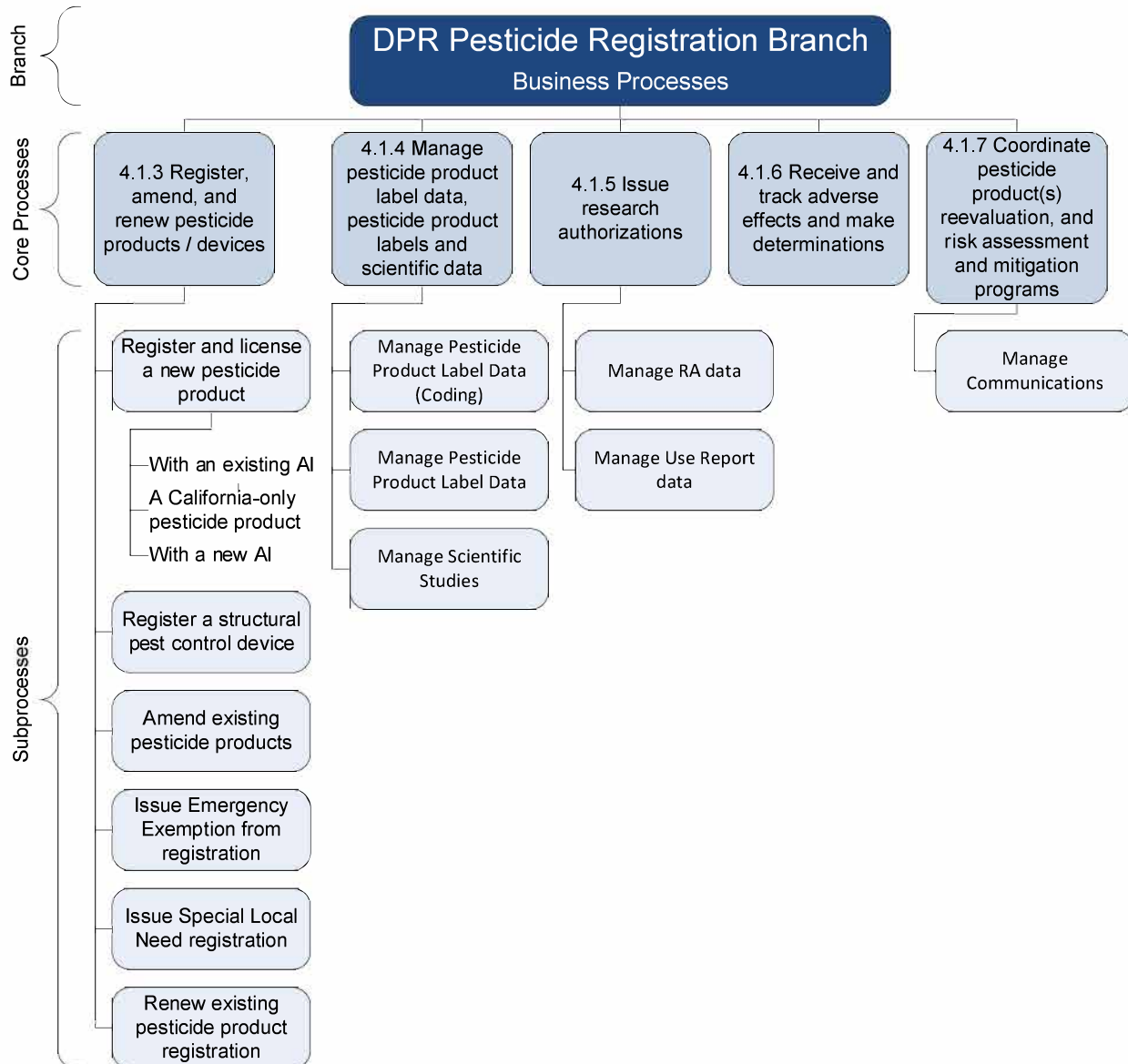
1. Register, amend, and renew pesticide products/devices
2. Manage pesticide product label data, pesticide product labels, and scientific data
3. Issue research authorizations
4. Receive and track adverse effects and make determinations
5. Coordinate pesticide product(s) reevaluation, and risk assessment and mitigation programs

The PRB relies on 24 separate and disparate tracking systems and databases to manage and support these business processes. The PRB uses these systems to log, index, manage, and track the work associated with PRB's five core business processes. These 24 systems and databases are not fully integrated. The lack of systems integration results in duplicate entry of similar and/or redundant information. For example, at least three of the major systems, Reg Tracking, Pesticide Data Index, and Product Label DB, contain many identical data elements that because of lack of integration pose a high risk to data integrity. The minor systems also contain much of the same structured data, which is reentered due to lack of integration. The systems include web-enabled databases, MS Access databases, and complex macro-driven MS Excel spreadsheets. In addition, each scientific evaluation station maintains its own stand-alone tracking system to log and assign submissions for scientific evaluation, which leads to confusion about where applications are in the review process. Most evaluation stations use MS Excel, MS Access, or paper logs to track incoming submissions, assignments, and other scientific evaluation process information.

The Regulatory Scientists commonly go to an individual workstation to check a submission status and identify the assigned evaluation staff. PRB staff and management only have limited visibility of workload per station, staff, and other information to manage the registration process, workloads, and backlogs.

Figure 4.1, below, presents the five core business processes and applicable supporting sub-processes. Each process is described in the following subsections as denoted in the figure.

Figure 4.1 Pesticide Regulations Branch Business Processes



4.1.1 Workload Volume

Table 4.1, below, shows the workload volumes by PRB process. Although PRB workload, staffing, and procedures remain stable, due to the level of effort and duration required to process submissions, PRB has a backlog of work given its current resource levels.

Table 4.1 PRB Workload by Process

Workload Type	2009	2010	2011	2012
New Products with currently registered AI	1,520	1,482	1,593	1,621
New California-Only Products	78	115	96	105
New Products with new AI	75	50	58	36
New Structural Pest Devices	3	1	0	1
Product Amendments	2,749	3,870	4,150	3,209
CA-Only Product Amendments	73	174	108	103
Emergency Exemptions	12	8	13	15
Special Local Need	17	34	69	42
Research Authorizations	523	566	593	628
Adverse Effects				644
On-going reevaluations				12
On-going risk assessments				22
New scientific studies indexed	6226	5381	6217	4733

4.1.2 Pesticide Product Labels and Scientific Data Studies Summary

Registrants submit many types of hard copy documents to DPR for review and evaluation. The most common documents are pesticide and device product labels and scientific data studies. PRB staff must manually enter data and information from these documents into their core systems. In addition, PRB staff must store and track these documents during and after the evaluation process. This makes it difficult for PRB staff to search for information and leaves staff routing large volumes of paper to support regular activities.

4.1.2.1 Pesticide Product Labels

Applicants submit pesticide product and device label hard copies to PRB for product registrations and amendments. The labels range in size from a portion of a page to more than 100 pages. Additionally, labels vary in size from 3" x 2.5" to 3' X 4'. Pesticide product label contents are governed by the Federal EPA. Required content may include: Ingredient Statement, Signal Word, First Aid, Precautionary Statements, Hazards to Humans and Animals, Personal Protective Equipment, Engineering Controls Statement, Environmental Hazards, Runoff Management, Endangered Species Advisory, Insect Resistance Statement, Directions for Use, Agricultural Use Requirements, Storage and Disposal, Application Information, Mixing Instructions, Crop Rotation Statement, Crop Use Directions, a list of all applicable use sites and pests controlled, Disclaimer of Warranties, Limitations of Liability, etc. **Figure 4.2** provides a sample of a product label, illustrating the first four pages of a 25-page product label.

Figure 4.2 Sample Pesticide Product Label



MOVENTO
GROUP 23 INSECTICIDE

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

ACTIVE INGREDIENT
Imidacloprid (9-cyano-2-imidazolidinylidene-1-methyl-2-pyrrolidone) 20.4%

INERT INGREDIENTS 79.6%

MOVENTO contains 2 pounds of spirodiclofen per US gallon, or 349 grams per liter.

STOP - Read the label before use

Produced for:
Bayer CropScience LP
P.O. Box 1000, 21 W. Alexander Drive
Research Triangle Park, North Carolina 27709
MOVENTO is a registered trademark of Bayer.
©2011 Bayer CropScience
Product of Germany

FIRST AID	
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first few minutes, then continue rinsing. Call a poison control center or doctor immediately for treatment advice.
<p>In case of emergency call toll free the Bayer CropScience Emergency Response Telephone line: 1-800-551-7577 (have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-354-7577 for emergency medical treatment information.)</p> <p>Note To Physician: No specific antidote is available. Treat patient symptomatically.</p>	

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION
Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROLS STATEMENT
When handlers use closed systems, or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.210 (d)-(4)), the hand of PPE requirements may be reduced or modified as specified in the WPS.

1

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using tobacco.
- Remove clothing immediately if pesticide gets inside. If it does, wash thoroughly and put on clean clothing.
- Remove Personal Protective Equipment immediately after handling this product.
- Wash the outside of gloves before removing.
- As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS
For Terrestrial Use: This pesticide is toxic to aquatic invertebrates and fishes. Do not apply directly to water. In areas where surface water is present, do not treat areas below the mean high water or mark. This product may contaminate water through drift of spray in wind. Do not apply when wind conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters or rinsate. This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where state or federal permits, particularly where the water table is shallow, may result in ground water contamination.

This product is particularly toxic to honey bee larvae through feeding in pollen and nectar, but not to adult honey bees. Exposure of adult bees to direct treatment or residues on flowering crops can lead to effects on honey bee larvae. See the "Directions for Use" section of this label for specific crop application restrictions that minimize risk to honey bee larvae.

Spray Drift Reduction Management
Do not apply when wind speed favors drift beyond the area intended for treatment. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions. Avoiding spray drift is the responsibility of the applicator.

Importance of Droplet Size: An important factor influencing drift is droplet size. Select nozzles and pressure of drive medium spray droplets as indicated in nozzle manufacturer's catalogs and in accordance with ASAE Standard S-672. Nozzles that deliver coarse spray droplets may be used to reduce spray drift provided application rate (APR) is increased to maintain coverage. For aerial application, spray droplets should be of the finest possible size consistent with good pest control and flight safety. Application methods that float above the crop canopy should be avoided. Low humidity and high temperature increase the evaporation rate of spray droplets and therefore the likelihood of spray drift to adjacent areas. Avoid spraying during conditions of low humidity and/or high temperature.

Wind Speed Restrictions: Do not operate nozzles at wind speeds of less than 3 mph (wind direction portable) or more than 10 mph. However, many factors, including droplet size, canopy, and equipment specifications determine drift potential at any given wind speed. Do not apply when winds are greater than 15 mph and avoid gusty or variable conditions. Avoiding applications when wind direction is toward an aquatic area can reduce risk exposure to sensitive aquatic areas.

2

Restrictions During Temperature Inversions: Do not make aerial or ground applications during temperature inversions. Drift potential is high during temperature inversions. Temperature inversions result in air near the ground, which causes small suspended droplets to remain close to the ground and move laterally in a concentrated cloud. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. This product can be applied by ground fog. However, if fog is observed, the movement of residues from a ground source can also identify inversions. Sprays that lower and move laterally in a concentrated cloud (due to low wind conditions) indicate an inversion, while smog that moves upward and rapidly dissipates indicates good vertical air mixing.

Airblast (Air Assist) Specific Recommendations: Airblast sprays carry droplets into the canopy of trees and into a central or lateral directed air stream. The following drift management practices should be followed:

- Adjust droplet size and air speed so that spray is confined to the canopy.
- Block upward pointed nozzles to prevent air from reaching canopy.
- Use enough air volume to penetrate the canopy and provide good coverage.
- Do not allow the sprayer to go beyond the edge of the cultivated area (i.e., turn off sprayer when backing up next row).
- For applications to the outside of rows, only spray inward, toward the other side of row.

RUNOFF MANAGEMENT
This product may contaminate water through runoff from drift spray nozzles. This product has a high potential for runoff to surface water after application. Paddy clearing soils and soils with shallow water tables are more prone to produce runoff that contains this product. A level well maintained vegetable truck tire before areas to which this product is applied and surface water features such as ponds, streams, and creeks will reduce the potential for contamination of water from agricultural runoff of this product will be reduced by avoiding applications when rainfall is forecast to occur within 48 hours.

ENDANGERED SPECIES ADVISORY
The use of any pesticide in a manner that may kill or otherwise harm endangered species or adversely modify their habitat is a violation of Federal law.

INSECT RESISTANCE STATEMENT
Some insects are known to develop resistance to insecticides. Also report user as will vary by site. The use of this product should conform to resistance management strategies established for the use area. MOVENTO contains an active ingredient with a mode of action classified as a Group 23 insecticide. Insect resistance management (IRM) studies to determine cross-resistance of Group 23 insecticides with other chemical classes have demonstrated no cross-resistance. Bayer CropScience strongly encourages that MOVENTO be applied alone or in tandem combination with another Group 23 product, be applied in a back-to-back or sequential approach with Group 16 insecticide, or be applied in a sequential approach with Group 16 insecticide using additional applications of Group 23 insecticides against the same target pest. Using a back-to-back or sequential approach with Group 16 insecticide practices is considered an additional strategy for preventing or delaying an insect pest's ability to develop resistance to a given class of chemical.

(continued)

3

4.1.2.2 Scientific Data Studies

Registrants submit hard copy scientific data studies with new and amended product registrations and other submissions (for example, product reevaluations, adverse effects, risk assessment). For uniformity, ease of identification, access, storage, and physical handling, PRB requires applicants to format and bind these scientific data studies to certain specifications. Oftentimes the studies are so numerous and large that they span multiple volumes when bound. It is not uncommon for a submission involving a new active ingredient (AI) to have as many as 100 volumes filled with studies that have to be indexed and stored by PRB. **Figure 4.3**, below, shows a 69-volume set of scientific data studies submitted for one new AI.

Figure 4.3 Scientific Data Studies



4.1.2.3 Process Outputs

Through the core processes and via ad hoc requests, PRB generates multiple outputs to registrants and other partners. Some of these outputs are printed or scanned and emailed, mailed, faxed, or posted online. These outputs include: licenses, renewal notifications, notices, letters (deficiencies and acceptances), labels, and data indexes.

4.1.3 PRB Core Process 1 – Register, amend, and renew pesticide products/devices

A pesticide product, and certain limited types of pest control devices, are required to be registered by DPR before the product can be sold, distributed, or offered for sale in California. California Food and Agricultural Code (FAC) Division 7 defines a “pesticide” as (1) any spray adjuvant, and (2) any substance, or mixture of substances that is intended to be used for defoliating plants, regulating plant growth, or for preventing, destroying, repelling, or mitigating any pest that may infest or be detrimental to vegetation, man, animals, or households, or be present in any agricultural or nonagricultural environment. Examples of pesticides include the following:

- | | | |
|--------------------------------|---------------------------|--|
| ■ Algacide | ■ Fertilizer | ■ Nematicide |
| ■ Antifoulant | ■ Fungicide | ■ Pheromone |
| ■ Antimicrobial | ■ Plant Growth Regulator | ■ Repellent |
| ■ Avicide | ■ Herbicide | ■ Slimicide |
| ■ Bactericide/
Bacteriostat | ■ Insect Growth Regulator | ■ Spray Adjuvant
(inc. water modifiers) |
| ■ Defoliant | ■ Insecticide | ■ Vertebrate Control |
| ■ Desiccant | ■ Miticide/
Acaricide | ■ Virucide |
| ■ Disinfectant/
Sanitizer | ■ Molluscicide | |

When a product is registered, a Certificate of Registration (license) is issued, authorizing sales for the remainder of the calendar year. Pesticide products and devices intended to control wood destroying insects may not be offered for sale in California until a Certificate of Registration has been issued. After a pesticide product is registered, it is subject to an annual renewal fee and a quarterly mill assessment based on sales of that product.

This subsection describes the **Register, Amend, and Renew Pesticide Products/Devices Process**. This core process is comprised of six sub-processes:

(1) *Register and license a new pesticide product:*

- a. *With an existing AI.* Register and license a new pesticide product with an AI currently registered in California. When a Registrant wishes to distribute or

- sell a new pesticide product in California, they first need to register the product with DPR. If a new product is substantially similar to other already California-registered product(s) with approved data evaluations, or a product that is currently inactive but was active in the last few years, the registration process is less complex.
- b. *A California-Only pesticide product.* The California definition of a “pesticide” is broader than the federal definition. Examples of California-only products include spray adjuvants (i.e., emulsifiers, spreaders, and other compounds that improve the effectiveness of a pesticide product), and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 25(b) products (minimum risk) exempt from U.S. EPA registration that do not meet California criteria for exemption.
 - c. *With a new AI.* If the new pesticide product being registered contains an active ingredient not found in any currently California registered pesticide product, the evaluation process is much more rigorous and evaluations more extensive. This sub-process may include “California-Only” products.
- (2) *Register a structural pest control device.* In addition to pesticide products, all structural pest control devices labeled for the control of wood destroying insects must be registered in California before being used. These devices follow a similar registration process as new pesticide products, with the addition of a structural integrity evaluation.
 - (3) *Amend existing pesticide products:* Once registered, changes (a.k.a., amendments) can be made to a product’s formulation, a product’s label to add or delete uses or amend use directions, precautionary statements, and/or storage and disposal statements. An amendment requires, at minimum, label review and may require formal evaluation. If approved, certain types of changes are recorded in the Product Label Database.
 - (4) *Issue Emergency Exemption from registration:* Grower’s Associations and other interested parties can apply for an exemption from registration to allow the unregistered use of a pesticide product in an emergency situation. Registrants cannot apply for an emergency exemption.
 - (5) *Issue Special Local Need registration:* Manufacturers and other interested parties can apply to register a product, or a new use for a product, to meet a special local need
 - (6) *Renew existing pesticide product registration:* Annually, all product licenses must be renewed. Registrants are sent a renewal package prior to the new calendar year, and can choose whether to renew or inactivate a product for the next calendar year.

In addition to the above six sub-processes and workloads, PRB receives and processes additional data that is not captured in the above sub-processes. For example, based on a memorandum of understanding, PRB assists the U.S. EPA in performing IR-4 reviews, analyzing residue studies for minor crops grown in

California. PRB provides the evaluation reports to U.S. EPA using U.S. EPA's report format, processing about four to six reports a year. Additionally, PRB regularly logs correspondence with registrants and other stakeholders, including incoming public comments, letters of support from grower groups, outgoing correspondence regarding pesticide determinations (whether or not a product requires registration as a pesticide), public information requests, and other miscellaneous announcements.

In 2012, DPR received a total of 1,762 new product submissions, of which 1,621 were regular submissions, 105 were California-only submissions, and 36 were new AI submissions. On average, it took 90 days to reach any final action for regular 2012 submissions. For new AI submissions received in 2010, the total overall average from receipt to first posting was 531 days (~18 months).

Key Process Features – Register and license a new pesticide product

All new product registration submissions follow a similar process, with four main processing areas: **intake and indexing, submission evaluation, formal scientific evaluation, and final determination**. Each area is discussed in detail on the following pages. There are slight nuances in processing between each registration type, and they are noted throughout.

Ten separate systems are used throughout the entire registration process, which leads to duplicate data entry and inefficiency during the registration process.

4.1.3.1 Intake and Scientific Study Indexing

Intake and indexing includes mail receipt and initial processing of all registration submissions. The process includes receiving, logging, tracking, and indexing registration submissions.

Intake and scientific study indexing is initiated when a registrant submits a "registration submission" to DPR's PRB. The submission may include an application, scientific studies, or information to support a previous submission, the proposed pesticide product label, a Confidential Statement of Formulation (CSF), fee, and other U.S. EPA documentation, as applicable. The intake staff log incoming mail into the system (mail log and tracking database). The Tracking Database assigns a unique identification number (tracking ID), and generates a "status/route sheet." Any scientific studies submitted with the registration submission are entered in the pesticide data index, which also supports a circulation system so that the documents can be checked out throughout the evaluation activities. Approximately 5,600 new scientific studies are indexed each year. After performing intake and indexing activities, staff route the submission to the appropriate PRB Regulatory Scientist (RS).

4.1.3.2 Evaluate New Product Submission

The RS assigned to the registrant evaluates the submission and determines whether the package has minor deficiencies that can be addressed by the registrant, has major deficiencies and needs to be returned to the registrant, should

be routed for formal scientific evaluation(s), or is complete and eligible for a registration decision. In addition, the RS confirms that the proposed label has all the correct Title 40 Code of Federal Regulations (40 CFR) elements, compare the proposed label to other labels (e.g., current DPR accepted labels, U.S. EPA stamped-accepted label, substantially similar product labels), confirm proposed label's signal word and precautionary statements meet Federal and State standards, and review U.S. EPA's Reregistration Eligibility Decision (RED), Pesticide Registration Notices (PR Notices) or memorandums, as necessary.

The RS serves as DPR's liaison to the registrant, and is responsible for monitoring registration submission progress and communicating any application deficiencies. If the submission has major deficiencies, or if the registrant does not provide requested items to resolve minor deficiencies in a timely manner, the RS prepares a return packet. If the submission does not have deficiencies, the RS decides whether or not the submission needs formal scientific evaluation. If no further formal scientific evaluation is needed, then the workflow skips to final action activity.

For a submission requiring formal scientific evaluation, the RS indicates the appropriate scientific evaluation workstations on the status/route sheet and then prepares and submits the submission(s) to the tracking coordinator. The designated new AI RS prepares new AI product submissions differently than regular submissions, creating multiple copies of the submission for simultaneous distribution to DPR's scientific evaluation workstations.

4.1.3.3 Formal Evaluation of Scientific Studies

Submissions requiring formal scientific evaluation, as determined by the RS, are routed through DPR's scientific evaluation process. A tracking coordinator is responsible for routing the submission to appropriate scientific evaluation workstations, collecting the evaluation reports, recording the Evaluation Scientist(s) recommendations, and updating the routing section of the status/route sheet in the RS's binder and the electronic tracking system database.

The tracking coordinator generally routes new AI submissions to evaluation workstations simultaneously, unlike other submissions that are routed sequentially, one workstation at a time.

Evaluation Scientists prepare written evaluation reports, after evaluating the data and pesticide product label. The evaluation report summarizes the study findings and documents the results of the evaluation.

Each time the tracking coordinator receives the submission and evaluation report from an evaluation workstation, the coordinator enters the results into the Registration Tracking System, noting a recommendation to register, conditionally register, or deny registration. The system automatically generates a status update email to the applicant and the RS, noting the recommendation and identifying evaluation workstations to which the submission has not yet been submitted. The tracking coordinator retains the original (signed) evaluation report, and distributes hard copies of the evaluation report to the RS.

After all required workstations' evaluations are complete, the tracking coordinator combines the evaluation reports with the submission and delivers them to the Environmental Program Manager's inbox. The manager conducts a final review, indicating whether the pesticide product submission should be approved or denied (based on the scientific evaluators' recommendations), by signing the status/route sheet. The RS then receives the submission and proceeds with the registration action and notification process. This final process can take less than a day to complete.

4.1.3.4 Provide Public Comment

Regulations require that DPR consult with specified state and local agencies as well as post certain registration actions for a 30-day public comment period. On a weekly basis, the tracking coordinator generates from the tracking database a list of pesticide product submissions entering the formal scientific evaluation process. PRB posts the Material Entering Evaluation (MEE) notice to DPR's external website, in addition to sending the notice to two email listservs. This allows individuals on the Pesticide Registration and Evaluation Committee (PREC) member group listserv to receive the list of pesticide products entering the formal scientific process as well as the first page of the submitted label. Individuals on the MEE listserv receive an email containing the MEE notice only.

Once the Environmental Program Manager signs off on the submission, the RS is responsible for reviewing any evaluation reports and the manager's decision in order to determine whether there are any concerns or inconsistencies. The RS communicates any deficiencies, unmitigated hazards or adverse effects, or recommendations for conditional registration to the registrant. The RS submits a weekly "Action Log" to the tracking coordinator who uses that information and the tracking database to create the weekly Notification of (Proposed and Final) Decision postings (NOD). The four NOD lists are: (1) 30-day Proposed to Register, (2) 30-day Proposed to Deny, (3) Final to Register, and (4) Final to Deny. Management reviews and approves the final lists prior to staff posting to the website and sending electronically to the listserv. Staff also mail copies to each of the three Enforcement Branch Regional Offices (ROs), allowing the ROs to file a hardcopy for public viewing. A copy is also sent to the California Resources Agency for required public posting. DPR must respond in writing to all comments received during the public comment period before taking final action on any submission.

4.1.3.5 Final Action

If, after scientific evaluation, the recommendation is to register, and no comments were received or all comments have been responded to, or the RS determines that the product can be registered without formal scientific evaluation, the RS prepares the registration package and submits it to the Licensing Unit. If the product is to be conditionally registered, the registrant must agree to the conditions in writing before final action can be taken. Licensing staff create the Certificate of Registration (license).

Upon receiving the final submission from the RS, Licensing staff review and verify the submission information is complete and accurate, enter new product information and update product information in the product label database, print the license and make copies, as necessary, create the new product license letter, and assemble the complete full registration or conditional registration package. The package is returned to the RS for review, and is then routed to the RS's supervisor for approval. The RS supervisor places the new product package in the box to be mailed. Support staff separate the various documents, mailing a copy of the letter, license, and stamped accepted label to the registrant. Copies of the documents are sent to the RS, Registration Resource Center (RRC), and the Coding Unit.

If, after scientific evaluation, the recommendation is to deny registration, the RS prepares a denial packet with a letter to the registrant explaining the reason for the denial. Once the RS's supervisor approves the letter, it is placed in the box to be mailed. Before mailing, support staff separate the copies and mail a copy of the letter to the registrant and route copies to the RS and RRC for filing.

Since 2006, to assist registrants with identifying new product registrations with possible data compensation issues, DPR provides a query on its public website. By entering date search parameters, a stakeholder can obtain a list of all new products, regardless of whether they entered formal scientific evaluation, that DPR registered within a designated time period.

Key Process Features – Register a Structural Pest Control Device

The process for registering a structural pest control device follows the same process as the *Register and license a new pesticide product process* with the difference of being routed to fewer scientific evaluation workstations and requiring an additional evaluation not required for other submission types. Device applicants are required to prove structural integrity (i.e., safe to use in homes and buildings). Since DPR has no scientists that specialize in this area, DPR requires applicants to provide a certification from a California State licensed professional engineer (P.E.) with documented structural engineering expertise, that use of the device will not weaken the structural integrity or cause damage to the structure of the property being treated. Structural pest control devices have a lower registration fee, and do not need to be renewed annually.

Key Process Features – Amend existing Pesticide Products

DPR receives requests to amend currently registered pesticide products. The change (or product amendment) may be a change in formulation or a modification of the product label (i.e., the addition or deletion of a use site or target pest or the modification of the environmental hazard statement or the precautionary statement). Pesticide product amendments fall into three categories:

- A major amendment that requires formal scientific evaluation.
- A minor amendment to the formulation or label that does not require evaluation.

- Minor amendments allowed to be made by Notification, such as removing a site or pest, or adding language required by another State of California department or U.S. EPA.

Similar to the *register and license a new pesticide product process*, amendment submissions move through four main activities: intake and indexing, submission evaluation, formal scientific evaluation, and final determination. No matter how minor, all label changes require comparison to existing approved labels.

Key Process Features – Issue Emergency Exemption

Emergency Exemptions from Registration (FIFRA Section 18) are authorized by the U.S. EPA and allow for an unregistered use of a pesticide for a limited time if an emergency condition exists. An emergency condition, as defined by Section 18, is an urgent, non-routine situation that requires the use of a pesticide(s). Emergency exemption requests may be made by commodity or grower groups, University of California (UC) Extension personnel, state agencies, individual growers, and others. There are four types of emergency exemptions:

Specific: Requested when an emergency condition exists, in order to prevent significant economic loss or a significant risk to endangered or threatened species, beneficial organisms, or the environment. Requests typically come from growers, and this exemption may be authorized for up to one year at a time. Most requests fall into this category.

Quarantine: Request to control the introduction or spread of an invasive pest species not previously known to occur in the United States. This type of exemption request may be authorized for up to three years at a time.

Public Health: Request to control a pest that will cause a significant risk to human health. This exemption may be authorized for up to one year at a time.

Crisis: Request for immediate need for a specific, quarantine, or public health exemption. The State lead agency, following communication with the U.S. EPA, may issue a crisis exemption allowing the unregistered use to proceed for up to 15 days, after which a specific exemption must be obtained or the use halted.

Within DPR, there is one Regulatory Scientist (RS) that serves as the point of contact for any grower or association (emergency exemptions cannot be requested by chemical manufacturers) wanting to file a request for a Section 18 Emergency Exemption. The RS is responsible for providing the packet to Intake and Indexing, after which the RS initiates the scientific evaluation needed by both DPR and the U.S. EPA.

Key Process Features – Issue Special Local Need Registration

Under authority of FIFRA Section 24(c), states may register an additional use of a federally registered pesticide product, or approve a new end use for a product to meet the needs of a specific geographical area. In order to declare a "Special Local Need" (SLN), DPR must find that an existing or imminent pest problem exists within the state that cannot be mitigated by a currently registered product. DPR must

show that the additional use is covered by any necessary tolerances or exemptions from tolerance.

If the proposed product falls into one of the following categories, and DPR has determined that it will not cause unreasonable adverse effects to human health or the environment, it can be considered for the SLN registration:

- The product does not contain a new active ingredient unregistered by the U.S. EPA.
- Use of the product involves a use pattern that is not similar to a federally registered use of the same product or a product of similar composition.
- Use of the product, or uses of a product of similar composition, have not had registration denied, disapproved, suspended, or canceled by the administrator of the U.S. EPA.

In order to streamline the SLN submission process, the U.S. EPA has put much of the responsibility of administering the application on the State, so unlike Section 18 Exemptions, this process does not result in a waiting period for U.S. EPA review.

Within DPR, there is a specific RS that is the point of contact for all companies or associations submitting a SLN registration. There is significant up front dialogue before an entity submits a SLN application, and therefore packets are fairly complete upon receipt and there are few to no denials. The RS routes the submission through formal scientific evaluation, and serves as the liaison with the registrant through the entire process.

The SLN process is similar to the *register and license a new pesticide product process*.

Key Process Features – Renew Existing Pesticide Product Registration

At the end of each calendar year, registrants are required to renew their active pesticide product registrations. This process is managed by the Licensing Unit, with financial and technical support from outside the Branch. The process is initiated every year in early October, although the actual date can change slightly from year to year.

In 2012, approximately 94 percent of registrants responded to DPR's renewal letters, of which 85 percent of the renewals were received on time (postmarked on or before January 31). To issue and process renewals, PRB staff utilize eight separate systems and databases. Unlike other PRB processes, the renewal process is completed almost entirely by Licensing Technicians, with assistance from Regulatory Scientists on conditional registrations.

Using information contained in the Product Label database, the Licensing Technician works with staff from the Information Technology Branch to generate Applications for Renewal of Registration forms for all registrants with active products registered with DPR. The Application for Renewal lists all the registrant's active products with the conditional registrations at the top, followed by the full registrations. Each Application for Renewal is also stored electronically in an intranet accessible

repository. The Licensing Technician then uses the database to print a list of all active registrants and checks each Application for Renewal to verify that one has been printed for each registrant. Each year about 1,500 Applications for Renewal are generated, one for each registrant, and manually assembled for mailing by the Licensing Technicians.

Prior to printing the Applications for Renewal, the Licensing Technician and other Branch staff update a renewal instructions letter that is included with each Application for Renewal mailed to registrants. While the Licensing Technician is generating the Applications for Renewal and preparing the letters to be mailed, another staff member cross checks active registrations with the U.S. EPA product/label database for any products that have been federally inactivated and cannot be renewed. The staff member then generates a letter for registrants that might be affected by product inactivation, and it is included with the renewal packet.

After the initial mailing of the Application for Renewal, the Licensing Technician tracks new registrations that occur between October until the end of November. As additional products are registered, supplemental renewals are generated and sent to the registrant.

Once a registrant receives its renewal application, they have the opportunity to decide which product licenses to renew, and which to inactivate. The cost of each product renewal is \$750, and the payment must be included when the Application for Renewal is returned to PRB.

Upon receipt of an Application for Renewal and fees, the Licensing Technician checks for completeness. If it is not complete, the registrant is issued a deficiency letter and must provide the missing items in order to obtain renewal of its products. The licensing technician enters specific information into the Renewal Tracking application to generate a deficiency letter to the registrant. It is the responsibility of the registrant to return the items requested by the Licensing Unit in order to complete the renewal process. If the renewal application is complete, the Licensing Technician indicates it in the Renewal Tracking application and updates the product Label Database. The payment is processed and a new license is issued after January 1st of the new calendar year. An image of the license is also automatically stored in a repository. If the registrant provides an email address, the license is first emailed to the registrant, which is then followed by a mailed hard copy of the license.

The postmark deadline for submitting a renewal application is on or before January 31. If the Licensing Unit does not receive the renewal application from a registrant by that date, the Licensing Technician enters specific information into the Renewal Tracking application to generate a penalty letter to the registrant. At that time, the registrant can still submit the renewal application, but they also incur a penalty fee of \$150 in addition to the \$750 per product renewal fee. If the Licensing Unit still has not received a renewal application by February 1, around April 1st, DPR sends those registrants a letter stating their products have been inactive since December 31. Within the first year of inactivation, if the registrant later wishes to reactivate

an inactive product, they may do so after paying the renewal fee plus the penalty fee. If they wait longer than one year, the product is subject to the full registration process.

4.1.4 PRB Core Process 2 – Manage pesticide product label data, pesticide product labels and scientific data

PRB maintains hard copies of all pesticide product labels, applications for registration and amendment, evaluation reports, status/route sheets, and scientific studies related to registration actions. Also, DPR maintains a Product Label Database that contains information on each registered and inactive pesticide product. After the submission of a registration action, the process of managing the pesticide label, data from the pesticide label, and the scientific studies submitted to support the product is triggered.

The Manage Pesticide Product Label Data, Pesticide Product Labels, and Scientific Studies process consists of three sub processes:

- (1) Manage Pesticide Product Label Data (Coding):** When issuing a license for a new pesticide product, Licensing Technicians enter a minimal amount of information (what is needed to generate a license) about the product into the Product Label Database. The remainder of the information regarding the product is entered into the Product Label Database after registration. Data is also entered into the Product Label Database after acceptance of certain types of label amendments or special exemptions.
- (2) Manage Pesticide Product Labels:** Product files, which contain an application for registration or product amendment, Confidential Statements of Formulation (CSF), all accepted versions of the product label, federal accepted product label, and other required federal documentation are maintained in the Registration Resource Center (RRC).
- (3) Manage Scientific Studies:** Hard copies of evaluation reports and status/route sheets and scientific studies are filed and the tracking identification number associated with the submission is marked as "archived" in the Registration Tracking Database and Circulation System. Electronic copies of more recent evaluation reports are also stored in an intranet accessible repository.

These three sub-processes ensure that data regarding all registered and inactive products is stored in the Product Label Database, and that the hard copy status/routing sheets, evaluation reports, stamped accepted labels, and scientific studies are stored in a central location and accessible to DPR staff.

In 2012, DPR coded 2,200 labels for new products and product amendments, and entered the information into DPR's Product Label Database. In addition, in 2012, DPR received 4,458 new product and amended product labels, and 4,733 new scientific studies. On average, in 2012, it took approximately 80 days to code a new product or label amendment into the Product Label Database; 30 days to file new and amended product labels into the Registration Resource Center; and 90 days to

file evaluation reports and scientific studies. These timeframes do not meet DPR's goals. To manage pesticide product label data, product labels, and scientific studies, DPR staff use six separate systems and databases. The use of six systems creates issues with duplicate data entry and slows the research and review process.

Key Process Features

4.1.4.1 Manage Pesticide Product Label Data

At the time of license issuance, the Licensing Technician enters a minimal amount of information from the new product label into the Product Label database. Support staff outside the Licensing Unit then receives the registration package from a supervisor to separate out sections of the package and route to different areas of the branch. One of the sections separated out is the "coding package." The support staff route the coding package to the Coding Lead.

Certain types of label amendments also need to be entered into the Product Label Database. The Regulatory Scientist prepares a package for coding, which is separated from the rest of the package by support staff. The support staff route the coding package to the Coding Lead.

The Coding Lead assigns a coding package to a Coding Technician. The technician enters the information from the coding package into the Product Label Database. The technician enters information such as chemical formulation, signal word, specific gravity/density, pesticide type, application methods, target pests, sites of application, and human and environmental health hazards. The technician returns the package to the coding lead upon completion of entering information into the Product Label Database. Confidential information is shredded upon completion of this process.

4.1.4.2 Manage Pesticide Product Labels

A technician outside the Licensing Unit receives the registration/amendment package from a supervisor to separate out sections of the package and route to different areas of the branch. One of the sections separated out is marked "Product File," which is distributed to the Registration Resource Center (RRC).

Hard copy materials are filed and tracked in the RRC. There, staff receive the product file, which contains surname approval of the cover letter, the application, U.S. EPA documentation, registration documentation, and the stamped accepted label. Individual product files are filed behind a separate company file. A copy of the license that was issued for that product is filed and maintained in the separate company file of licenses as well as in a binder in the Licensing Unit. An electronic copy of all company licenses is also available to DPR staff on the intranet.

RRC staff maintain individual Product Files and provides copies of labels upon request. RRC staff also answer questions regarding active and inactive pesticide products.

If a registered product becomes inactive, the RRC staff stamp the product file "inactive" with the year the product was last registered, and the file is moved to the

inactive files. Annually, the RRC staff must physically move the inactive files in order to make room for the next year's new product files.

RRC staff also stamp "Conditional" on the files of conditionally registered products. Once the conditional registration has either been extended or removed, staff also note this on the product file and write the date of extension or removal.

4.1.4.3 Manage Archival of Scientific Studies and Evaluation Reports

After PRB issues the license and the registration or amendment action is complete, the RS prepares the submission for archiving, providing submission documentation to archiving staff. The Archiving Technician retrieves the RS binder copy from the tracking coordinator station. The technician compares the two packages, verifying that the evaluation reports, memorandums of registration, and correspondence are the same as in the RS prepared file. The technician duplicates any document found only in one package to ensure both are complete. The Archiving Technician takes an action in the Registration Tracking System and in the InMagic database, and sends both packages to the RRC staff. RRC staff place the original set in the first volume of data, if data were submitted, and place the second set (copies), or the originals, if no data was submitted, in the completed binder, alphabetized by product name.

4.1.5 PRB Core Process 3 – Issue research authorizations

With the exception of those exempted by Title 3, California Code of Regulations (3 CCR) section 6268, a written authorization for research must be obtained from DPR before any experimental, unregistered use of a pesticide in California. A Research Authorization (RA) allows researchers to collect field data under California use conditions to support California registration of a pesticide product.

If the product and the proposed use are federally registered, there is no limit on the field size for the RA. However, any RA application for more than 100 acres per crop requires specific justification. If the product or proposed use is NOT federally registered, the RA is limited to ten acres or less, on land, or one surface acre or less, in water. If the product or proposed use is on more than 10 acres of land or one surface acre of water, the researcher must obtain a federal Experiment Use Permit (EUP) from the U.S. EPA. If a federal EUP is obtained, researchers have the option of either applying to carry out the research under an RA or to conditionally register the federal EUP in California for the term and conditions specified by U.S. EPA.

In 2012, DPR received 635 RA requests. On average, in 2012, it took 4 days to reach an approval or denial decision. In addition, DPR receives approximately 100 Research Authorization amendment requests each year, which typically took 2 days to reach an approval or denial decision. For this process, the Research Authorization Scientist (RA scientist) uses one database to process an RA. As of August 2013, DPR completed a new application/database design that will support this process.

Key Process Features

The RA process begins when a researcher submits a Pesticide RA Application to the RA Scientist, typically by email. The application is printed, date stamped, and then placed in the Research Authorization informal work queue. The RA Scientist then begins to assemble the RA Request. If more information is needed, or the researcher has been previously blocked from receiving RAs, the RA Scientist communicates that information to the researcher.

Once the RA request is deemed complete by the RA Scientist, the request is routed to appropriate scientific evaluation stations. Some RAs are evaluated solely by the RA Scientist. Evaluation Scientists that evaluate the RA request provide feedback to the RA Scientist verbally, by email, or in a report based on the complexity and amount of feedback. The RA Scientist then reviews the feedback, and if the research is acceptable, assigns applicable conditions under which the research may be performed, then signs and dates the application to approve the RA.

The RA Technician receives the approved RA and stamps it with the assigned RA number. The authorization is then sent to the researcher to allow him or her to conduct the requested trials. The technician enters RA data into the Research Authorization Database, and files the hard copies.

Less than 10% of the time, a researcher needs to amend an approved RA; for example, the researcher desires to add an additional crop, site, or active ingredient. When this occurs, the researcher submits the amendment request by mail or email. The RA scientist reviews the request and, if acceptable, amends the RA on file. If the RA is needed right away, the RA Scientist scans the revised RA and emails it to the researcher. The RA Technician enters the updated information in the database, makes copies for DPR files, and mails the amended RA to the researcher.

The researcher conducts the trial, under the conditions established in the RA. When the study is complete, it is the responsibility of the researcher to file a Use Report with the DPR. The Use Report is sent directly to the RA Scientist to be assessed for completeness. If it is determined to be complete, the Use Report is sent to the RA technician to be entered into the Research Authorization Database, and close out the RA. The hard copy of the Use Report is filed in a binder with the other RA submission materials.

The RA Scientist must continue to track the RAs and make sure that all Use Reports are filed as required. The Research Authorization Database is the main tool used. Every week the RA Scientist runs a query to track for overdue Use Reports. If it is found that a Use Report has not been returned, or the RA Scientist has been made aware of any other violation, the RA Scientist can use the database to generate a letter to the researcher. Any researcher that violates their authorization can be blocked from receipt of future RAs. Violations can include failure to return a Use Report or non-compliance with the conditions specified in the RA.

4.1.6 PRB Core Process 4 – Receive and track adverse effects and make determinations

State law and California regulations (Title 3, CCR Section 6210) require registrants to submit any evidence of adverse effect, or risk to human health or the environment, of any of their pesticide products with active or pending registrations. California regulations (Title 3, CCR Section 6220) also require DPR to investigate all reports of actual or potentially significant adverse effects to people or the environment resulting from the use of pesticides. If DPR has reason to believe that a pesticide may cause unreasonable adverse effects to people or the environment, the regulations require DPR to take further action, which could be either a reevaluation of the product, incorporating the results into a risk assessment, or cancellation or suspension of the product's registration.

In 2012, pursuant to 3 CCR 6219, DPR received 644 adverse effects submissions, for a total of over 9,000 separate reports containing over 100,000 incidents. On average, in 2012, it took 30 days to review adverse effects submissions not needing formal scientific evaluation, and 154 days to complete those needing formal scientific evaluation. To receive and track adverse effects, DPR staff use eight separate systems and databases.

Key Process Features

The process to track and evaluate adverse effects reports is triggered when a company submits a potential adverse effect report through the intake and indexing process. About 650 adverse effects submissions are received each year, but often the adverse effects that are reported are minor or otherwise determined to not need further evaluation. In all situations, the adverse effect report is logged and tracked in the Adverse Effects Spreadsheet, and the registrant who submitted the adverse effect report is notified whether additional formal scientific evaluation is needed.

If additional formal scientific evaluation of the submission is not needed, the status/routing sheet and scientific studies are archived. If the Adverse Effects Scientist (AE Scientist) determines that formal scientific evaluation is needed, which usually takes place if scientific studies are submitted, the adverse effects submission is routed to relevant evaluation stations. Those stations submit an evaluation report to the AE Scientist. If DPR scientists determine that the adverse effect is substantial, it is noted and incorporated into the risk assessment process. In the event the effect is of immediate concern, the active ingredient is sent for reevaluation consideration. Both pesticide product(s) reevaluation, and risk assessment and mitigation are discussed in the next subsection.

4.1.7 PRB Core Process 5 – Coordinate pesticide product(s) reevaluation, and risk assessment and mitigation programs

Coordinate Pesticide Product(s) Reevaluation

California law (Food and Agricultural Code section 12824) requires DPR to continuously evaluate pesticides once they are registered, and eliminate those that endanger the environment, are not beneficial for the purpose sold, or are misrepresented. DPR does this through its reevaluation program. Upon receipt of information indicating that use of a pesticide may have caused or is likely to cause an adverse effect to people or the environment, DPR is required to investigate. Based on that investigation, if DPR finds that the pesticide has caused or may have caused a significant adverse effect, a product reevaluation is triggered. When a pesticide product enters reevaluation, DPR reviews existing data and may require registrants to provide additional data. The goal is to determine the extent of the potential hazard, and to identify ways to reduce or eliminate the problem.

Note, U.S. EPA administers a program called Special Review that parallels DPR's reevaluation process. However, California's process deals with a broader range of issues that may affect only certain products rather than all products containing an active ingredient, and focuses on conditions specific to California use.

In 2012, DPR managed 12 reevaluations. In 2012, no new reevaluations were initiated; however, DPR concluded two reevaluations. During this process Scientists must draw together data from potentially hundreds of products, data studies, and study reviews as well as consult with external stakeholders. As a result, it may take several years to complete a reevaluation of pesticide product(s). DPR staff use five systems to execute the reevaluation process.

Key Process Features

The process for reevaluation begins when DPR receives information indicating that a pesticide product may need to be reevaluated. Upon receipt of a request, the Reevaluation Scientist reviews the information and assembles the reevaluation package that is then sent to the Executive Office and all Branch Chiefs for comment and sign off. Once the Branch Chiefs and the Executive Office have signed off on the reevaluation request, DPR's Director makes the final decision whether to initiate a reevaluation.

If the Director orders a reevaluation to be initiated, the Reevaluation Scientist initiates the reevaluation by preparing a public notice and sending letters to each registrant with products to be included in the reevaluation. Pursuant to the reevaluation, DPR may require additional data to determine the nature, or the extent, of the potential hazard and identify appropriate mitigation measures. Data required pursuant to reevaluation is received through the intake and indexing activities. Once the data is logged and indexed, it is routed to the Reevaluation Scientist.

The Reevaluation Scientist routes the reevaluation package and scientific data to appropriate evaluation stations for formal scientific evaluation. Each Evaluation Scientist prepares an evaluation report, which is sent to the Reevaluation Scientist. Reevaluation is an iterative process that is driven by science--The Evaluation Scientists must draw together data from potentially hundreds of products, data studies, and study reviews as well as consult with external stakeholders. Pursuant to Food and Agricultural Code section 12825, DPR has the authority to cancel the registration of a pesticide if the registrant fails to submit data required as a part of a reevaluation. The Reevaluation Scientist is also responsible for coordinating meetings with registrants, preparing status reports, and giving presentations.

In order to conclude a reevaluation, the Reevaluation Scientist must put together a final reevaluation package. The DPR Director receives all reevaluation materials and decision recommendations, and makes the final determination. The Reevaluation Scientist receives the Director's determination, and if the reevaluation is to be concluded, prepares a public notice and letters to all registrants with products included in the reevaluation. Title 3, CCR Section 6225 requires DPR to prepare a semi-annual report describing pesticides reevaluated, under reevaluation, or for which factual or scientific information was received but no reevaluation was initiated. Reevaluations may conclude that no further mitigation is needed, that further mitigation is needed, or that the product must be cancelled.

Coordinate Risk Assessment and Mitigation Program

PRB is responsible for the coordination of information and data between DPR and registrants with regard to risk assessment and risk mitigation. The Risk Assessment Scientist (RAS) serves as the process coordinator, routing documents, generating notifications, tracking, and communicating with the registrant, as needed.

DPR initiates risk assessments for a number of reasons, focusing on pesticides that pose the greatest potential risk. The process involves many partner agencies, including the Office of Environmental Health Hazard Assessment (OEHHHA) and the U.S. EPA. Active ingredients are prioritized into one of three groups (high, medium, or low priority) for risk assessment. Each year, DPR senior scientists identify and prioritize a smaller group of 10 candidates for risk assessment initiation. From the ten, approximately two to three active ingredients are annually selected to enter the risk assessment process.

Risk assessment is a process designed to answer questions about how toxic a chemical is, what exposure results from its various uses, what the likelihood is that use will cause harm, and how to characterize that risk. Risk assessment plays a critical role in DPR's evaluation of the potential human health hazards associated with pesticide exposure. DPR's comprehensive approach assesses potential dietary (food and drinking water), workplace, residential, and ambient air exposures.

Risk assessment is often the driving force behind new regulations and other use restrictions. DPR's Medical Toxicology Branch manages the risk assessment process, with exposure assessments developed by the Worker Health and Safety Branch, and environmental fate reviews by the Environmental Monitoring Branch.

Because the risk assessment involves a comprehensive review of toxicology and exposure data, it may take several years to complete a risk assessment. If the risk assessment identifies potential exposures and levels of risk that are unacceptable, DPR develops a strategy to mitigate these risks to an acceptable level. This process is called risk management, and is separate from risk assessment. The risk mitigation process is initiated when DPR issues a Risk Management Directive (RMD)

The RAS serves as the liaison between all entities and the registrants during the risk assessment and risk mitigation processes. The RAS is also responsible for communicating the risk assessment status and mitigation process with the public. The RAS prepares and posts a public notice when the risk assessment is initiated and completed, and when the risk assessment determines that there is a need for mitigation of unacceptable exposures. This may require several notices throughout the process.

In 2012, DPR initiated 3 active ingredient risk assessments for a total of 25 active ingredients currently in the risk assessment process. DPR staff use four systems and databases during the risk assessment and mitigation process.

Key Process Features

Once a risk assessment for a particular active ingredient is initiated by the Medical Toxicology and Worker Health and Safety branches, the RAS drafts a notice for departmental routing and approval. Upon approval, the notice is sent to registrants of the active ingredient, posted on DPR's website as a Notice to Stakeholders, and sent by email to the California Notice listserv.

The Medical Toxicology and Worker Health and Safety Branches then prepare a final draft risk characterization document (RCD) and an exposure assessment document (EAD), which are then sent to the RAS to be sent to the U.S. EPA and OEHHA for scientific peer review. A memo is included with the RCD/EAD assessment package, and routed to the Branch Chiefs and Assistant Director for approval. Upon receiving approval from these parties, the RCD/EAD and memo are submitted to U.S. EPA and OEHHA.

The RAS notifies all registrants that have an actively registered product containing the active ingredient undergoing risk assessment that the draft assessment is available. At this point, registrants can request a copy of the draft assessment and may submit comments. If comments are received, they are received through the regular intake and indexing process. The comments are recorded and registrants are notified by letter that comments have been received and will be responded to when DPR responds to the peer review comments.

Comments from OEHHA and U.S. EPA are received directly by the RAS, who records the comments, submits the comments through the intake process, and routes them to the Medical Toxicology and Worker Health and Safety Branches for review. Comments are incorporated as needed, and Medical Toxicology and Worker Health and Safety provide final signoff on the status/route sheet when the comments are

ready to send to OEHHA and U.S. EPA. The final RCD/EAD is then sent to the Assistant Director for signoff.

The RAS records the completion date and issues a number for the RCD/EAD. After the Assistant Director reviews the RCD/EAD, the Assistant Director submits it to the Deputy Director, along with a memo requesting a RMD, if necessary. At this time, the RCD/EAD are ready to be publically released and are posted on DPR's website along with the comments from OEHHA and U.S. EPA and DPR's responses to these comments. The RAS prepares a notice that the final risk assessment documents are available. The notice is posted to the DPR website and sent through the distribution list. Registrants with products containing the assessed AI are emailed the notification separately.

If the RMD was determined to be necessary, DPR's Executive Office prepares a draft RMD, identifying unacceptable exposure scenarios or margins of exposure that require mitigation and proposed actions that may be part of the mitigation strategy. The RAS prepares a public notice and routes it with the draft RMD for review and approval. Upon approval, PRB sends the notice and draft RMD to key agencies, registrants, and other interested parties, and posts the RMD on DPR's website for comment. Comments on the RMD are received directly by the RAS, who records the comments, submits the comments through the intake process, and routes them to the Worker Health and Safety Branch and the Assistant Director. Next, the Worker Health and Safety Branch Develops a draft mitigation proposal and submits it to the RAS for review and approval routing. After the Executive Office approves the mitigation proposal for release to the public, the RAS sends the mitigation proposal to key agencies, registrants, and other interested parties and posts it on DPR's website.

4.2 Technical Environment

This section discusses the current systems and technical environment supporting the PRB business processes in scope for the proposed new solution.

4.2.1 Existing Infrastructure

To support the business processes and current method described in Section 4.1, PRB manages, maintains, and supports 24 systems for almost 100 total users across multiple branches. For the purpose of this FSR, these 24 systems have been classified as either “core” or “supporting” systems. DPR anticipates that all 24 supporting systems will be retired within two years of system implementation. The data will be retained for historical purposes.

The remainder of this section details each.

4.2.1.1 PRB Core Systems

Table 4.2, below, lists and briefly describes the PRB core systems. Core systems are the primary systems PRB staff use to complete essential business activities. Each core system is web-enabled for access from the DPR Intranet and, in some cases, the Internet. The systems all use ColdFusion (CF) or Perl for the front end and some make use of an Embedded PL/SQL Gateway (EPG). The systems which employ security use Windows security groups built on Active Directory. The systems with no security are read-only.

Table 4.2 PRB Core Systems

ID	PRB System	Description	Security	Web Enabled	Intranet / Internet
PRB1	Registration Tracking Database	Provides registration submission tracking capabilities, allowing for status updates and automatic email notifications to the registrant and PRB liaisons; and provides statistics and workload reports.	Groups	CF	Intranet
PRB2	Master Chemical Database	Tracks and stores chemical information for use in multiple applications. Data is publicly searchable.	Groups	CF	Both
PRB3	Pesticide Data Index Database & Circulation System Application	Indexes individual studies within scientific data volumes, which supports the Circulation System. Catalogues data studies, capturing key content information, location, check-out history, and other information for each data volume; and provides search and check-out/check-in capabilities. Data is publicly searchable.	Groups	CF, Perl	Both
PRB4	Registration Licensing Application	Front end of the Registration Product Label database, producing printed license and storing license images in the License Database by year, company, and date. These link to the Registration Intranet reporting functions.	Groups	CF, EPG	Intranet

ID	PRB System	Description	Security	Web Enabled	Intranet / Internet
PRB5	Renewal/Tracking	Log of renewal activity. Tracks whether or not renewal applications are complete. Generates acceptance, penalty, and deficiency letters.	Groups	CF, EPG	Intranet
PRB6	Registration Product Label Database	Maintains product information for registered and inactive pesticides, including critical elements of the product label.	None	CF, Perl	Both
PRB7	Human Resources	Maintains DPR user data and provides a directory of all staff.	Groups	CF	Intranet

4.2.1.2 PRB Core Databases

The PRB core systems are all built on an Oracle database with six separate databases (schema), one for each system. These schemas are able to “share” data between each other. One benefit of this architecture is that systems are able to access key information from other systems to eliminate (or minimize) duplicate data. For example, the Circulation System can access user information in the Human Resources System to verify that the user is cleared to check out scientific data studies. However, not all PRB system/data interactions are automated; some are manual. A manual interaction represents a situation where data from one system/database is manually entered (duplicated) in another system. This introduces the potential for data inconsistencies. For example, an incorrectly keyed Tracking ID. **Table 4.3**, below, maps each logical schema to the core system(s) it supports. The current systems have generated approximately 20 million records over the last 25 years, an average of 800,000 records per year.

Table 4.3 PRB Core Databases ^A

ID	PRB System	PRB Core Schema					
		Licensing	Tracking	Registration Library	Product Label	Human Resources	Chemicals
PRB 1	Registration Tracking Database	✓	✓	✓		✓	✓
PRB 2	Master Chemical Database				✓		✓
PRB 3	Pesticide Data Index Database & Circulation System Application	Manual	Manual	✓	Manual	✓	✓
PRB 4	Registration Licensing Application	✓		✓	Manual		
PRB 5	Renewal/Tracking	✓	✓		✓		

PRB 6	Registration Product Label Database	✓			✓		✓
PRB 7	Human Resources	✓	✓			✓	

^A The cells highlighted in yellow indicate the primary schema for each system.

The following subsections provide additional detail for each core schema:

Registration Tracking Database (Tracking) – This database is the core application that supports tracking of registration submissions, workload, and required reporting, and serves as the base of information and activity for the email notification application. The tracking system incorporates information from firm information, chemical data, phone data, etc. The application is a transaction-based system controlled by a complex set of rules that describe the business process. These rules are built into the screen scripts and generate the input screens based on the rules. As with many complex business and governmental decision-making processes, there are many exceptions that require the controlling rules to be overridden.

This database has tracked all the registration submissions submitted to the DPR since the late 1980's, approximately 7,000 per year. Each submission has a series of records that comprise a history of how the submission was handled, timeframes, actions, etc. Extensive reporting features allow management and staff to determine workload, status, and performance metrics. Track also supports the registration mail log which is used to log and track all mail addressed to the Registration Branch.

Chemical Data – DPR Master Chemical Ingredient Database (Chemicals) – The DPR Master Chemical Ingredient database stores information on all chemicals contained in or relative to pesticide products. Data from the Master Chemical Ingredient database are used by most DPR branches. Data features enhance integration with U.S. EPA Office of Pesticide Program data and other national data sets. Access to the data management application uses windows authentication.

Company Information – Firm/ Registrant Database (Licensing) – Firm/ Registrant Database contains information on all pesticide registrants in the Registration Licensing Database. This database tracks company information and historical name changes. Name, address information, phone, and contact person are also captured relative to company "assignments." This data is utilized by other core and supporting systems (e.g., Maillog, Tracking, Mill Assessment, Label, Licensing). Company data is managed by PRB staff during intake and licensing processes. Product Compliance uses data to mail quarterly mill statements to companies with registered products. Mill statements are a fee assessed on all California pesticide sales.

Staff/ Phone Information – Human Resources data (Human Resources) – The Human Resources System was originally developed in 1994 as the first online application for Cal/EPA. This system replaced a once-a-year hardcopy directory. The database was ported to Oracle in 2008 and the front end was converted from Perl

to ColdFusion. Information from the Human Resources System is used in several other core systems used by DPR. Staff report that the data in the Human Resources System is not always up to date and the database only includes DPR staff information that is relative to PRB activities.

Product / Label (Product Label) – Since the early 1970s, DPR has maintained a database on all pesticide products currently (and previously) registered for use in California. The database contains information on approximately 58,000 pesticide products. There are approximately 13,000 active products at any given time. An average of 1,000 new products are added to the database annually, and a similar number of products are inactivated due to non-renewal, suspension, or cancellation. Between 2,000 and 3,600 label amendments are processed annually.

Data collected on each pesticide include the California registration number, product name, type of registration, type of pesticide, formulation type, active ingredients, percent of each active ingredient, specific gravity, commodity/crop/sites on which the product may be used, health and environmental hazards, target pests, signal word, pre-harvest and reentry intervals. The product/label database is available to all DPR staff and the public via the Internet.

Pesticide Data Index (Registration Library) – This database is the second largest pesticide data index in the United States. Created in 1984 to track data gaps, the database contains indexed information on 190,000 individual studies submitted to California to support pesticide product registration.

Discreet data from the chemical, registration tracking, firm/registrator, and phone databases are used to establish relationships with the pesticide data. The data can be searched by most criteria, online, and is available to the public on the Internet. In order to assist registrants with data cost sharing activities, PRB publishes this data for public use.

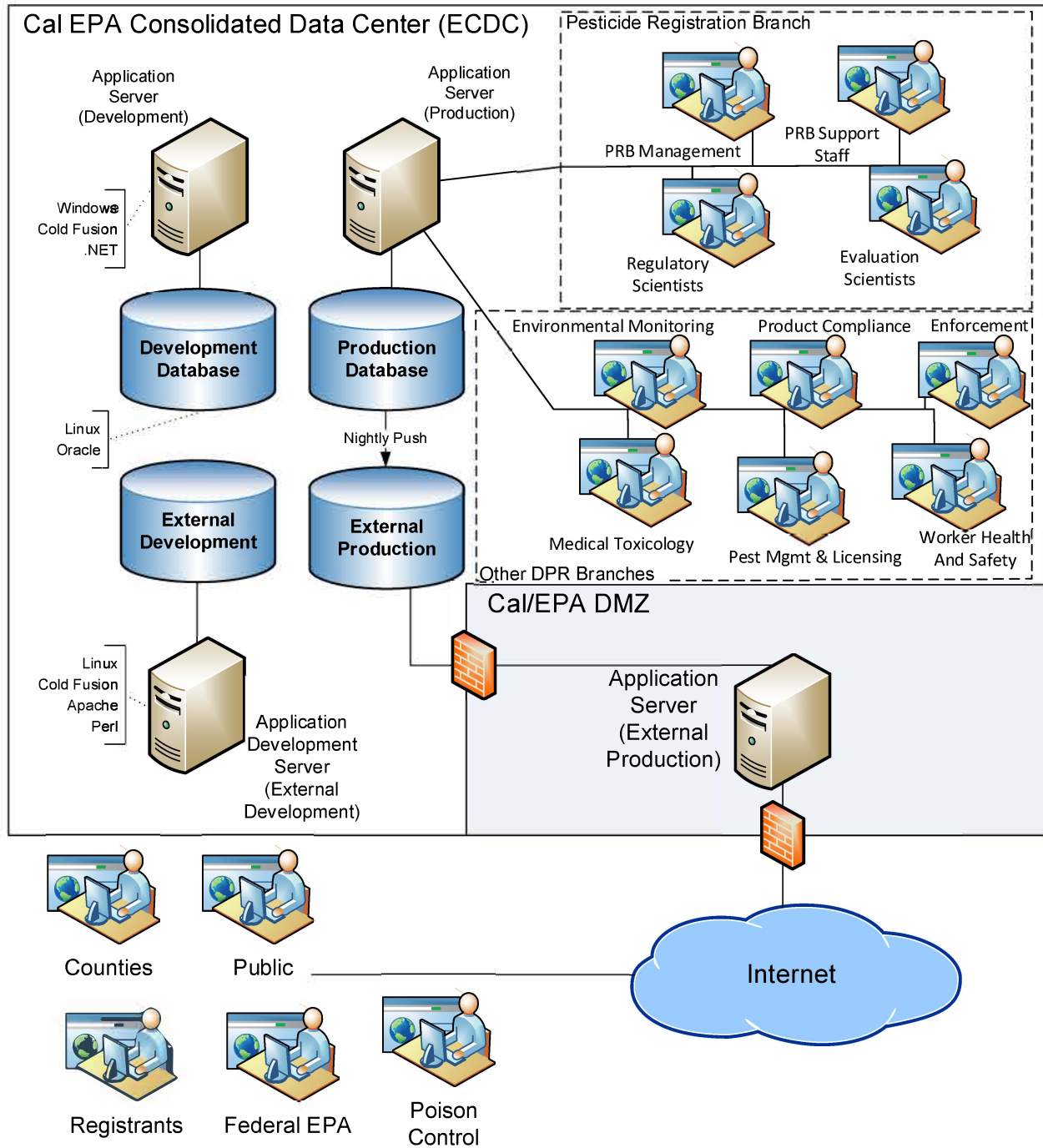
4.2.1.3 PRB System and Database Architecture

The PRB core systems and databases are all housed at the Cal/EPA Consolidated Data Center (ECDC). **Figure 4.4**, on the following page, provides an overview of the PRB system and database architecture. DPR's current application server architecture consists of a blend of both Windows and SUSE Linux environments. The current database architecture consists of both Oracle and MS SQL Server systems. Going forward, DPR's internal staff-based application development will be performed in a Windows environment with an MS SQL Server database backend. The existing Oracle database, however, is not planned for decommissioning during the life of this project. Key features of this figure are:

- **Databases** – The Development, Production, External Development, and External Production databases are all separate instances of the Oracle database containing the schema used for the PRB systems.
- **External Databases** – To insulate internal data from the Internet, DPR established mirrored databases for external-facing applications. The External Databases are updated via a nightly push.

- **Development and Production Application Servers** – The application servers used to drive the PRB systems internally run on Windows servers. DPR IT staff develop new functionality, test, and resolve defects in Development and then migrate to Production.
- **External Development and External Production** – DPR utilizes External Development and External Production environments to develop, test, and run external-facing functionality. Unlike the internal Production and Development servers, these servers run on Linux.

Figure 4.4 System and Database Architecture



- **Nightly Push** - The entire Product/Label database, updated nightly, is made available for download on the DPR web/FTP site. A scheduled job produces the individual raw data tables and a zipped file of all the tables. The data tables on the FTP site are utilized by a number of vendors with either proprietary or public access to their presentation of the data. (<ftp://pestreg.cdpr.ca.gov/pub/outgoing/product/>)
- **Cal/EPA DMZ** – External-facing functionality runs on the Staging and Production servers located in the Cal/EPA DMZ.

4.2.1.4 PRB Supporting Systems

In addition to the core systems, PRB leverages multiple support systems that are built on a variety of platforms including Oracle, SQL Server, Microsoft (MS) Access, and MS Excel. PRB seeks to replace these systems with the proposed new solution. **Table 4.4**, on the following pages, provides information on these 17 systems.

4.2.1.5 PRB Application Development, Maintenance, and Support Staff

DPR has a centralized IT Branch to provide help desk support, application development, database management, and system maintenance needs for all DPR divisions, branches, and offices. The Application Development, Database Administration, and Webshop Branch (App Dev) provides most of the IT application support. App Dev has 16 resources including Retired Annuitants, Programmer Analysts, Information System Analysts, and Data Processing Managers.

4.2.1.6 System Documentation

DPR does not employ a system to track all application documentation. DPR uses templates to collect and maintain requirements. The templates and completed documents are stored in network folders and created or updated as needed. Staff report that not all documentation is up-to-date.

4.2.1.7 PRB System Reliability and Uptime

PRB users indicate the systems used to support their activities are reliable and fast. DPR IT staff estimate the system uptime for all systems to be greater than 99%.

4.2.1.8 Change Control

The change control process employed by DPR and PRB follows one of two paths: one for defects and another for enhancements. Users report defects by opening a Track-It (the department's help desk tracking tool) ticket. DPR IT reviews the request and confirms the scope, and assigns the defect for resolution. Enhancements (e.g. new functionality) must be part of the department's IT Project Roadmap. The content of the roadmap is governed by a departmental change control board.

Table 4.4 PRB Supporting Systems

ID	PRB System	Description	Security	Platform	Web Enabled	Intranet/ Internet	Other
PRB8	Mail Log Database	Provides database to log received mail. The contents of each mail packet received determine if staff need to enter and track the submission in the Registration Tracking Database.	Groups	Oracle	Cold Fusion	Intra	
PRB9	Email Notification (Module of Tracking System)	Generates the notification of receipt email to the registrant/submitter and assigned RS, but does not store or modify any data. System simply emails a status interpretation of a current snapshot of the data that comes from the status and statistical information tables. The initial email lets the registrant know when DPR received a submission, the Tracking ID assigned, the product name, and the assigned staff person's name, email, and telephone number (from RegHR). The email also specifies the next step in the process: to indexing if data were sent, or to the assigned RS for further processing.	Groups	Oracle	Cold Fusion	Intra	
PRB10	Adverse Effects Submissions – Electronic Notification	Part of the existing email notification system identified in core systems. The registrant automatically receives a notification at each transaction step of the submission, as the submission proceeds through the intake and review process. Email includes Tracking ID assigned and short description of each step in the process.	None	Oracle	Cold Fusion		Part of tracking email notification
PRB11	InMagic Library Suite	Contains a duplicate record of the Pesticide Data Index Database to identify the physical location of a volume, and whether it has been archived. The system maintains a field for adding explanatory notes such as changes in record numbers, missing files, and why a document was shredded (duplicate data). The system was upgraded to a web-based application in fiscal year 2011/12.	None	COTS	No		
PRB12	Firm/Registrant Database	Stores registrant information. Information must be in this application prior to entering information into the Registration Tracking system. Maintains relationships between firms and RS staff.	None	Oracle	Cold Fusion, PERL, EPG	Both	
PRB13	Section 18 Emergency Exemption Database (internal and external)	Tracks specific products that are not registered by U.S. EPA or DPR. DPR receives a request from an individual/company and works with the U.S. EPA to obtain approval. There is a searchable external component to the Section 18 database.	Groups	Oracle	Cold Fusion	Both	
PRB14	Section 24 Special Local Need Database (internal and external)	The special local needs database. States may register an additional use of a federally registered pesticide product, or approve a new end use for a product to meet the needs of a specific geographical area.	Groups	Oracle	Cold Fusion	Both	

ID	PRB System	Description	Security	Platform	Web Enabled	Intranet/ Internet	Other
PRB15	Research Authorization Database	Tracks individual research conducted in California under the Research Authorization (RA) program. The application stores data for active research approved and various data elements for actual research conducted.	Groups	SQL Server	.NET	Intranet	
PRB16	Licensing Registration Log	Retains a licensing staff maintained spreadsheet of licensing actions, annually. The log is organized by the type of registration action (e.g., new product license, licensing amendments, company name changes, voluntary cancellations). This database is placed on a shared directory.	None	MS Excel	No	Intranet	
PRB17	Coding Log	Tracks coding case load. Used by the Coding Supervisor to track labels to be coded, coding assignment, and complete date.	None	MS Excel	No	N/A	
PRB18	Risk Assessment Log	Tracks prioritization of products for risk assessment, and those presently in assessment.	None	MS Excel	No	3 Users	
PRB19	Reevaluation Log	Tracks individual product specific reevaluation activity, including mailings, telephone conversations, and various data values (i.e., emission potential of individual products, leach rate values for each boat paint, data generators, and progress of study development) for volatile organic compounds, pyrethroids, antifoulant paints, neonicotinoids, and rodenticides.	None (Network Drive)	MS Access	No	Intranet (3 Users)	
PRB20	Adverse Effects Log	Maintains key reported adverse effects information within a searchable MS Excel file.	None (Network Drive)	MS Excel	No	Intranet (4 Users)	
PRB21	U.S. EPA Product/Label Database	Creates a static copy of U.S. EPA's data tables and links to a static copy of the Registration Product Label Database. A formula outputs those products that should not be renewed in California, due to no longer being actively registered at U.S. EPA. The application also tracks product transfers to new companies and identifies each product as such.	None (Network Drive)	MS Access	No	(1 User)	
PRB22	PRB Evaluation Scientists' Application	Allows for searching Pest and Disease Protection evaluation report memorandums performed over a given amount of time. The interface allows for the entry of new evaluation report memorandums and updates to existing memorandums.	None (Network Drive)	SQL Server	.NET	Intranet (4 Users)	
PRB23	Microbiology	An MS Excel spreadsheet used to track microbiology data.	None (Network Drive)	MS Excel	No	Intranet (2 Users)	
PRB24	Phone Database (a.k.a., RegHR)	Supports eight other applications. Provides information about PRB and any other DPR staff who check out scientific data volumes or access product files.	Groups	Oracle	Cold Fusion	Intranet	

4.2.1.9 Desktop and Staff Productivity Infrastructure

DPR PRB staff work from desktop personal computers running the Windows 7 operating system. Authentication and security are governed using Active Directory. Staff use the Microsoft Office suite for most activities. Regulatory and Evaluation Scientists use some specialized software for electronic comparison, modeling and statistical analysis.

4.2.1.10 Regional Office Computing

DPR's Enforcement Branch, Product Compliance Branch, and Environmental Monitoring Branch staff can work from home or one of three regional offices: Northern, Central, or Southern. Field staff use laptops with Wi-Fi, but none of the laptops has an air card. Field staff do not have VPN access to internal systems; however, they can access it through secure circuit via DPR's firewall when in a field office.

4.2.1.11 Bar Coding

Because of the large volume of paper associated with current PRB business practices, PRB uses bar coding for tracking. Staff can check in and out product files (which include the labels) and scientific data studies.

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Section 5.0

Proposed Solution

5.0 Proposed Solution

DPR proposes to implement an integrated, comprehensive solution to automate and streamline the core business processes discussed in Section 4. The proposed solution provides the best value to the State and allows DPR to address the business process problems and opportunities presented in Section 3 of this FSR. In order to fully assess feasible solution alternatives, DPR issued a Request for Information (RFI) to the vendor community, and conducted numerous interviews with other states and other State of California departments.

5.1 Product Registration Data Management System RFI

In October 2013, DPR issued a Request for Information (RFI) to the vendor community via California's BidSync procurement system. The RFI solicited information from the vendor community about solutions that could satisfy the Product Registration Data Management System (PRDMS) business, functional, and technical requirements. Through the RFI solicitation process, DPR received seven vendor responses, representing a range of solution alternatives: commercial-off-the-shelf (COTS); modified-off-the-shelf (MOTS); and, custom developed. In addition, DPR obtained cost estimates to implement the proposed vendor solutions. Through the RFI responses, DPR identified viable custom developed and COTS solutions. Below are the key findings resulting from evaluation the RFI responses:

- COTS solutions exist in the marketplace; however, the COTS solutions presented require considerable modification and configuration to meet DPR's needs.
- Pesticide registration COTS solutions exist in the marketplace; however, they do not satisfy core functional requirements such as workflow, document management, and document comparison.
- MOTS solutions presented did not meet DPR's requirements.
- Custom developed solutions presented in the RFI responses meet DPR's needs. The options presented satisfy DPR's requirements by building on existing workflow, document management, and document comparison products. These proposed solutions are not necessarily 100% custom developed but rather a hybrid solution leveraging proven marketplace tools.

Other State and State of California Department Interviews

In addition to issuing and evaluating responses to the RFI, DPR conducted interviews with representatives from Health Canada, three other states, and one State of California department. The targeted organizations were selected because they recently automated their pesticide registration and/or renewal processes. In the case of the State of California department, they automated processes similar to DPR's. These interviews yielded the following high-level observations relevant to the solution alternative evaluation process:

- Other states' pesticide registration processes are significantly simpler than California. Most states' do not evaluate the pesticide product for registration

but rather rely on the US EPA's evaluation; California is mandated to perform its own evaluation process.

- Other state systems do not include workflow, document management, or document comparison functionality.

The following subsections detail the proposed solution as well as the alternatives considered. The remainder of this section is organized as follows:

5.2 Solution Description

5.3 Rationale for Selection – Custom Developed Solution

5.4 Other Alternatives Considered

5.2 Solution Description

Based on the extensive nature of California's pesticide registration process, the PRDMS proposed solution is a custom developed solution that contains some components of COTS, where applicable and available. The following section represents a combination of information obtained from the RFI solicitation, interviews, and DPR processes, policies, and expectations. Where specific detail is presented about the proposed solution, DPR presents the cost details. Note, there are multiple permutations of viable custom developed solutions possible. The implemented solution may vary based on the final solutions presented during the project's Request for Proposal procurement phase.

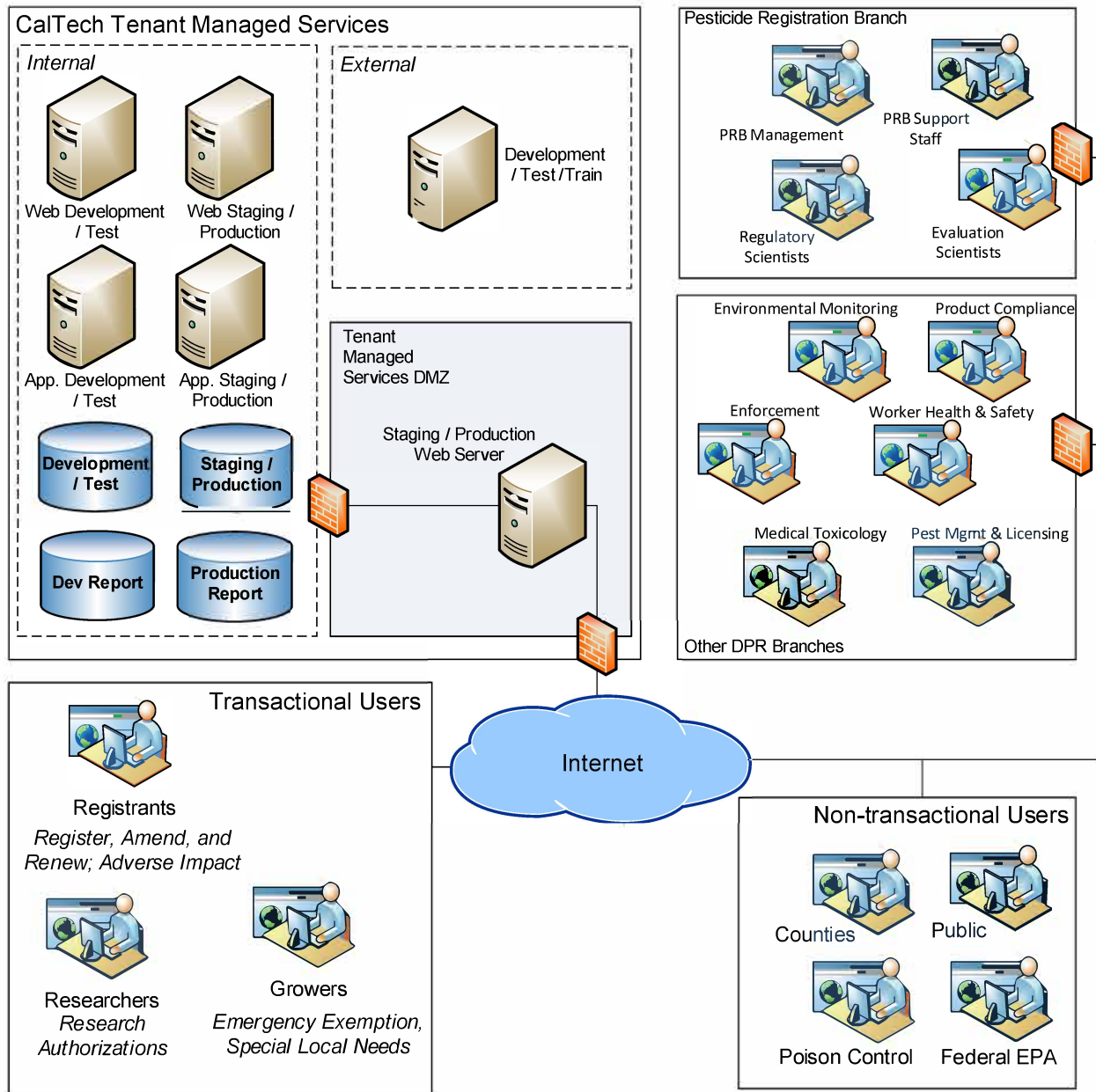
Figure 5.1, on the next page, depicts a conceptual architecture of the proposed solution. The conceptual architecture communicates a solution that enables key external users such as registrants, growers, and researchers gaining transactional access. This access transitions the main processes from paper-based to online processing and payment. The conceptual architecture shows hardware that presents one possible configuration. DPR anticipates that the final solution hardware may vary. In addition, the conceptual architecture hardware enables DPR to develop costs included in Section 8 the Economic Analysis Worksheets.

Figure 5.1 Notes:

- DPR will not develop, process, or store any payments or payment information; all payment processing will follow state-approved processes via state-approved payment processing providers
- Development and Test will reside on the same physical servers; however, they will be in separate environments.
- Staging and Production will reside on the same physical servers; however, they will be in separate environments.
- The DPR standard for reporting (Dev Report and Production Report) is SQL Server Reporting Services (SSRS)

- Though not depicted, DPR anticipates Pesticide Registration Branch and Other DPR Branches users will be authenticated via Active Directory. Transactional Users will authenticate via a web browser using industry authentication standards.

Figure 5.1 PRDMS Conceptual Design



1. Hardware

The anticipated proposed solution hardware requirements are described below. DPR anticipates the system will run on existing hardware.

- Six servers running the latest version of Microsoft Windows operating system: one each for internal and external production; one each for internal and external test/staging; and, one each for internal and external development. Each server will be virtualized.
- Four database servers running the latest version of Microsoft Windows; one database server for development/test environments; one database server for staging/production environments; one database to support report development; and one database server to support production reports.

2. Software

The anticipated proposed solution software requirements are:

- Four database licenses – e.g., Microsoft SQL Server 2012
- Workflow management software – this could be a configurable workflow engine.
- Document management software – the proposed solution will manage documents; however, DPR does not anticipate procuring an enterprise-level document management system as part of this effort.

3. Technical Platform

PRDMS will run on Windows-enabled servers with the most recent version of Microsoft's operating system.

4. Development Approach

The proposed solution will not be 100% custom developed. DPR has the opportunity to leverage pre-built, configurable COTS components that speed the development process (workflow engines, document management components, etc.). Based on the RFI responses, DPR anticipates the custom developed-to-COTS ratio to be 80%-20%.

DPR employs a waterfall system development approach for internal applications because it generates discrete checkpoints/stage gates during system development. Given the nature of the proposed solution and functionality, DPR anticipates using the same software development approach to develop the PRDMS solution. The key steps in the waterfall development approach are:

- Requirements Definition and Analysis – All business rules and design-level requirements are defined and mapped for traceability in this phase. Requirements are documented, validated and approved before development.
- System Design and Development – System layouts are generated, key system functionality is prototyped, unit tested and then finalized per the approved requirements.
- Integration Testing – All pieces of the system are assembled and tested to ensure they function as specified.
- Acceptance Testing – PRDMS users test the system to ensure it meets the specified needs.

- Deployment – The final, approved system is deployed to production.
- Maintenance – The system transitions to maintenance for regular activities and enhancements.

5. Integration Issues

PRDMS will replace and eliminate the various standalone, disparate systems currently maintained by PRB. Other DPR systems operated by the other Branch’s will integrate, at least partially, with the PRDMS. For example, the Pesticide Use Reporting (PUR) database within the Pest Management and Licensing Branch leverages a small dataset from one of the existing PRB systems. DPR Information Technology Branch staff maintain these systems and will modify the systems, as needed, to integrate with PRDMS.

6. Procurement Approach

<input type="checkbox"/> IFB	<input type="checkbox"/> RFI	<input checked="" type="checkbox"/> CMAS	<input type="checkbox"/> MSA	<input checked="" type="checkbox"/> RFO	<input checked="" type="checkbox"/> RFP	<input type="checkbox"/> Other	<input type="checkbox"/> None
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The project requires advanced, highly specialized skills in system design, configuration, development, and implementation. DPR does not have access to State employees specialized in these areas either internally or through another channel. For this reason, the project meets the requirements of Government Code section 19130(b)(3)e Therefore, DPR will issue a request for Proposal (RFP) to secure the services of a system integrator for the PRDMS project.

DPR has retained the services of the FSR contractor to support the procurement process for the solution vendor. DPR anticipates completing the procurement process in time to award the contract by July 2015 to coincide with the 2015/2016 fiscal year start.

DPR will procure the solution vendor via a request for proposal (RFP)e The selection will be based on “best value” with cost being weighted 40%.

In addition, CalTech recommends DPR secure the services of an Independent Verification and Validation (IV&V) contractor for the PRDMS project. CalTech recommends allocating approximately 10% of the EAW Total One-time IT Costs for IV&V; \$500,000 for the proposed solution. These services are most efficiently procured using the Information Technology California Multiple Award Schedule (IT-CMAS)e The IV&V services will begin concurrently with the system integrator’s services.

Finally, DPR will reimburse CalTech for IPOC services provided during the life of the project.

Table 5.1, below, provides for the procurement approach to secure the services necessary to implement the PRDMS.

Table 5.1 PRDMS Procurement Approach

Contract Number	Contract Type	Awarded (Y/N)	Award Date	Start Date	End Date	Amount	Inter-Agency (Y/N)	Performance Based (Y/N)	Competitive Award (Y/N)	Alternative Financing (Y/N)
TBD	Solution Vendor	N	TBD	Jul 2015	Dec 2017	\$3,148,958			Y	
TBD	IV&V	N	TBD	Jul 2015	Dec 2017	\$530,000			Y	
TBD	IPOC	N	TBD	Jul 2015	Dec 2017	\$225,120	Y			

7. Technical Interfaces

Table 5.2, below, describes the PRDMS technical interfaces. PRDMS will consume data from two federal data sources—the National Pesticide Information Retrieval System and the Accepted Labels State Tracking and Repository. This interface will come in the form of files that NPIRS and ALSTAR send to DPR. The PRDMS will have a real-time connection with either system at the time of implementation.

Table 5.2 PRDMS Technical Interfaces

System Name	System and Interface Description	Interface Type
NPIRS	National Pesticide Information Retrieval System – NPIRS. The Federal pesticide data repository. At a minimum, DPR anticipates collecting the product’s federal status.	As-needed, files-based
ALSTAR	Accepted Labels State Tracking and Repository – ALSTAR. The ALSTAR system exchanges, accepts, and stores registrant pesticide label information	As-needed, files-based

8. Accessibility

The browser-based components of the PRDMS will meet California Government Code 11135 and Section 508 (29 U.S.C. § 794) accessibility standards.

9. Testing Plan

The proposed solution vendor will develop and execute the PRDMS testing plan. At a minimum, DPR requires test plans to address the following:

Unit Testing – Tests that each system module performs as designed and provides the information and functionality specified by DPR. Unit testing is defined as the verification of the accuracy and completeness of the individual processes, programs, modules, objects, functions, and procedures that make up the system.

System Integration Testing – Tests that system components work together as designed

User Acceptance Testing – Tests by users of the complete system to confirm that it functions in accordance with system requirements.

Regression Testing – Tests to confirm that any new designs, changed design, or added functionality do not negatively impact the production system functionality.

Load Testing – Tests to validate that the software and hardware operate together in a manner that meets the expected average and peak performance requirements. Stress testing is dependent on scripting as test scripts mimic the expected production environment.

Security Testing – Tests to ensure, at a minimum, authentication (user login) and authorization (user role) function as specified.

10. Resource Requirements

Table 5.3, below, summarizes the estimated one-time DPR resource requirements for IT staff and business resources by fiscal year. This estimate is reflected in the Economic Analysis worksheets in Section 8. These resources will be redirected from existing activities to support the system implementation. Post-implementation, the existing systems will be retired and these resources will be allocated to supporting the new system.

Table 5.3 PRDMS Resource Requirements

Resource Type	15/16	16/17
IT Staff	3.8	3.8
Business Resources	1.3	1.3

Table 5.4 provides the detail supporting table 5.3 and lists each resource's project role.

Table 5.4 PRDMS Resource Detail

DPR Staff Costs	Area	Project Role	FY 15/16 Allocation	FY 16/17 Allocation	Source
Data Processing Manager III	IT	Project Director	0.2	0.2	Redirect
Data Processing Manager II	IT	Project Manager	0.8	0.8	Redirect
Staff Programmer Analyst (Spec)	IT	DPR Technical Lead	0.9	0.9	Redirect
Associate Programmer Analyst (Spec)	IT	2 Programmers at .5 and .3	0.8	0.8	Redirect
Associate Information Systems Analyst (Spec)	IT	Business Analyst	0.9	0.9	Redirect
Staff Information Systems Analyst (Spec)	IT	Network Admin / Configuration	0.2	0.2	Redirect
Research Program Specialist II	PRB	Super User/Admin	0.8	0.8	Redirect
Senior Environmental Scientist (Spec)	PRB	Subject Matter Expert	0.2	0.2	Redirect
Environmental Scientist (Range C)	PRB	Subject Matter Expert	0.2	0.2	Redirect
Staff Services Analyst (Range C)	PRB	Subject Matter Expert	0.1	0.1	Redirect
Total:			5.1	5.1	

11. Training Plan

DPR anticipates the solution vendor to train both the DPR technical staff on how to maintain the final product and the internal/external system users. The techniques employed will include the following:

- Train-the-trainer – train DPR staff to train other internal and external users.
- Webinars – web seminars conducted to train the initial users. This ensures that users external to DPR will understand how to use the system.
- Web Based Videos – intent-based videos that could be posted to a video site (i.e., YouTube) that demonstrate discrete functions users will encounter (e.g., register for an account, login, register a product, amend a product, etc.).

Technical Training

DPR will have IT staff collaborate with the project team to facilitate knowledge transfer. In addition, the PRDMS solution vendor will train DPR IT staff on the following activities:

- System Maintenance – How to maintain and enhance the system.
- System Administration – How to administer the system for DPR. (e.g., manage users, archive data)

User Training

The PRDMS solution vendor will develop training materials for internal and external PRDMS users. The vendor will train up to 100 internal users on-site and conduct webinars for external users.

12. On-going System Maintenance

Ultimately, the DPR Information Technology Branch (ITB) will maintain the PRDMS. In addition to required knowledge transfer activities during the project, DPR requests a six-month post-implementation-support period to ensure DPR ITB staff are fully able to maintain the PRDMS. The post-implementation-support requires the solution vendor to supply two technical resources to work side-by-side with DPR ITB staff during defect resolution and system support.

13. Information Security

California state policy requires the use of information security controls listed in the National Institute of Standards and Technology (NIST) Special Publication 800-53 revision 4 (NIST 800-53 rev4)

14. Confidentiality

The PRDMS will collect both confidential and non-confidential product data. The confidential data collected will be the confidential statement of formulation (CSF) for every registered product. The CSF lists, among other data, both active and inert product ingredients by percent. DPR collects the CSF data via

the application form or registrants may submit the U.S.EPA Confidential Statement of Formula Form. Additionally, registrants submit Chemistry Data Volume which contains confidential manufacturing process information. DPR anticipates capturing the CSF data, whereas the manufacturing process will be a supplemental file. As such, the project team will work with the Information Security Officer to ensure DPR and State information confidentiality policies and guidelines are followed. For example, the requirements call for the secure transaction of data. In addition, system access will be governed by a user's role and access privileges.

15. End User Impact

Internal

This system will substantially modify the way approximately 100 internal users interact with and manage pesticide data. The complete scope of impacts was identified and documented during a business process assessment (BPA) completed by DPR. DPR is in the process of gradually introducing the changes recommended in the BPA to ease the transition into the new system.

External

DPR currently houses pesticide information for almost 1300 active registrants. DPR will communicate the changes in advance to the external users and incorporate their feedback into the final system. In addition, the interviews conducted for the FSR revealed that other states have achieved very high levels of participation from the registrants.

Other impacted users include California's growing community, researchers, and the general public (for activities such as public comment). DPR will communicate changes to the impacted users via the DPR website.

16. Existing System Impact

DPR plans to convert/migrate essential data from the existing systems into the PRDMS. The goal is to retire the existing system within two years of the new system implementation date. DPR plans to archive the data from the existing systems that cannot be converted/migrated to the new system, in case users require access to old data. The complete list of databases for conversion are included in **Table 4.3 PRB Core Databases**. DPR will work with the solution vendor to determine the best method of data conversion and which data to convert.

Data conversion will be the responsibility of the vendor with some assistance from DPR. As reflected in Phase III, Stage 4 of the PRDMS Project Schedule (Exhibit 6.2.3), the vendor will be expected to develop a data conversion plan, process, and schedule. DPR staff will be integral in data cleansing, as they have the business knowledge to decipher or interpret problematic data.

The existing system is supported by a substantial library of physical documents. Scanning and conversion of these documents into the new system is outside the scope of this effort.

17. Consistency with Overall Strategies

The proposed PRDMS solution is consistent with DPR's Enterprise Architecture as described in Section 4 of this FSR. Also, in Section 3, DPR's business strategy is presented and how the proposed PRDMS solution aligns to achieve the mission and goals of DPR.

18. Impact on Current Infrastructure

The PRDMS will leverage existing servers. In addition, DPR users will use dual monitors to facilitate the product evaluation process; currently, DPR is deploying dual monitors to begin the transition to the new environment. Finally, DPR does not anticipate that PRDMS will exceed the bandwidth of the existing network.

19. Impact on Data Center

The PRDMS will be housed in DPR's existing environment. DPR is in the planning phase of migrating all systems and hardware to the CalTech tenant managed services (TMS) environment.

20. System Hosting/Data Center Consolidation

DPR is in the planning phase of migrating all systems and hardware to the CalTech tenant managed services (TMS) environment.

21. Backup and Operational Recovery

The proposed solution will comply with the DPR Technology Recovery Plan and will be added to the Department's Technology Recovery Plan during the deployment phase. At that time, the application's maximum allowable outage (MAO) will be determined and the MAO recovery requirements will be built into the application deployment process.

22. Public Access

Public Access to the PRDMS will extend to registrants/applicants who will have the ability to request to register, renew, and modify pesticide products in California online. In addition, the public will have the ability to search registered products for a limited scope of data.

5.3 Rationale for Selection – Custom Developed Solution

Based on the market analysis, the RFI results, interviews with other states, and DPR policies, DPR proposes a custom developed PRDMS solution. **Table 5.5**, below, provides a high level summary of advantages and disadvantages of a custom developed solution.

Table 5.5 Proposed Solution Advantages and Disadvantages

Advantages	Disadvantages
<ul style="list-style-type: none"> • The proposed solution achieves all solution objectives defined in FSR Section 3.0. • The proposed solution satisfies all technical and functional requirements defined in FSR Section 9.0. • The proposed solution will be purpose-built to meet California’s extensive pesticide registration and regulatory needs. • The proposed solution will be maintained by DPR IT staff. • Custom development provides flexibility and development options not available with the other options. • The proposed solution costs less for DPR to maintain than other alternatives. 	<ul style="list-style-type: none"> • The time frame associated with the full customization cycle is longer than the other options considered. • The PRDMS will not benefit from regular version upgrades seen with COTS solutions. It must rely on the availability and skills of internal staff which may pose a risk.

5.4 Other Alternatives Considered

The RFI process revealed COTS solutions for DPR to analyze and consider. The COTS solutions aggregate into two types of solutions: existing pesticide registration systems; and existing COTS systems that can be re-purposed to meet DPR’s needs. Each is discussed below.

5.4.1 Alternative 1: COTS – Existing Pesticide Registration Systems

The existing COTS pesticide registration systems are not a viable option for PRDMS because they lack essential functionality and do not meet DPR’s functional and technical requirements. **Table 5.6**, below, provides a summary of the advantages and disadvantages of an existing COTS pesticide registration system.

Table 5.6 Alternative 1 Advantages and Disadvantages

Advantages	Disadvantages
<ul style="list-style-type: none"> Pesticide registration systems are in place in other states. 	<ul style="list-style-type: none"> Do not have workflow capabilities. Do not provide for the ability to compare documents (labels and scientific data studies) Do not meet DPR functional and technical requirements without substantial modification. The solutions are not scalable. In other states, the registration work is performed by two to three staff versus almost 100 employees for DPR. Do not collect product data, confidential statements of formulation, or scientific data studies DPR requires. DPR would be reliant on vendors to maintain and upgrade the system. DPR custom functionality and future enhancements would be dependent upon vendors and not DPR's priorities. This alternative has the highest annual costs post-implementation.

5.4.2 Alternative 2: COTS – Re-purposed Permitting Systems

The existing COTS pesticide registration systems are not a viable option for PRDMS because they lack essential functionality and would require substantial reconfiguring in order to meet the DPR's needs. **Table 5.7**, below, provides a summary of the advantages and disadvantages of a re-purposed COTS permitting system.

Table 5.7 Alternative 2 Advantages and Disadvantages

Advantages	Disadvantages
<ul style="list-style-type: none"> A repurposed permitting system may be configured more quickly than a custom developed solution. Permitting systems have workflow integrated into their solution. Permitting systems offer third-party opportunities to incorporate document management and document review. 	<ul style="list-style-type: none"> Requires substantial customization and configuration to meet DPR functional requirements. DPR would be reliant on vendors to maintain and upgrade the system. DPR custom functionality and future enhancements would be dependent upon vendors and not DPR's priorities.

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Section 6.0

Project Management Plan

6.0 Project Management Plan

The California Department of Pesticide Regulation (DPR) is committed to the successful implementation of the Registration Program Reengineering Project (RP²), including achievement of its goals and objectives. This includes implementation of the Product Registration Data Management System (PRDMS). DPR has developed a project management plan following the California Project Management Methodology (CA-PMM), as required by the California Department of Technology. DPR will utilize this structured project management approach to help ensure the success of the PRDMS implementation.

The remainder of this section is organized as follows:

- 6.1 Project Organization
- 6.2 Project Plan
- 6.3 Authorization Required

6.1 Project Organization

The proposed DPR PRDMS project organization is illustrated in **Figure 6.1.1**, on the following page. The specific project roles and responsibilities of the project participants are described in Section 6.2.1. The Pesticide Registration Branch organization chart, which contains the internal stakeholders and management directly impacted by the implementation of PRDMS, are shown in **Figure 6.1.2**, on page 3. Implementation of the PRDMS is also expected to impact another fifty-five DPR staff located in other branches within DPR, who are also an integral part of the pesticide registration process. DPR's Office of Technology, which is shown in **Figure 6.1.3**, will be providing the technical and application support for the implemented solution.

The project management methodology adopted for the PRDMS project is the CA-PMM, which is based on the Project Management Institute's Project Management Body of Knowledge (PMBOK®). The DPR's Office of Technology will provide IT project oversight by providing a project manager and project sponsor(s) that can work alongside a vendor project manager to manage and guide all aspects of the project. In addition to providing a governance structure to the system integrator the project manager will be involved in all aspects of the system implementation and will play an active role in: risk management, requirements management, assessing readiness for implementation, and managing scope. The project manager will also work closely with the department information security officer to ensure that all possible security risks are analyzed and appropriately mitigated. The DPR project manager will also be responsible for ensuring that the project is executed according to the CA-PMM.

As the person responsible for the PRDMS, the project manager must have the skills and knowledge to successfully lead the project effort through implementation. These skills are defined by complexity assessment attached in Appendix A of this document. The complexity assessment indicates that a PM Level 2 is required with the following specific experience and professional knowledge:

Experience: 3 – 5 years as a key team member on a medium or large IT project or as a Project Manager on small or medium IT project. Technical experience commensurate with the proposed technology.

Professional Knowledge: Strong working knowledge of the CA-PMM, department's methodology, Software Development Life Cycle. Familiar with CA Budgeting, procurement and Contracting processes.

DPR will assign a Project Manager who meets or exceeds the required experience and professional knowledge qualifications required by the CA-PMM.

The PRDMS project manager, assisted by the system integrator, will use Microsoft Project software to develop the project schedule and to manage and track project progress. The PRDMS project manager will identify tasks and activities for inclusion in the project plan and will report status for each defined task throughout the project.

The executive (project) sponsors oversee and provide direction and guidance to the project team. The project sponsors work with the project director and program manager, defining the project's vision, mission, objectives, and priorities. The project sponsors review and determine approval for any project change request. The executive sponsors, project director, project manager, and program manager will serve as the PRDMS steering committee. Additionally, the PRDMS project will utilize vendor and interagency contract support for the following:

System Integrator – responsible for all aspects of the project development, test/training and production environments (e.g., software configurations, data migration, reports, training, documentation, implementation, and post implementation support)

IPOC (Independent Project Oversight Consultant) –The IPOC partner will review ongoing project processes, activities, and documentation to determine if the project is on schedule; review and verify that project planning deliverables sufficiently meet project standards; identify project risks; monitor the risk management process; report compliance with the appropriate project management practices; develop Independent Project Oversight Reports (IPORs); reporting directly to the steering committee. CalTech will provide this service through a service request.

IV&V (Independent Validation and Verification) – The IV&V partner is responsible for independent review and analysis of specific project activities and documentation to determine project risks specific to the requirements and solution. The IV&V partner will Provide independent review and analysis of specific project activities and documentation related to the solution and requirements; monitor the requirements to ensure they meet the stated business need; monitor the solution to ensure it meets the requirements; review ongoing project processes and activities; identify project risks related to the requirements and solution; report on any other material findings, conclusions, and recommendations; and, IV&V will report to the Department of Technology at a minimum on a quarterly basis.

For a tabular breakdown of the project team, by role, including their classification and PY need please refer to Section 5 Table 5.4.

Figure 6.1.1 PRDMS Project Team Organization

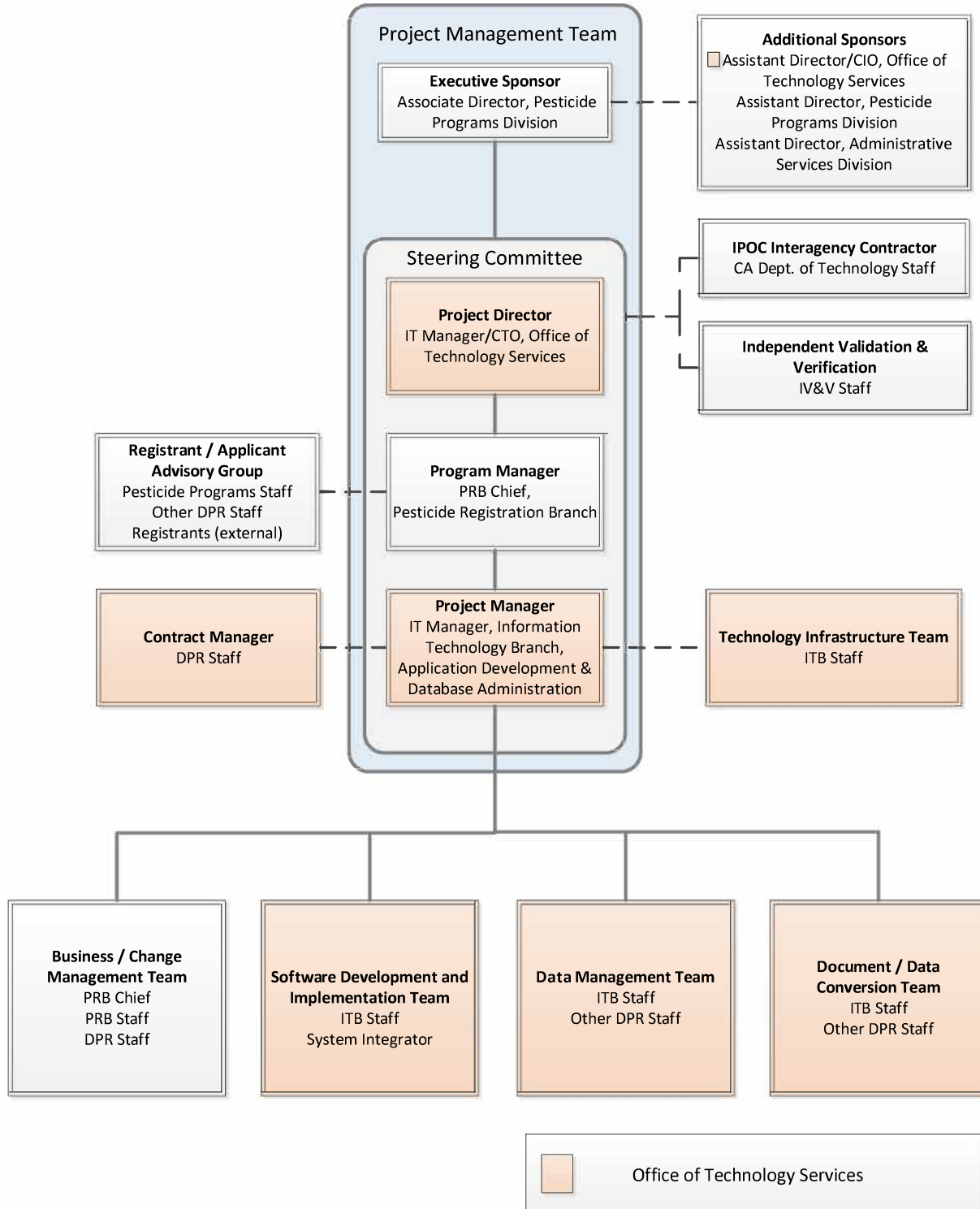


Figure 6.1.2 Pesticide Registration Branch Organization

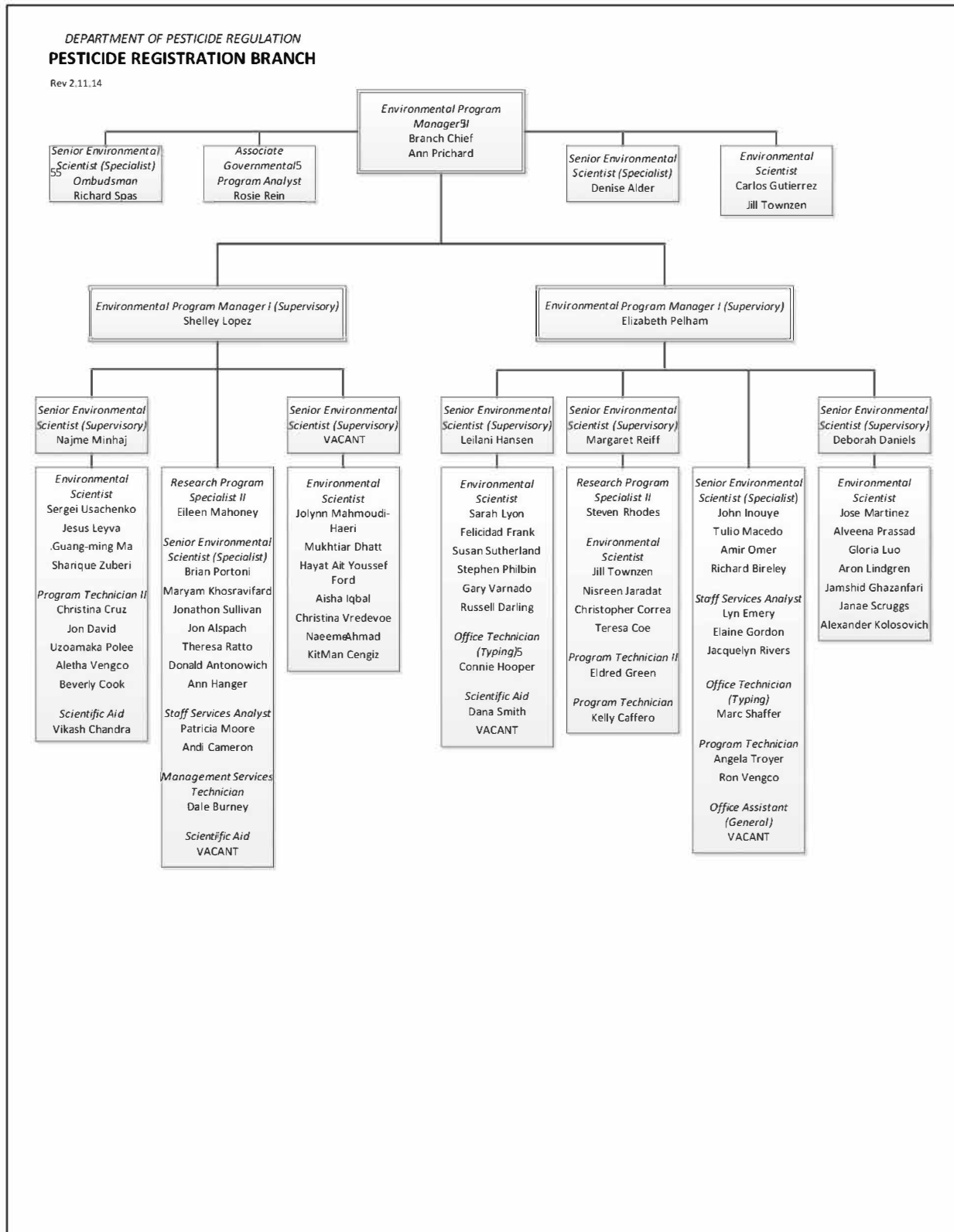
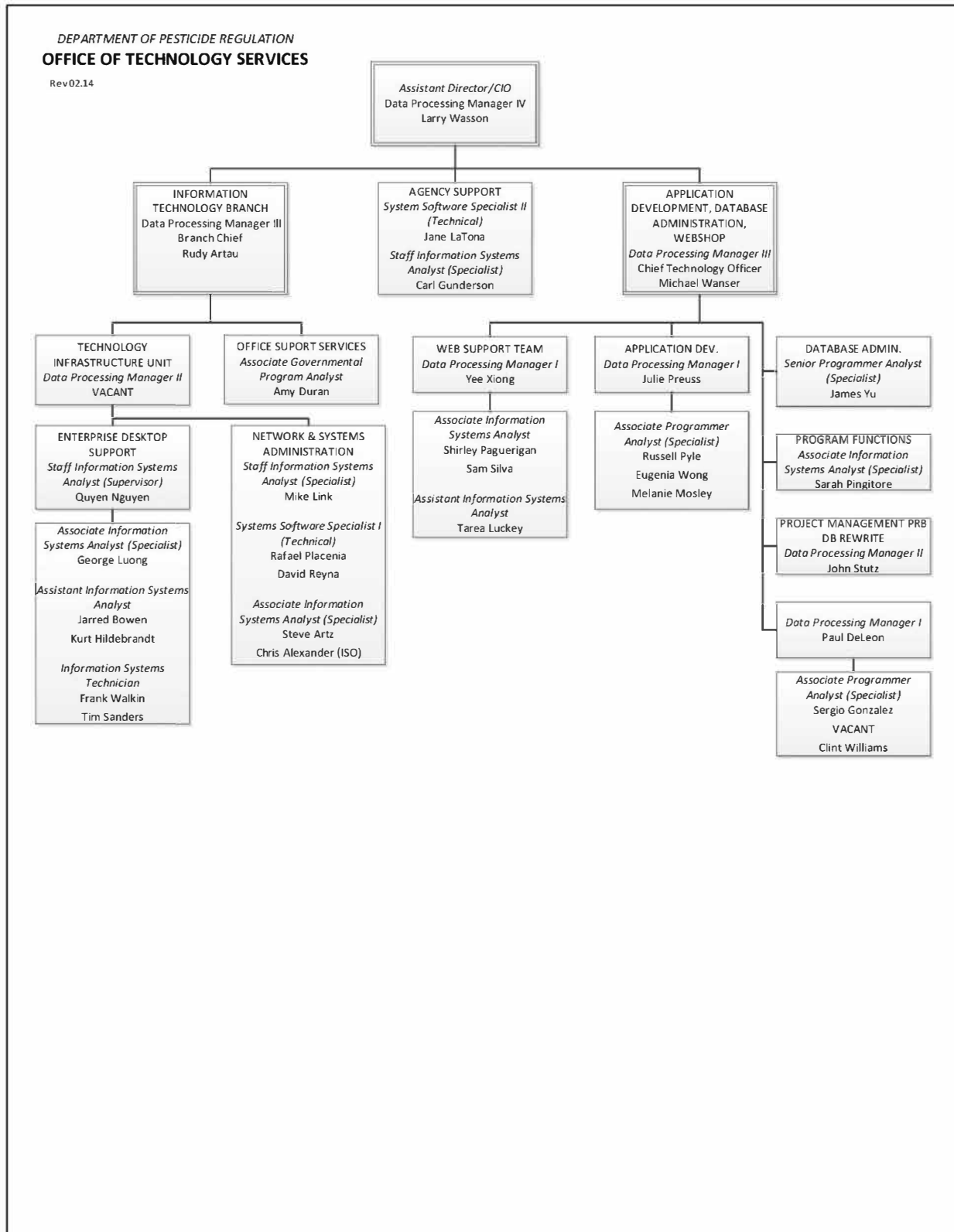


Figure 6.1.3 Office of Technology Services



6.2 Project Plan

Project planning defines the project activities to be performed, end products to be delivered, and how the activities will be accomplished. The purpose of project planning is to define each major task, estimate the time and resources required, and provide a framework for management review and control.

Project Scope

The scope of the PRDMS is to implement a custom developed solution that meets the DPR's needs in the following PRB core registration program business areas:

- Register, amend, and renew pesticide products/devices
- Manage pesticide product label data, pesticide product labels, and scientific data
- Issue Research Authorizations (RAs)
- Receive and track adverse effects and make determinations
- Coordinate pesticide product(s) reevaluation, risk assessment, and mitigation programs.

The PRDMS solution will replace 24 systems and databases currently used to support PRB in its core activities. The PRDMS will consist of those tasks and activities required to achieve the following:

- Develop communication plan to: (1) prepare stakeholders for planned improvements, (2) define objectives for the project, (3) describe what will be accomplished and by when, (4) describe how the project will be developed and implemented, and (5) describe what benefits are expected when PRDMS is fully deployed
- Develop applications required to implement and operate the PRDMS solution.
- Construct development, test, staging, and production environments, and establish configuration management processes and procedures.
- Develop detailed requirements specifications.
- Design and develop the PRDMS solution.
- Integrate PRDMS with the DPR's existing systems.
- Perform PRDMS system testing and integration testing.
- Develop a comprehensive training plan.
- Perform PRDMS training for end users, system administration staff, and support staff.
- Perform user acceptance testing.
- Perform required data cleanup and conversion of existing data to the PRDMS.
- Perform implementation and production cutover.
- Provide post-implementation systems support and enduser help desk.
- Retire existing databases, and any desktop databases and spreadsheets used to support core PRB functions.

Project Assumptions

The DPR makes the following assumptions for the project:

- The DPR director and Cal/EPA Agency Chief Information Officer will approve the FSR, and the RFPs for the System Integrator and the Independent Validation and Verification Vendor.
- The Department of Technology will review and approve the FSR.
- Executive sponsorship will continue through project completion.
- The DPR will redirect the required funding, through an approved budget change proposal (BCP), and the funds will be available throughout the project's life.
- The RFP will be finalized, approved, and ready for release prior to start of project.
- Functional requirements will not substantially change during the project.
- Higher priority issues will not impact the resource or schedule needs.
- The DPR will partner with a systems development and integration vendor and IPOC vendor (CalTech) to augment DPR's existing IT resources during development, testing, and implementation phases.
- The DPR will partner with a systems development and integration vendor and IPOC vendor (CalTech) to augment DPR's existing IT resources during development, testing, and implementation phases.
- The DPR will partner with an Independent Validation and Verification vendor to supplement the oversight efforts of the DPR.
- Negotiations with vendors will result in a budget no greater than estimated in FSR Section 8, Economic Analysis Worksheets, and will result in executed contracts as scheduled.
- The DPR project team will adhere to a formal project management methodology and project schedule; and follow proactive risk, issue, and change control management strategies.
- Qualified DPR program and technical staff will be available to participate, as needed, in design, development, testing, and implementation of the proposed solution.
- DPR program staff will take ownership of and buy into the new system.
- Subject matter experts from DPR will be available to participate in defining requirements and participate in the design, development, and implementation of PRDMS system.
- The DPR will follow a rigorous organizational change management approach to manage resistance to change and to assist other stakeholders' transition to the new system, and to processes embedded in commercial components of the new system.
- All new hardware and applications required for the PRDMS system will be available on-time and will comply with DPR technology standards approved at time of contract execution.

6.2.1 Project Phasing

The DPR expects planning, implementation, and operation of the PRDMS will occur in the following five major project phases, presented in **Figure 6.2.1**, below. Key deliverables are presented in **Section 6.2.2 Project Schedule**.

Figure 6.2.1 Project Phasing

Project Phase	Phase Deliverable/Task
Phase I: Procurement	<ul style="list-style-type: none"> • Award system integrator contract • Award IV&V contract • Execute IPOC interagency agreement
Phase II: Project Initiation and Planning	<ul style="list-style-type: none"> • Project charter development • Communication and dispute resolution planning • Project planning • Organizational change management program planning • Configuration management plan
Phase III: Development	<ul style="list-style-type: none"> • Architecture and design specification • Component Development • Data Conversion systems development • Testing
Phase IV: System Deployment	<ul style="list-style-type: none"> • User acceptance testing • Pilot and implementation • Training
Phase V: Post Implementation	<ul style="list-style-type: none"> • Post implementation support • Project closeout and transition • Post implementation review

Roles and Responsibilities

The critical participants in the project will be the executive sponsors, project director, program manager, project manager, and project team leads, as displayed in Figure 6-1.1. This formal project structure provides participants with a clear understanding of the authority and responsibility necessary for successful accomplishment of project activities, and enables project team members to be held accountable for effective performance of their assignments.

Exhibit 6.2.2, on the following pages, summarizes key PRDMS project roles and responsibilities. A team member may have multiple project responsibilities.

6.2.2 Project Schedule

Exhibit 6.2.3 and **Exhibit 6.2.4**, following Exhibit 6.2.2, provide a project schedule reflecting the following:

- High-level tasks include procurement, design, programming, systems development, data conversion, installation, training for end users, and training for technical staff
- Schedule allows for status reporting against which the project managers will monitor completion of tasks during the course of the project. The schedule provides the duration of critical tasks, major management decision points, and progress reporting milestones
- Milestones reflect products and major events that are readily identified as completed or not completed on the specific date
- Milestones spaced at reasonable intervals that allow management and control agency monitoring of the project's progress.

The last column on the right in Exhibit 6.2.3 presents the planned schedule to develop each of the project deliverables indicated in the Exhibit. When final approval is received for this FSR, the DPR will update the schedule, if necessary.

6.3 Authorization Required

The project requires approval from the PRDMS project executives, project director, program manager, and DPR executive management. The project also requires approvals for project technical approach and costs (CA Dept. of Technology) and procurement approach (Statewide Technology Procurements Division). Additionally any budget actions will be reviewed by the Department of Finance.

Exhibit 6.2.2 Roles and Responsibilities

Project Team Role	Responsibility
1. Executive Sponsors	<ul style="list-style-type: none"> • Assume project ownership, providing highest level of project review, policy leadership, and oversight, as needed • Serve as key business decision-maker of the project; provide decision-making authority • Establish project goals and priorities • Provide executive management sponsorship and support for the project • Resolve significant issues and scope changes that cannot be resolved by project director • Determine project funding and resources • Review and approve significant changes to project scope, budget, or schedule • Mediate issue resolution • Make final decision on vendors retained throughout the project
2. Project Director	<ul style="list-style-type: none"> • Ensure overall success of project • Provide a centralized structure to coordinate and manage the project, staff resources, teams, activities, and communication structured project management methodologies • Direct activities of state and vendor personnel assigned to the project • Review and approve deliverable expectation documents (DEDs), detailed functional specifications and design, and vendor project deliverables • Determine that the implemented solution addresses the project’s and associated program objectives • Determine quality control and quality assurance activities are performed in accordance with quality management plan; participate in quality planning, assurance, and control • Communicate project status to DPR management, executive sponsors, and external stakeholders, as needed • Monitor planning, execution, and control of activities necessary to support implementation of the PRDMS • Provide leadership to state staff assigned to manage project teams • Coordinate and monitor project charter, plan, and performance • Facilitate and approve internal and external service level agreements (SLAs) • Attend recurring steering committee meetings • Participate in identification, quantification, and mitigation of project risks
3. Program Manager	<ul style="list-style-type: none"> • Be an active participant within the project management team • Manage relationship with registrant/applicant advisory group, acting as liaison between DPR and external stakeholders; manage stakeholder expectations; and ensure that stakeholder communications plan is properly executed • Facilitate preparation of functional and technical requirements specifications to be placed in solicitation document • Complete deliverable sign-off upon receipt of completed and approved deliverables • Control project scope by taking ownership of functional requirements

Project Team Role	Responsibility
	<p>and schedule for implementing each requirement</p> <ul style="list-style-type: none"> • Determine active and timely participation of DPR staff and subject matter experts during life of the project • Assist in resolving or escalating significant issues related to project management, communication, staffing, and scope • Provide guidance to project manager and contract manager • Participate in final decisions on vendors and individuals retention • Facilitate change management process • Attend recurring steering committee meetings
4. Project Manager	<ul style="list-style-type: none"> • Coordinate with executive sponsors and registrant/applicant advisory group to manage their expectations, meet their needs, and ensure that stakeholder communications plan is properly executed • Conduct monthly project management team meetings to review the following topics: project status, changes, issues for resolution, bottlenecks, and risk avoidance actions • Regularly communicate project and issue status and provide updates to project sponsors, project director, program manager, and stakeholders • Prepare vendor procurement documents; facilitate development of PRDMS SLAs • Facilitate actions assigned to project management team • Coordinate and oversee day-to-day project activities; act as liaison to project teams • Develop/prepare the following deliverables: project charter, scope, budget, purchase orders, stakeholder communications plan, work breakdown structure, project schedule, relevant SIMM forms, and other project management-related deliverables • Maintain project work plan and institute controls to determine adherence to work plans and schedule • Determine problems, issues, and changes are recorded, maintained, and tracked in project's tracking database • Develop and execute risk management plan to mitigate risks • Manage and provide quality assurance • Plan, coordinate, and conduct regular team meetings to review performance indicators, identify bottlenecks, assign action items, and review action item status for each team • Report, at least monthly, the following topics to project sponsors, project director, and program manager: status of project management deliverables, project work items, performance indicators, bottlenecks, and bottleneck resolution actions • Assist program manager in resolving or escalating significant issues related to project management, communication, staffing, and scope • Facilitate change management process • Coordinate with technology infrastructure team to determine that project infrastructure and infrastructure services are planned, acquired, and made available on-time and as-needed • Determine project is completed within budget as identified in purchase

Project Team Role	Responsibility
	<p>orders, and review vendor invoices</p> <ul style="list-style-type: none"> • Attend recurring steering committee meetings
5. Registrant/ Applicant Advisory Group	<ul style="list-style-type: none"> • Consult on project goals, scope, strategies, and directives • Consult on critical project issues • Provide support to project activities affecting end-users, including SLAs, requirements verification, and change management activities • Support project by communicating DPR's vision and working to reduce barriers and mitigate risks for the registrant/applicant community, as applicable • Attend and constructively participate in registrant/applicant advisory group meetings
6. Technology Infrastructure Team	<ul style="list-style-type: none"> • Assist PRDMS project team, particularly during planning, analysis, and development activities • Coordinate and oversee procurement, setup, and operation of project's technical environment, including acquisition of hardware and applications • Support preparation of PRDMS SLAs for project infrastructure, infrastructure services, system interfaces, and transitioning of legacy system(s) • Participate in technical architecture design for system interfaces • Coordinate implementation of PRDMS technical architecture required for system interfaces • Attend and constructively participate in project management team meetings • Report status of team deliverables, team performance indicators, bottlenecks, and bottleneck resolution actions, including the following: <ul style="list-style-type: none"> ○ Unit, system, and integration tested network layer ○ Support operational project environment infrastructures (Servers, networks, software, etc.) ○ Operation and maintenance of development physical databases, as necessary ○ Infrastructure help desk environment (staffing and infrastructure) ○ Confirm technical architecture meets with DPR standards, and where applicable, state standards
7. Contract Manager	<ul style="list-style-type: none"> • Participate in procurement processes to secure systems development and integration vendor services • Maintain/manage contract documentation, contract change requests, and addendums • Determine that application licenses are in place when needed • Confirm that services are proceeding in accordance with contract timelines • Determine that products and services are in accordance with contract requirements and DPR standards; monitor contract to confirm compliance with contract provisions • Confirm that invoices reflect costs incurred to-date in performance of the agreement and that costs are within applicable restrictions; maintain information on contracted costs versus actual costs • Report status of project contractual documents, performance indicators, bottlenecks and bottleneck resolution actions for following deliverables:

Project Team Role	Responsibility
	<ul style="list-style-type: none"> ○ Contract Management Plan ○ Vendor contracts, purchase orders, and invoices ○ Application licenses
<p>8. Business/ Change Management Team</p>	<ul style="list-style-type: none"> • Coordinate with project managers; participate constructively in interviews and working sessions with PRDMS project team • Plan, track, and approve communication plan; work with stakeholders to determine communication between end-users, stakeholders, and project teams • Provide input to business needs, assessments, evaluations, and the final solution; participate in validating user documentation • Work with project managers to develop and implement an organizational change management program • Assist with validating requirements, and completing requirements decomposition and gap analysis; determine that business functional requirements of PRDMS SLAs and operating level agreements (OLAs) are met • Facilitate definition of current and future data elements, data relationships, and data definitions • Provide input into design and development of custom programs • Take ownership of project information system, determining that contents, inputs, and outputs (e.g., deliverable documents) are accurate, complete, and on-time • Facilitate agreed-upon data clean-up, transformation, and load activities with data owners of each legacy system to be converted • Identify changes to existing, and potentially new, policies and procedures • Participate in integration, system, and user acceptance testing • Provide input into project risk and issue efforts, and resolve as assigned; coordinate resolution of policy, standard, and procedure issues • Assess change readiness, monitor change impact and develop/execute mitigation strategies; execute appropriate implementation and roll out, "go-live" strategies • Execute training strategy for selected end-users; participate in user training and knowledge transfer activities • Take ownership of configuration management system determining that contents, inputs, and outputs (e.g., configuration item inventories and the sequence, and queuing work units for functional and technical teams) are accurate, complete, and on-time • Participate in transition to post-implementation support organization • Monitor impact of policy, standard, and procedure changes, and develop and execute mitigation strategies • Provide input into project risk and issue efforts, and resolve as assigned • Report status of team deliverables, team performance indicators, bottlenecks, and bottleneck resolution actions deliverables, such as: <ul style="list-style-type: none"> ○ Requirements specifications and traceability matrix ○ DPR policies and procedures mapped to requirements ○ Specifications of as-is and target (to-be) business processes, rules, setups, reports, user views, and workflows

Project Team Role	Responsibility
	<ul style="list-style-type: none"> ○ Business function and legacy system transition requirement sections of PRDMS SLAs ○ PRDMS user workflows and user profiles, privileges, permissions, and authorizations ○ Data clean-up plan and readiness assessment and data conversion plan, schedule, and resources ○ New business process documentation (e.g., procedures, business rules, use cases, and workflows) ○ User acceptance test scripts and test results ○ Functional help desk environment (staffing and infrastructure) ○ Functional user training materials and end-user training ○ Organizational change management plan, documentation, and processes ○ Communication plan, dispute resolution plan, implementation and training plans, transition plan, configuration management plan and processes, change management training materials
<p>9. Software Development and Implementation Team</p>	<ul style="list-style-type: none"> • Design and deliver system that meets all contract requirements • Adhere to vendor project plan schedule and communication plan schedule • Conduct detailed requirement confirmation sessions; assist with validating requirements, and completing requirements decomposition and gap analysis • Prepare presentation and applications system requirement sections of PRDMS SLAs and determine requirements are met • Determine technology architecture required for system interfaces and data exchange • Design and develop project environments, as defined by requirements, business needs, and DPR IT standards • Develop and administer PRDMS and configuration management system • Conduct unit and systems integration tests • Develop environment for user acceptance testing; oversee user acceptance testing • Coordinate with representatives from other internal and external systems to which PRDMS project will interface • Design, test, and document system interfaces • Participate in user training and knowledge transfer activities and transition to post-implementation support organization • Report status of team deliverables, team performance indicators, bottlenecks, and bottleneck resolution actions for deliverables, such as: <ul style="list-style-type: none"> ○ Conceptual and logical designs for project environments, as required ○ Capacity, scaling, and performance specifications for project environments ○ Applications instance management plan for project environments ○ Detailed project environments system designs, system design document ○ Systems maintenance plan ○ An operational configuration management system ○ Unit, system, and integration tested presentation, applications layers and test results ○ User acceptance testing environment

Project Team Role	Responsibility
	<ul style="list-style-type: none"> ○ Applications help desk environment (staffing and infrastructure) ○ Presentation and applications layer technical training materials, operational systems training
10. Data Management Team	<ul style="list-style-type: none"> • Confirm standards for unique identifiers of companies, products, and submissions • Prepare database requirements sections of PRDMS SLAs • Determine that database requirements of PRDMS SLAs are met • Define current and future data elements, data relationships, and data definitions • Conduct data model walkthrough sessions • Serve as a DPR resource to system development and implementation team • Report status of team deliverables, team performance indicators, bottlenecks, and bottleneck resolution actions for the following deliverables: <ul style="list-style-type: none"> ○ Data needs definition, data element dictionary, data mapping to current production data (as applicable) ○ System interface specifications, system interface fit / gap analysis ○ Integrated conceptual and logical data models, physical data model ○ Development, testing, and implementation of custom application programming interfaces (APIs) ○ Assist data conversion team in data loading and data conversion validation on all appropriate environments ○ Data conversion system and data conversion readiness assessment ○ Unit, system, and integration tested physical database ○ Database technical training materials ○ OLAs for backup and restore function
11. Document / Data Conversion Team	<ul style="list-style-type: none"> • Coordinate with project manager, data management team, and technology infrastructure team • Facilitate data clean-up plan and readiness assessment • Facilitate data conversion plan, schedule, and resources assistance • Cleaned-up data ready for transformation and loading to target system • Assist with data transformation and loading • Document data conversion processes
12. IPOC	<ul style="list-style-type: none"> • Review ongoing project processes, activities, and documentation to determine if the project is on schedule • Review and verify that project planning deliverables sufficiently meet project standards • Identify project risks • Monitor the risk management process • Report compliance with the appropriate project management practices • Develop Independent Project Oversight Reports (IPORs) • Report directly to the steering committee
13. IV&V	<ul style="list-style-type: none"> • Provide independent review and analysis of specific project activities and documentation related to the solution and requirements.

Project Team Role	Responsibility
	<ul style="list-style-type: none">• Monitor the requirements to ensure they meet the stated business need• Monitor the solution to ensure it meets the requirements• Review ongoing project processes and activities• Identify project risks related to the requirements and solution• Report on any other material findings, conclusions, and recommendations

Exhibit 6.2.3 PRDMS Project Gantt Chart

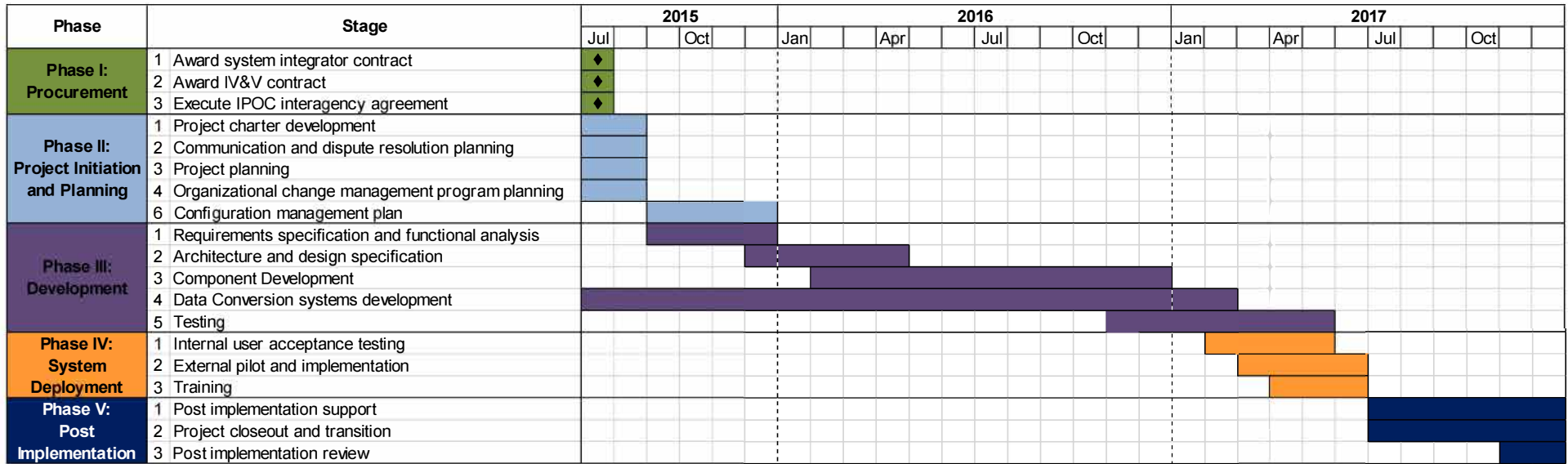


Exhibit 6.2.3 PRDMS Project Schedule

Phase/ Stage	Stage	Key Deliverables	Duration
Phase I: Vendor Procurements and Contract Approvals			
1	<ul style="list-style-type: none"> Award system integrator contract 	<ul style="list-style-type: none"> Vendor contract Contract Management Plan 	July 2015
2	<ul style="list-style-type: none"> Award IV&V contract 	<ul style="list-style-type: none"> Vendor contract 	July 2015
3	<ul style="list-style-type: none"> Submit service request to OTech for IPOC services 	<ul style="list-style-type: none"> OTech Service Request 	July 2015
Phase II: Project Initiation and Planning			
1	<ul style="list-style-type: none"> Project charter development 	<ul style="list-style-type: none"> Project charter and scope Governance structure and formal agreements Relevant SIMM forms 	July 2015 – Sep 2015
2	<ul style="list-style-type: none"> Communication and dispute resolution planning 	<ul style="list-style-type: none"> Communication plan Dispute resolution plan 	July 2015 – Sep 2015
3	<ul style="list-style-type: none"> Project planning 	<ul style="list-style-type: none"> Work Products <ul style="list-style-type: none"> Scope Management Plan Configuration Change Control Human Resource Plan Risk Management Plan Cost Management Plan Quality management Plan Schedule management Plan Procurement Plan Work Breakdown Structure Mobilized Project Team Refined Scope Statement with functional and technical requirements specifications Key Deliverables <ul style="list-style-type: none"> Project Management Plan Project Schedule Relevant SIMM forms 	July 2015 – Sep 2015
4	<ul style="list-style-type: none"> Organizational change management program planning 	<ul style="list-style-type: none"> Change management plan Management and Operations transition plan Communication and stakeholder enrollment plan 	July 2015 – Sep 2015

Phase/ Stage	Stage	Key Deliverables	Duration
5	<ul style="list-style-type: none"> Configuration management plan 	<ul style="list-style-type: none"> An operational configuration management plan 	Sept 2015 – Dec 2015
Phase III: Development			
1	<ul style="list-style-type: none"> Requirements specification and functional analysis 	<ul style="list-style-type: none"> Work products: <ul style="list-style-type: none"> Refined Process Models Confirmation Requirements Validation Requirements Mapping (and repository creation) Use Cases and Business Rule Documentation Story Boards and Mockups Conception and Logical Data Models JADs, Field Trips, Ad Hoc Meetings with SMEs Key Deliverables: <ul style="list-style-type: none"> Solutions Requirements Document 	Sep 2015 – Dec 2015
2	<ul style="list-style-type: none"> Architecture and design specification 	<ul style="list-style-type: none"> Work products: <ul style="list-style-type: none"> System Architecture Application Architecture Class Diagrams Sequence Diagrams Key Deliverables: <ul style="list-style-type: none"> Architectural Design Document Detailed Design Documents 	Dec 2015 – Apr 2016
3	<ul style="list-style-type: none"> Component development 	<ul style="list-style-type: none"> Work Products <ul style="list-style-type: none"> Application Tier: Workflow, Collaboration, Business Rules Integration Tier Data Tier Imaging/Document Storage Conversion Configuration/Customization Other Configuration Version Control Data Dictionary Key Deliverables: <ul style="list-style-type: none"> System Code and Configuration 	Feb 2015 – Dec 2016
4	<ul style="list-style-type: none"> Data conversion systems development 	<ul style="list-style-type: none"> Work Products: <ul style="list-style-type: none"> Data conversion plan, schedule, and 	Jul 2015 – Feb 2017

Phase/ Stage	Stage	Key Deliverables	Duration
	(as required)	<ul style="list-style-type: none"> resources Develop data conversion processes Unit, system, and integration tested data conversion Data clean-up plan and readiness assessment Data conversion readiness assessment Key Deliverables: <ul style="list-style-type: none"> Data Conversion Plan Data Conversion Code/Processes 	
5	<ul style="list-style-type: none"> Testing 	<ul style="list-style-type: none"> Work Products: <ul style="list-style-type: none"> System/Integration Master Scenarios System/Integration Test Scripts System/Integration Test Data Perform System/Integration Test and Log Issues Fix Issues, Unit Test, Deploy Fixes Track and Monitor Test Results Key Deliverables: <ul style="list-style-type: none"> Test Cases and Results 	Nov 2016 - May 2017
Phase IV: Implementation			
1	<ul style="list-style-type: none"> Internal User acceptance testing 	<ul style="list-style-type: none"> User acceptance test script User acceptance testing environment Unit, system, integration, and performance testing User acceptance testing User acceptance test results Final data conversion Production technology environment End-user systems training Operational systems training Updated documentation Change management program 	Feb 2017 – May 2017
2	<ul style="list-style-type: none"> External Pilot and implementation 	<ul style="list-style-type: none"> Transition and implementation plan Established release management processes Final pilot and implementation approach Help desk environment (e.g., staffing and infrastructure) 	Mar 2017 – June 2017

Phase/ Stage	Stage	Key Deliverables	Duration
		<ul style="list-style-type: none"> • Systems operations and maintenance manual • Backup and recovery procedures • Functional and technical training materials and sessions • Converted, loaded, and tested production data • Tuned and optimized presentation, application, database, and network layers • Tuned and optimized system interfaces • Application in full production • Change management program • Production deployed system 	
3	<ul style="list-style-type: none"> • Training 	<ul style="list-style-type: none"> • IT and program staff system administrator training • IT staff functionality and technical architecture training • Internal/external end user training 	Apr 2017 – June 2017
Phase V: Post Implementation			
1	<ul style="list-style-type: none"> • Post implementation support 	<ul style="list-style-type: none"> • Maintenance and operations structure in place • Ongoing support 	July 2017 – Dec 2017
2	<ul style="list-style-type: none"> • Project closeout and transition 	<ul style="list-style-type: none"> • Final system documentation • Business process changes assessment • Archived documents • Archived project information system • Archived configuration management system 	July 2017 – Dec 2017
3	<ul style="list-style-type: none"> • Post implementation review 	<ul style="list-style-type: none"> • Post implementation evaluation report (PIER) 	Nov 2017 – Dec 2017 ^A

^A The PIER shall be completed subsequent to one year of system implementation



Section 7.0

Risk Register

7.0 Risk Register

The DPR developed and will use a risk management plan to mitigate the risks involved with implementing the proposed Product Registration Data Management System (PRDMS), in compliance with the California Department of Technology's CA-PMM, as presented in SIMM Section 17.

The DPR is committed to the success of the PRDMS, which includes management, planning, and mitigating risks throughout the project lifecycle. The DPR's risk management plan provides a comprehensive framework for assessing each aspect of the project, identifying and assessing risks, and taking steps to reduce risks to an acceptable level, this includes avoiding or mitigating the risk, as appropriate. The remainder of this section presents the risk management plan.

Risk Management Plan

The PRDMS project team conducted multiple risk assessment sessions to identify and rank key project risks. The risk assessment is based on identification, analysis, quantification, and prioritization of the identified key project risks.

In preparation for the risk management plan, the team performed a complexity assessment to identify the complexity of the project, assessing the business complexity and technical complexity, based on rating the complexity of over 30 attributes. In sum, the team determined a low business complexity, medium technical complexity, and medium overall complexity. *Appendix A* provides the complexity assessment.

The risk management plan, on the following pages, lists the preliminary risks associated with the PRDMS project. As the project continues, project risks will be tracked in a database. PRDMS project managers will maintain the database of these and other risks for tracking, updating, and reporting.

The risk level for each of the identified risks is based on probability and impact of the risk, and the timing of the response to the particular risk. *Probability of Impact Scales* figures provide the rating assignment associated with the probability and impact of the risk. The evaluation also includes assessing the timing of the necessary risk management action. The timing of the risk management action fell into one of three categories: (1) within the next six months, (2) six months to a year from now, and (3) over a year from now.

Based on the probability, impact, and action timeline, an overall risk level is assigned. The overall risk level categories are low, medium, and high, based on a 25 point scale. A risk level under 10 points is low, 10 to 15 points is medium, and 16 to 25 points is high risk level.

The following process(es) will be used to identify risks:

The PRDMS project’s risk management approach is based on early detection, swift response, continuous monitoring, impact minimization, and thorough recovery. The PRDMS project management team plans to facilitate early detection by encouraging project team members and stakeholders to identify possible project risks, which are vulnerabilities that could be exploited by some circumstance or event. The project management team will empower team members and stakeholders to communicate identified potential project risks to the project team, throughout the project lifecycle. This will occur through formal mechanisms, such as risk assessment worksheets, project status meetings, risk assessment sessions, and informal mechanisms. The team will also review project documentation (e.g., project schedule and cost estimates) to identify potential risks. The project managers will document and evaluate each identified risk.

The process used to escalate risks beyond the PM’s level of authority is:

Working with executive sponsors, the project team will develop and maintain the risk management plan. The project team will perform risk analyses and prioritization of the risk(s), assigning a risk priority based on the impact and probability of occurrence. Project management will pay attention to risks with increasing risk priorities to determine the need for a response, including the amount of effort and type of action necessary to minimize the impact of each identified risk. The project managers will update the executive sponsors and key stakeholders, as appropriate. The assigned risk priority level and associated risk area will help the project team determine the appropriate “owner” of the risk. The owner will implement an appropriate planned response to the risk, reporting the effectiveness of the planned response to the project managers. Project managers will determine whether further action is necessary.

Definition of Probability and Impact Scales

Instructions: Assess the probability and the impact of potential risk items, and develop a response strategy for risks rated High and, where feasible or appropriate, for other risks rated Medium or Low.

Rating	Probability
1	• Unlikely/Highly Unlikely (<20%)
2	• Modest/Doubtful (21 – 40%)
3	• Moderate (41 – 60%)
4	• Likely/Probable (61 – 80%)
5	• Highly Likely/Certain (>81%)

Rating	Potential Impact
1	• <5% change to schedule, scope, budget, or quality
2	• 5 -10% change to schedule, scope, budget, or quality
3	• 11 - 15% change to schedule, scope, budget, or quality
4	• 16 - 24% change to schedule, scope, budget, or quality
5	• 25% or more change to schedule, scope, budget, or quality

Risk Register

Instructions: Consider each potential risk and quantify the risk level. Use the definitions in the student notebook for clarity. Add other constraints and obstacles to the list as you identify them.

* 1-9 = Low Risk Level, 10-15 = Medium Risk Level, 16-25 = High Risk Level

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
1	Audit and Control Needs	2	2	Over a year from now	1.32 Green	Insufficient/ weak project management, management and development processes, quality control	Potential impact to project budget, schedule, and quality	Implement and maintain project management and quality assurance leading practices; incorporate formal review checkpoints into project plan/schedule; build time into schedule to accommodate internal audit and control mechanisms; perform external audits	Implement audit recommendation immediately; perform root cause analysis; implement steps to avoid recurrence; revalidate existing audit processes and determine areas that may need additional modification
2	Budget	2	5	Within the next six months	10 Yellow	Insufficient funding budget; unexpected budget cuts and contract freezes, actual costs exceed budgeted costs; new or additional requirements or change orders	Potential impact to project budget, schedule, and quality	Ensure business case accuracy; budget request covers anticipated project costs; work with internal/external stakeholders for project support	Monitor project spending; review project schedule, scope, and key project metrics; reconfirm project priority with sponsors; identify project adjustments needed; break project out into phases so a smaller portion of project functionality can be delivered with impacted budget

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
3	Client/Server Architecture	2	5	Over a year from now	3.3 Green	IT project team unfamiliarity with architecture; appropriate support staff not receiving adequate knowledge transfer; inadequate training	Potential impact to project budget, schedule, and quality	Provide training for new architecture and technologies to be used on project; embed IT project team into vendor team, IT project team ownership of portions of system development; schedule weekly knowledge transfer (instead of all at end)	Ensure IT staffing involvement in review and development of technical specifications and design; provide remedial training; perform root cause analysis
4	Customer Sophistication	2	4	Over a year from now	2.64 Green	Appropriate stakeholder and/or SMEs not involved in project, inadequate training, difficult to use software product, inconsistency in end user experience	Potential impact to project budget, schedule, and quality	Provide outreach and training and solicit input throughout project lifecycle; consider ramifications of user interface during system development; promote consistency in design amongst multiple teams and developers; create acceptable graphical user interface (GUI) standards with vendors	Review GUI standards; executive sponsorship to reinforce project goals with stakeholders/SMEs; determine source of lack of involvement, and remedy

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
5	Design and Implementation	2	5	Over a year from now	3.3 Green	Overly complicated design and large amount of custom development increases number of failure points in the design; flawed system design; poor system documentation; inability to make business decisions that impact the software development life cycle; component and/or data conversion issues	Potential impact to project budget, schedule, and quality	Ensure business processes are clear to the design and development team; clearly document business rules that allow for clarification and modification as well as change control through the SDLC; ensure IT project team involvement in design and implementation; promote questions and alternative solutions	Simplify design; consider possible process over automation, can the user be more involved in the process; correct documentation and seek alternative designs
6	Development Environment	2	5	Over a year from now	3.3 Green	Improper or delayed environment; poor performance of development/test environment; tools do not work as expected; unfamiliarity with tools	Potential impact to project budget, schedule, and quality	Validate development environment requirements with system integrator; perform training on required tools (SDE, RDP, etc.); Establish environments ahead of time; consider asking vendor to create pre-development environment	Immediately focus on establishing environments; identify and eliminate any roadblocks preventing progress; consider alternatives including cloud based solutions

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
7	External Environment	2	4	Within the next six months	8 Green	Untimely project approvals (e.g., FSR, BCP, RFP); lack of registrant involvement/input into the project	Potential impact to project budget, schedule, and quality	Work closely with external organizations to identify any potential issues ahead of time; develop Registrant Advisory Group early on in the project and ensure project involvement; work with Registrant Advisory Group to develop and test interfaces	Escalate issue(s) as appropriate; determine reason for non-approval and resolve issue(s); create more open channel of communication with Registrant Advisory Group and other external organizations
8	Facilities	1	2	Six months to a year from now	1.32 Green	Unavailable or insufficient facility availability (e.g., workspace, work environment, storage, telecommunications); inability to support remote access and lack of access to software tools need for design and development	Potential impact to project budget, schedule, and quality	Determine facility space required early on in project; provide alternative work arrangements; test facilities prior to staff arrival	House staff in different locations and implement an effective communication strategy; conduct regular project team meetings; provide virtual work environment

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
9	Human Resources: Skills, Availability	2	5	Six months to a year from now	6.6 Green	Insufficient staffing; inappropriate or unskilled/unqualified staffing; unavailable management oversight	Potential impact to project budget, schedule, and quality	Continually review schedule to ensure resource requirements and skill sets are meeting required timeline and quality requirements; evaluate quality of product to ensure team members have required skills and are meeting expectations; provide training before project starts	Document staffing gaps and secure approval to address them; obtain external support
10	Infrastructure	1	4	Over a year from now	1.32 Green	Incompatible or insufficient existing infrastructure; inability to get required hardware/software for project staff, slow or poor network connectivity	Potential impact to project budget, schedule, and quality	Include details about existing infrastructure in the RFP; require vendor to identify needed changes/upgrades	Provide for any necessary infrastructure changes/upgrades in project plan/budget; monitor to ensure timely implementation of changes/upgrades
11	Legislation	1	4	Over a year from now	1.32 Green	Legislative impacts to business requirements or project support	Potential impact to project budget and schedule	Obtain legislative sponsorship/support prior to project initiation; review any potential legislation, addressing any possible concerns	Secure approval to implement new/future legislative requirements as an enhancement, post implementation

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
12	Litigation	1	5	Over a year from now	1.65 Green	Contractor performance issues; AB 906 union disputes; award protests; special interest group lawsuits (e.g., growers, pesticide producers)	Potential impact to project budget and schedule	Ensure contract is sound and enforceable; implement sound contract management processes; establish an escrow account to hold source code on the State's behalf	Engage DPR legal, DGS, CalTech, and other appropriate agencies; secure source code and system documentation; develop plan to continue project w/in-house staff or another vendor, if necessary
13	Management Processes	1	4	Within the next six months	4.0 Green	Inefficient or unfollowed project management processes and plans; lack of approved project management plan; inefficient project organization and responsibilities; untimely or inconsistent decisions, approvals, and/or feedback	Potential impact to project budget, schedule, and quality	Recruit experienced PM; adopt and use CA-PMM processes; obtain agreement on PM decision-making authority and autonomy; work closely with project Director and Executives to ensure charter and project management plan support the project goals and are signed off	Identify root cause and determine need for change to management process; modify management process and receive sign off, as appropriate
14	Other Projects	2	4	Six months to a year from now	5.28 Green	Conflicting resource priorities with other projects; project success dependent on other projects	Potential impact to project budget and schedule	Confirm project's priority in relation to other projects; secure dedicated project resources; build project plan to take into account potential impacts of other projects	Ensure project plan/schedule considers impacts of other projects and availability of resources; monitor and adjust schedule as necessary

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
15	Paradigm Shift / Change Management	2	5	Over a year from now	3.3 Green	Stakeholder resistant to change; ineffective change management or lack of change management plan; unrealistic level of change expected	Potential impact to project budget and schedule	Ensure project scope is clearly communicated to all stakeholders; develop an approach to obtain feedback throughout project; manage expectations; demonstrate incremental results	Review project deliverables w/users at key milestones to ensure expectations are being met; hold focus groups to address issues and concerns
16	Regulations	1	4	Over a year from now	1.32 Green	Changes to current regulation or additional regulations may impact project/solution and introduce new requirements	Potential impact to project budget and schedule	Work with sponsor to defer any regulatory changes until after project is implemented	Determine impact of change(s) and develop plan to minimize impacts
17	Requirements Management	3	5	Six months to a year from now	9.9 Green	Requirements not captured or incorrectly captured; lack of updates to requirements after refinements or clarifications; requirements not properly managed, leading to scope creep; lack of change control process	Potential impact to project budget and schedule	Obtain project scope/requirements signoff; develop requirements traceability matrix; implement change management process; require sponsor approval for changes with schedule or cost impact	Evaluate impact of change and determine if corrective action is required, modify change control process as needed; defer requirement change until after implementation

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
18	Schedule	3	4	Six months to a year from now	7.92 Green	Arbitrary/unrealistic estimates; unaccounted tasks; resources unavailable or insufficient; lack of resource knowledge and/or inability to complete assigned tasks; lacking project management or scope creep	Potential impact to project budget, schedule, and quality	Perform bottom up analysis to determine if plan timeline matches resource/ budget/schedule commitments; perform implementation in smaller phases; ensure contingency covers risk	Maintain project schedule; review project progress against schedule; timely communicate schedule risks; evaluate options to adjust schedule based on budget/time/ quality/scope parameters
19	Sponsorship Commitment	1	5	Over a year from now	1.65 Green	Lack of commitment and/or demonstrated involvement in project cause; change in priorities; outside political influence; change in leadership	Potential impact to project budget and schedule	Confirm project's priority; reach consensus on sponsor roles and responsibilities; emphasize project benefits; communicate project status frequently	Establish sponsor expectations; obtain signoff on commitments; meet w/sponsor to understand reason for lack of interest, make adjustments as needed
20	Structure of Installed Systems	2	3	Over a year from now	1.98 Green	Difficulty or inability to interface with other installed systems; lack of understanding of functionality of existing systems; lack of change control and/or documentation in legacy applications	Potential impact to project budget, schedule, and quality	Determine openness of systems prior to vendor onboarding, asking vendors for experience interfacing with legacy systems as part of the RFP; retrieve legacy system documentation	Evaluate alternatives to real time interface (batching, FTP, etc.); consider manual alternatives; bring in expert interface skill sets

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
21	Supplier/Vendor Capability/ Capacity	2	5	Over a year from now	3.3 Green	Inadequate vendor performance; inadequate vendor resources; product not meeting requirements	Potential impact to project budget, schedule, and quality	Clearly document expectations in the solicitation document; formalize deliverables expectation document (DED) process; work with vendor to develop DEDs; include penalties in the contract for poor performance and clear criteria for leveraging penalties; develop issue escalation process	Identify root cause of poor performance; work with vendor executives to resolve issues; engage DPR OLA, DGS, and CalTech, as needed
22	System Architecture	1	5	Over a year from now	1.65 Green	Integration issues; system architecture overly complicated for required functionality; system architecture not sound/stable	Potential impact to project budget, schedule, and quality	Use solution-based procurement model and compensate based on sound and stable system; define system performance technical requirements up front; clearly define criteria for performance testing and begin early; review system architecture with internal IT project team; request alternative analysis of system architecture	Implement alternative architecture; considering bringing in expert skill sets to evaluate architecture

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
23	Technology	1	5	Over a year from now	1.65 Green	Technology unavailable; available technology unstable; technology unsuitable/inappropriate; technology obsolete; technology unable to meet performance needs	Potential impact to project budget, schedule, and quality	Ask vendors to provide workable alternatives; consider modifying business process to incorporate workaround for unavailable/underdeveloped technologies; analyze alternatives solutions	Select alternative solution; modify business process
24	Turnover	4	5	Over a year from now	6.6 Green	Staff turnover; delays to bring new staff up to speed; unable to obtain appropriate staff (e.g., skill level, software/programming/architecture knowledge); institutional knowledge loss	Potential impact to project budget, schedule, and quality	Clearly define roles, responsibilities, and skill levels; develop cross training plan and cross train staff prior to staffing turnover; identify backup or alternative staff; manage succession planning and knowledge transfer; maintain thorough documentation to get staff up to speed quickly	Assess existing staff workload and adjust as needed; work with project executive/sponsor to secure new resources, if necessary; review and update documentation as necessary
25	Security	2	4	Over a year from now	2.64 Green	Security breach; implications during external user testing; security implications for confidential registrant, product, and other critical information	Potential impact to project budget, schedule, and quality	Ensure clearly defined and communicated security requirements; select solution that has built in security versus designing a brand new security infrastructure; ensure project plan includes security testing; conduct validation testing for security provisions/features	Lock off system until root cause of security breach is identified and fixed; set up tighter tolerances; exclude suspicious or non-approved IP addresses at firewall

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
26	System Performance	3	3	Over a year from now	2.97 Green	Overly complicated application design; poor database design; poor coding practices; slow or overtaxed hardware; over-reliance on front end logic; run-away processes; poor infrastructure	Potential impact to project budget, schedule, and quality	Identify required best practices; allow time for code review and logic discussions; determine skill sets required for front end, business tier, and database tier; provide developers with adequate and realistic test data; provide guidelines for performance on longer, more complicated transactions	Review poor performance and determine alternatives; consider modifications to business processes, alleviating poor performing areas; determine root cause for poor performance and remedy via hardware, software, or business change
27	Relational Data Concerns	3	3	Over a year from now	2.97 Green	Business users inability to decide who owns data; end-user inability to work with or learn child/parent relationship patterns; difficulty understand new security paradigm	Potential impact to project budget, schedule, and quality	Provide users with training on new relationships between data; restrict user access by role; support data sharing so users and teams can be granted access to records they do not normally own (i.e., collaborative work effort)	Provide one-on-one training for users struggling to adapt; create list of frequently asked questions for user reference; create coaches or expert users to support system users

#	Risks	Probability (1 - 5)	Potential Impact (1 -5)	Risk Management Action must begin...	Risk Level* (1-25)	Cause	Consequences	Avoidance Plan	Mitigation Plan
28	Data Exchange Standards	3	3	Over a year from now	2.97 Green	Identify a standard for data exchange; develop new standard for data exchange with help from industry	Potential impact to project budget, schedule, and quality	Identify existing standards for data exchange specific to industry and determine if these will meet needs; work with vendor and Registrant Advisory Group to determine viable automated data exchange standard; ensure project standard aligns with existing project data model	Consider supporting only online applications until standard can be completed and implemented in the system

The plans for monitoring the high and medium level risks are:

Risk identification and monitoring will occur throughout the project lifecycle. The project manager will develop and maintain the Risk Management Plan, periodically revisiting the assumptions and premises of each risk to determine the continued validity. The team will determine changes that may affect the nature or impact of the risk, as the risk may change sufficiently so that the current mitigation strategy is ineffective and a new approach is needed. The project team may also determine that a risk may be reduced and no longer need the same level of resources. Throughout the project lifecycle, the team may identify new risks or modify existing risks.

The approach to measuring the effectiveness of the plan is:

The project team will continuously maintain the risk management plan, identifying and tracking issues that arise throughout the project lifecycle. The project team will monitor and document the risk response activities. The project team will compare actual outcomes to expected outcomes, evaluating whether the actions actually achieved the intended objective, and the reasons for the differences. The team may also employ tools such as stakeholder surveys and external reviews to evaluate the effectiveness of the plans. These tools will aid in developing subsequent risk management alternatives and more effective risk management decisions for future issues that arise in the current project as well as future projects.



Section 8.0

Economic Analysis Worksheets (EAWS)

8.0 Economic Analysis Worksheets (EAWs)

The Economic Analysis Worksheets (EAWs) included in this section provide a comparative analysis of the costs associated with the PRDMS alternatives that satisfy the project objectives contained in Section 3 and the requirements presented in Section 9. The two alternatives evaluated were the custom developed solution (the proposed alternative) and the commercial-off-the-shelf solutions (alternative)e

All costs present the full implementation cost plus one year of maintenance in order to reflect estimated ongoing maintenance and operations costs and establish the ongoing PRDMS baseline support costs.

8.1 Existing System Cost Worksheet

The existing system cost worksheet documents the cost of the existing program and systems if the proposed solution were not implemented. The represents the baseline cost.

Figure 8-1 Existing System Cost Worksheet

SIMM 20C30C, Rev. 03/2011 EXISTING SYSTEM/BASELINE COST WORKSHEET
 Department of Pesticide Regulation (DPR) All costs to be shown in whole (unrounded) dollars. 10/1/2014
 Pesticide Registration Data Management System (PRDMS)

	FY 2015/16		FY 2016/17		FY 2017/18		FY 2018/19		TOTAL	
	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts
Continuing Information										
Technology Costs										
Staff (salaries & benefits)	0.7	81,491	0.7	81,491	0.0	0	0.0	0	1.4	162,983
Hardware Lease/Maintenance		0		0		0		0		0
Software Maintenance/Licenses		0		0		0		0		0
Contract Services		0		0		0		0		0
Data Center Services		0		0		0		0		0
Agency Facilities		0		0		0		0		0
Other		14,700		14,700		0		0	0	29,400
Total IT Costs	0.7	96,191	0.7	96,191	0.0	0	0.0	0	1.4	192,383
Continuing Program Costs:										
Staff	125.0	13,017,383	125.0	13,017,383	125.0	13,017,383	125.0	13,017,383	500.0	52,069,530
Other		2,625,000		2,625,000		2,625,000		2,625,000		10,500,000
Total Program Costs	125.0	15,642,383	125.0	15,642,383	125.0	15,642,383	125.0	15,642,383	500.0	62,569,530
TOTAL EXISTING SYSTEM COSTS	125.7	15,738,574	125.7	15,738,574	125.0	15,642,383	125.0	15,642,383	501.4	62,761,913

8.2 Proposed Alternative Cost Worksheet – Custom Developed

The proposed alternative cost worksheet documents the projected one-time costs and continuing costs for the chosen alternative. The following information influenced this alternative's costs:

- DPR anticipates a July 1, 2015 start date.
- Hardware Costs are for six application and four database servers.
- Software Purchase/License includes costs for database, workflow components, and development/configuration software.
- Telecommunications costs are for an 800 line and Basic Agent call functionality to manage phone contacts.
- Software Customization includes all configuration services, project management, conversion, documentation, training, and change management activities.
- Project Oversight is for CalTech project oversight at \$9,380 per month.
- IV&V Services are a separate contract for IV&V activities.
- Other covers Operating Expenses and Equipment (OE&E) for DPR PYs.
- The Contract Services costs shown in 2017/18 under Continuing IT Project Costs are for six months of post-implementation support.
- DPR anticipates the proposed alternative will take 24 months to implement. As implementation costs are distributed across the 2015/16 and 2016/17 fiscal years.
- 2018/19 represents the first full year of maintenance costs without any one-time costs.
- The Data Center costs assume the solution will be hosted by the State data center in the OTech Tenant Managed Services.

Figure 8-2 Proposed Alternative Cost Worksheet

SIMM 20C30C, Rev. 03/2011

PROPOSED ALTERNATIVE: Custom Developed Solution

10/1/2014

Department of Pesticide Regulation (DPR) All Costs Should be shown in whole (unrounded) dollars.
Pesticide Registration Data Management System (PRDMS)

	FY 2015/16		FY 2016/17		FY 2017/18		FY 2018/19		TOTAL	
	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts
One-Time IT Project Costs										
Staff (Salaries & Benefits)	5.1	574,631	5.1	574,631	0.0	0	0.0	0	10.2	1,149,262
Hardware Purchase		0		0		0		0		0
Software Purchase/License		123,000		123,000		0		0		246,000
Telecommunications		1,271		4,751		0		0		6,022
Contract Services		0		0		0		0		0
Software Customization		1,455,736		1,455,736		0		0		2,911,473
Project Management		0		0		0		0		0
Project Oversight		112,560		112,560		0		0		225,120
IV&V Services		265,000		265,000		0		0		530,000
Other Contract Services		0		0		0		0		0
TOTAL Contract Services		1,833,296		1,833,296		0		0		3,666,593
Data Center Services		0		0		0		0		0
Agency Facilities		0		0		0		0		0
Other		107,100		107,100		0		0		214,200
Total One-time IT Costs	5.1	2,639,298	5.1	2,642,778	0.0	0	0.0	0	10.2	5,282,076
Continuing IT Project Costs										
Staff (Salaries & Benefits)	0.0	0	0.0	0	0.7	81,491	0.7	81,491	1.4	162,983
Hardware Lease/Maintenance		0		0		0		0		0
Software Maintenance/Licenses		0		0		159,500		159,500		319,000
Telecommunications		0		0		3,480		3,480		6,960
Contract Services		0		0		237,485		0		237,485
Data Center Services		0		0		0		0		0
Agency Facilities		0		0		0		0		0
Other		0		0		14,700		14,700		29,400
Total Continuing IT Costs	0.0	0	0.0	0	0.7	496,656	0.7	259,171	1.4	755,828
Total Project Costs	5.1	2,639,298	5.1	2,642,778	0.7	496,656	0.7	259,171	11.6	6,037,904
Continuing Existing Costs										
Information Technology Staff	0.7	81,491	0.7	81,491	0.0	0	0.0	0	1.4	162,983
Other IT Costs		14,700		14,700		0		0		29,400
Total Continuing Existing IT Costs	0.7	96,191	0.7	96,191	0.0	0	0.0	0	1.4	192,383
Program Staff	125.0	13,017,383	125.0	13,017,383	125.0	13,017,383	125.0	13,017,383	500.0	52,069,530
Other Program Costs		2,625,000		2,625,000		2,625,000		2,625,000		10,500,000
Total Continuing Existing Program Costs	125.0	15,642,383	125.0	15,642,383	125.0	15,642,383	125.0	15,642,383	500.0	62,569,530
Total Continuing Existing Costs	125.7	15,738,574	125.7	15,738,574	125.0	15,642,383	125.0	15,642,383	501.4	62,761,913
TOTAL ALTERNATIVE COSTS	130.8	18,377,872	130.8	18,381,352	125.7	16,139,039	125.7	15,901,554	513.0	68,799,817
INCREASED REVENUES		0		0		0		0		0

8.3 Alternative Cost Worksheet – COTS

The alternative cost worksheet documents the projected one-time costs and continuing costs for the alternative that met the objectives and satisfied the system requirements. The following information influenced this alternative's costs:

- DPR anticipates a July 1, 2015 start date.
- Hardware Costs are for six application and four database servers.
- Software Purchase/License includes costs for database, workflow components, and development/configuration software.
- Telecommunications costs are for an 800 line and Basic Agent call functionality to manage phone contacts.
- Software Customization includes all configuration services, project management, conversion, documentation, training, and change management activities.
- Project Oversight is for CalTech project oversight at \$9,380 per month.
- IV&V Services are a separate contract for IV&V activities.
- Other covers Operating Expenses and Equipment (OE&E) for DPR PYs.
- The Contract Services costs shown in 2017/18 under Continuing IT Project Costs are for six months of post-implementation support.
- DPR anticipates the proposed alternative will take 24 months to implement. As implementation costs are distributed across the 2015/16 and 2016/17 fiscal years.
- 2018/19 represents the first full year of maintenance costs without any one-time costs.
- The Data Center costs assume the solution will be hosted by the State data center in the OTech Tenant Managed Services.

Figure 8-3 Alternative Cost Worksheet

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ALTERNATIVE #1: Commercial Off the Shelf

10/1/2014

Department of Pesticide Regulation (DPR)

All Costs Should be shown in whole (unrounded) dollars.

Pesticide Registration Data Management System (PRDMS)

	FY 2015/16		FY 2016/17		FY 2017/18		FY 2018/19		TOTAL	
	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts
One-Time IT Project Costs										
Staff (Salaries & Benefits)	5.1	568,699	5.1	568,699	0.0	0	0.0	0	10.1	1,137,397
Hardware Purchase		0		0		0		0		0
Software Purchase/License		21,375		21,375		0		0		42,750
Telecommunications		1,271		4,751		0		0		6,022
Contract Services		0		0		0		0		0
Software Customization		2,068,333		2,068,333		0		0		4,136,667
Project Management		0		0		0		0		0
Project Oversight		112,560		112,560		0		0		225,120
IV&V Services		320,000		320,000		0		0		640,000
Other Contract Services		0		0		0		0		0
TOTAL Contract Services		2,500,893		2,500,893		0		0		5,001,787
Data Center Services		0		0		0		0		0
Agency Facilities		0		0		0		0		0
Other		106,050		106,050		0		0		212,100
Total One-time IT Costs	5.1	3,198,288	5.1	3,201,768	0.0	0	0.0	0	10.1	6,400,056
Continuing IT Project Costs										
Staff (Salaries & Benefits)	0.0	0	0.0	0	0.7	81,491	0.7	81,491	1.4	162,983
Hardware Lease/Maintenance		0		0		0		0		0
Software Maintenance/Licenses		0		0		319,800		319,800		639,600
Telecommunications		0		0		3,480		3,480		6,960
Contract Services		0		0		314,496		0		314,496
Data Center Services		0		0		0		0		0
Agency Facilities		0		0		0		0		0
Other		0		0		14,700		14,700		29,400
Total Continuing IT Costs	0.0	0	0.0	0	0.7	733,967	0.7	419,471	1.4	1,153,439
Total Project Costs	5.1	3,198,288	5.1	3,201,768	0.7	733,967	0.7	419,471	11.5	7,553,495
Continuing Existing Costs										
Information Technology Staff	0.7	81,491	0.7	81,491	0.0	0	0.0	0	1.4	162,983
Other IT Costs		14,700		14,700		0		0		29,400
Total Continuing Existing IT Costs	0.7	96,191	0.7	96,191	0.0	0	0.0	0	1.4	192,383
Program Staff	125.0	13,017,383	125.0	13,017,383	125.0	13,017,383	125.0	13,017,383	500.0	52,069,530
Other Program Costs		2,625,000		2,625,000		2,625,000		2,625,000		10,500,000
Total Continuing Existing Program Costs	125.0	15,642,383	125.0	15,642,383	125.0	15,642,383	125.0	15,642,383	500.0	62,569,530
Total Continuing Existing Costs	125.7	15,738,574	125.7	15,738,574	125.0	15,642,383	125.0	15,642,383	501.4	62,761,913
TOTAL ALTERNATIVE COSTS	130.8	18,936,862	130.8	18,940,342	125.7	16,376,350	125.7	16,061,854	512.9	70,315,408
INCREASED REVENUES		0		0		0		0		0

8.4 Economic Analysis Summary

The Economic Analysis Summary compares the estimated costs of the proposed alternative, other alternative meeting the objectives and functional requirements, and the existing system.

Figure 8-4 Economic Analysis Summary

SI MM 20C30C, Rev. 03/2011

ECONOMIC ANALYSIS SUMMARY

10/1/2014

Department of Pesticide Regulation (DPR)

All costs to be shown in whole (unrounded) dollars.

Pesticide Registration Data Management System (PRDMS)

	FY 2015/16		FY 2016/17		FY 2017/18		FY 2018/19		TOTAL	
	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts
EXISTING SYSTEM										
Total IT Costs	0.7	96,191	0.7	96,191	0.0	0	0.0	0	1.4	192,383
Total Program Costs	125.0	15,642,383	125.0	15,642,383	125.0	15,642,383	125.0	15,642,383	500.0	62,569,530
Total Existing System Costs	125.7	15,738,574	125.7	15,738,574	125.0	15,642,383	125.0	15,642,383	501.4	62,761,913
PROPOSED ALTERNATIVE										
Custom Developed Solution										
Total Project Costs	5.1	2,639,298	5.1	2,642,778	0.7	496,656	0.7	259,171	11.6	6,037,904
Total Cont. Exist. Costs	125.7	15,738,574	125.7	15,738,574	125.0	15,642,383	125.0	15,642,383	501.4	62,761,913
Total Alternative Costs	130.8	18,377,872	130.8	18,381,352	125.7	16,139,039	125.7	15,901,554	513.0	68,799,817
COST SAVINGS/AVOIDANCES	(5.1)	(2,639,298)	(5.1)	(2,642,778)	(0.7)	(496,656)	(0.7)	(259,171)	(11.6)	(6,037,904)
Increased Revenues		0		0		0		0		0
Net (Cost) or Benefit	(5.1)	(2,639,298)	(5.1)	(2,642,778)	(0.7)	(496,656)	(0.7)	(259,171)	(11.6)	(6,037,904)
Cum. Net (Cost) or Benefit	(5.1)	(2,639,298)	(10.2)	(5,282,076)	(10.9)	(5,778,733)	(11.6)	(6,037,904)		
ALTERNATIVE #1										
Commercial Off the Shelf										
Total Project Costs	5.1	3,198,288	5.1	3,201,768	0.7	733,967	0.7	419,471	11.5	7,553,495
Total Cont. Exist. Costs	125.7	15,738,574	125.7	15,738,574	125.0	15,642,383	125.0	15,642,383	501.4	62,761,913
Total Alternative Costs	130.8	18,936,862	130.8	18,940,342	125.7	16,376,350	125.7	16,061,854	512.9	70,315,408
COST SAVINGS/AVOIDANCES	(5.1)	(3,198,288)	(5.1)	(3,201,768)	(0.7)	(733,967)	(0.7)	(419,471)	(11.5)	(7,553,495)
Increased Revenues		0		0		0		0		0
Net (Cost) or Benefit	(5.1)	(3,198,288)	(5.1)	(3,201,768)	(0.7)	(733,967)	(0.7)	(419,471)	(11.5)	(7,553,495)
Cum. Net (Cost) or Benefit	(5.1)	(3,198,288)	(10.1)	(6,400,056)	(10.8)	(7,134,023)	(11.5)	(7,553,495)		

8.5 Project Funding Plan

DPR plans to fund the PRDMS project out of the DPR Fund. The DPR Fund is a special fund fed by three primary sources: annual certificates of product registration, pesticide-related business licenses, and a mill assessment collected on state pesticide sales. DPR plans to submit a BCP in fall 2014 to obtain the funds beginning July 1, 2015 to coincide with project initiation.

Figure 8-5 Project Funding Plan

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Department of Pesticide Regulation (DPR)

Pesticide Registration Data Management System (PRDMS)

PROJECT FUNDING PLAN

All Costs to be in whole (unrounded) dollars

10/1/2014

	FY 2015/16		FY 2016/17		FY 2017/18		FY 2018/19		TOTALS	
	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts
TOTAL PROJECT COSTS	5.1	2,639,298	5.1	2,642,778	0.7	496,656	0.7	259,171	11.6	6,037,904
RESOURCES TO BE REDIRECTED										
Staff	5.1	681,731	5.1	681,731	0.7	96,191	0.7	96,191	11.6	1,555,844
Funds:										
Existing System		0		0		0		0		0
Other Fund Sources		0		0		0		0		0
TOTAL REDIRECTED RESOURCES	5.1	681,731	5.1	681,731	0.7	96,191	0.7	96,191	11.6	1,555,844
ADDITIONAL PROJECT FUNDING NEEDED										
One-Time Project Costs	0.0	1,957,567	0.0	1,961,047	0.0	0	0.0	0	0.0	3,918,615
Continuing Project Costs	0.0		0.0		0.0	400,465	0.0	162,980	0.0	563,445
TOTAL ADDITIONAL PROJECT FUNDS NEEDED BY FISCAL YEAR	0.0	1,957,567	0.0	1,961,047	0.0	400,465	0.0	162,980	0.0	4,482,060
TOTAL PROJECT FUNDING	5.1	2,639,298	5.1	2,642,778	0.7	496,656	0.7	259,171	11.6	6,037,904
Difference: Funding - Costs	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
Total Estimated Cost Savings	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
FUNDING SOURCE*										
General Fund	0%	0	0%	0	0%	0	0%	0	0%	0
Federal Fund	0%	0	0%	0	0%	0	0%	0	0%	0
Special Fund	100%	2,639,298	100%	2,642,778	100%	496,656	100%	259,171	100%	6,037,904
Reimbursement	0%	0	0%	0	0%	0	0%	0	0%	0
TOTAL FUNDING	100%	2,639,298	100%	2,642,778	100%	496,656	100%	259,171	100%	6,037,904



Section 9.0
Requirements

9.0 Business Requirements

This section presents the business requirements, and key functional and technical requirements of the proposed solution, the Product Registration Data Management System (PRDMS). The project team, along with the collaborative efforts of numerous DPR managers and staff, developed functional requirements for the proposed solution that are driven by the business problems and needs identified in **Section 3, Business Analysis** (Section 3.2). Most functional requirements are relevant to more than one project goal or opportunity for improvement. Collectively, these functional requirements define the functional aspects for the proposed, new solution.

Exhibit 9.0, on the following pages, presents a compilation of business, functional, and technical requirements for the PRDMS. The business objectives, primarily supported by each functional requirement, are identified in the exhibit.

Exhibit 9.0 Requirements

ID	Requirement
Business Requirement and Associated Functional Requirement(s)	
BR1	DPR shall accept electronic submissions for pesticide product/device registration
FR1.1	The system shall accept electronic applications through internet/intranet
FR1.2	The system shall accept product label information
FR1.3	The system shall accept electronic product labels (master, market, EPA approved)
FR1.4	The system shall accept data study information
FR1.5	The system shall accept electronic data studies
FR1.6	The system shall accept electronic data interface (EDI) for transmission of data and information
FR1.7	The system shall accept electronic Confidential Statements of Formula
FR1.8	The system shall accept supporting registration documentation
FR1.9	The system shall have the ability to store and retrieve electronic documents
BR2	DPR shall accept only valid and complete submissions and renewals
FR2.1	The system shall validate information upon entry
FR2.2	The system shall check for completeness
FR2.3	The system shall check for accuracy
BR3	DPR shall maintain registrant information
FR3.1	The system shall provide the ability to enter and maintain registrant information and account status
FR3.2	The system shall capture type of registrant and applicant (i.e., applicant, manufacturer, distributor, consultants, international representative)
FR3.3	The system shall provide the ability to capture multiple contacts for a single registrant
FR3.4	The system shall provide ability to identify all products associated with a registrant
FR3.5	The system shall notify DPR staff of necessary account management activities
FR3.6	The system shall provide address verification

ID	Requirement
Business Requirement and Associated Functional Requirement(s) <i>(continued)</i>	
BR4	DPR shall maintain chemical ingredient information
FR4.1	The system shall provide the ability to enter and maintain chemical technical information
FR4.2	The system shall provide the ability to enter and maintain regulatory information about chemical ingredients
FR4.3	The system shall provide ability to identify all products associated with a chemical to assist with identifying "like" products
FR4.4	The system shall notify specific DPR staff of data management activities
FR4.5	The system shall provide intranet/internet standard reports on chemical information
FR4.6	The system shall provide ability to identify all chemicals associated with a registrant
BR5	DPR shall maintain structured product information
FR5.1	The system shall provide the ability to enter and maintain product technical information (e.g. sites, target pests, etc.) following registration/licensing of a product
FR5.2	The system shall provide the ability to consume electronic structured product data
FR5.3	The system shall provide the ability to manage "product" lookup tables
FR5.4	The system shall provide the ability to modify the structured data specification
FR5.5	The system shall provide intranet/internet ad-hoc and standard reports on product information
BR6	DPR shall accept electronic payment
FR6.1	The system shall calculate payment due
FR6.2	The system shall provide the ability to submit electronic payment via State approved processors
FR6.3	The system shall record completed payments
BR7	DPR staff shall have access and search capabilities
FR7.1	The system shall provide ability to search for same or similar products
FR7.2	The system shall provide the ability to access and search for data studies
FR7.3	The system shall provide the ability to search and access product labels
FR7.4	The system shall provide ability to search and access submissions
BR8	DPR shall process regular submissions within statutory and regulatory requirements
FR8.1	The system shall provide the ability for parallel processing based on business rules
FR8.2	The system shall track submissions in each stage of registration/amendment/review process
FR8.3	The system shall provide information regarding submissions in the work queue
BR9	DPR shall make product label data and labels available to stakeholders and the public
FR9.1	The system shall provide the ability for public and stakeholder access to product label data
FR9.2	The system shall provide the ability for public and stakeholder access to product labels
BR10	DPR staff shall have the ability to compare product labels
FR10.1	The system shall provide the ability for electronic comparison of product labels
FR10.2	The system shall provide historical product labels

ID	Requirement
Business Requirement and Associated Functional Requirement(s) <i>(continued)</i>	
BR11	DPR shall have the ability to assign, track and manage work
FR11.1	The system shall incorporate workflow business rules for each type of submission
FR11.2	The system shall incorporate approvals and procedures into workflow business rules
FR11.3	The system shall allow for concurrent evaluations
FR11.4	The system shall route and assign work according to defined business rules
FR11.5	The system shall provide the ability to manage workload by business process
FR11.6	The system shall have the ability to flag products when critical dates are approaching
BR12	DPR shall perform scientific evaluations for applicable submissions
FR12.1	The system shall capture scientific evaluation outcome(s)
FR12.2	The system shall provide a status of scientific evaluation(s)
BR13	DPR shall link supplemental documents to submissions
FR13.1	The system shall allow supplemental documents to be electronically submitted
FR13.2	The system will link supplemental documents submitted to original submission
FR13.3	The system will allow registrants to amend their original product label submission
BR14	DPR shall standardize business processes
FR14.1	The system shall incorporate standardized business rules for each process
FR14.2	The system shall provide standardized input and forms
FR14.3	The system shall generate and store standard forms, letters, and notices
FR14.4	The system shall generate standard reports
BR15	DPR shall allow registrants to track the status of submissions
FR15.1	The system shall allow registrants to track each of their submissions
FR15.2	The system shall allow registrants to perform an online query of all submissions in process
BR16	DPR shall automate communication with stakeholders, registrants, and applicants
FR16.1	The system shall generate standard email notices and alerts based on pre-defined events
BR17	DPR shall have the ability to track similar products.
FR17.1	The system shall identify similar product(s) based on pre-defined criteria
FR17.2	The system shall provide the ability to search for similar product(s) based on pre-defined criteria
FR17.3	The system shall provide the ability to link a similar product to a submission
BR18	DPR shall have the ability to manage an iterative review with registrants
FR18.1	The system shall flag submissions requiring additional information from applicants
FR18.2	The system shall track the amount of time a submission is with DPR versus the applicants (i.e. Stop the clock)
FR18.3	The system shall allow DPR to "return" submissions
FR18.4	The system shall reassess an application fee if supplemental information is submitted for a returned submission beyond a specified time period

ID	Requirement
Business Requirement and Associated Functional Requirement(s) <i>(continued)</i>	
BR19	DPR shall provide access to intelligent work tools
FR19.1	The system shall provide links to policies and procedures on key steps of a business process
FR19.2	The system shall provide information to further explain a data field or process step
BR20	DPR shall maintain a product record and registration history
FR20.1	The system shall maintain product registration history
FR20.2	The system shall maintain product label version history
FR20.3	The system shall maintain product ownership history
FR20.4	The system shall maintain company ownership history
BR21	DPR shall identify repack, multi-pack, and sub registration of products
FR21.1	The system shall categorize types of product registrations (i.e., repack, multi-pack, sub-registration)
FR21.2	The system shall relate sub-registrations to main registration
FR21.3	The system shall allow query of product to sub-registrations, repacks, multi-packs
BR22	DPR shall issue product licenses and permits
FR22.1	The system shall issue electronic product licenses
FR22.2	The system shall maintain electronic product licenses
FR22.3	The system shall issue permits
FR22.4	The system shall maintain electronic permits
BR23	DPR shall issue emergency exemptions
FR23.1	The system shall accept electronic emergency exemption requests through internet/intranet
FR23.2	The system shall capture information about data studies
FR23.3	The system shall accept electronic submission of data studies
FR23.4	The system shall accept for supplemental documents for exemption requests
FR23.5	The system shall accept electronic recertification requests through internet/intranet
FR23.6	The system shall issue electronic exemptions
FR23.7	The system shall maintain exemptions
FR23.8	The system shall provide public access to current and historical exemptions
BR24	DPR shall issue Special Local Needs Registration
FR24.1	The system shall accept electronic Special Local Need registration requests through internet/intranet
FR24.2	The system shall capture information about data studies
FR24.3	The system shall accept electronic submission of data studies
FR24.4	The system shall accept supplemental documents for Special Local Need registration requests
FR24.5	The system shall accept product label data information
FR24.6	The system shall accept electronic product label submission
FR24.7	The system shall issue electronic Special Local Need registrations
FR24.8	The system shall maintain Special Local Need registrations
FR24.9	The system shall provide public access to current and historical Special Local Needs Registration

ID	Requirement
Business Requirement and Associated Functional Requirement(s) <i>(continued)</i>	
BR25	DPR shall issue research authorizations
FR25.1	The system shall accept electronic research authorization applications through internet/intranet
FR25.2	The system shall accept amendment to research authorization
FR25.3	The system shall accept electronic submission of Material Safety Data Sheet
FR25.4	The system shall accept for supplemental documents for research authorization requests
FR25.5	The system shall issue electronic Research Authorization
FR25.6	The system shall maintain Research Authorizations
FR25.7	The system shall allow electronic submission of Research Authorization Use Reports
FR25.8	The system shall provide DPR access to current and historical Research Authorizations
FR25.9	The system shall accept electronic submission of notice of intent
BR26	DPR shall associate master labels and market labels
FR26.1	The system shall categorize and associate master and market labels
FR26.2	The system shall allow query of associated product labels
BR27	DPR shall maintain a historical record of changes
FR27.1	The system shall maintain historical record of changes made to product record
FR27.2	The system shall maintain historical record of changes made to product label
BR28	DPR shall track the mandated performance metrics
FR28.1	The system shall track key metrics for each pre-defined business process
FR28.2	The system shall provide standardized reports and real-time information regarding key metrics
BR29	DPR shall maintain product registration status
FR29.1	The system shall track product registration status (i.e., pending, active, inactive, deactivated, conditional)
FR29.2	The system shall automatically inactivate products based on business rules
FR29.3	The system shall maintain historical record of product registration status
FR29.4	The system shall allow for conditional registrations
FR29.5	The system shall provide the ability to automatically flag conditional registration status
FR29.6	The system shall provide the ability to cancel or suspend a product
BR30	DPR shall renew eligible pesticide products
FR30.1	The system shall provide ability to renew products electronically
FR30.2	The system shall calculate renewal payment due
FR30.3	The system shall allow registrant to inactivate their products
FR30.4	The system shall assess a late fee for late renewals
FR30.5	The system shall allow product reactivation within a specified time period
BR31	DPR shall provide a means for the public to search product and study data
FR31.1	The system shall allow access for public searches of chemical, firm, product and study data

ID	Requirement
Business Requirement and Associated Functional Requirement(s) <i>(continued)</i>	
BR31	DPR shall provide a means for the public to search product and study data <i>(continued)</i>
FR31.2	The system shall limit searches to pre-defined search rules
FR31.3	The system shall limit information to comply with statutes, regulations, policies
BR32	DPR shall have the ability to receive and track adverse effects
FR32.1	The system shall accept electronic submission of adverse effect reports
FR32.2	The system shall maintain adverse effect reports
FR32.3	The system shall provide queries and tracking of adverse effects
BR33	DPR shall coordinate product reevaluations
FR33.1	The system shall accept electronic reevaluation request
FR33.2	The system shall flag products under reevaluation
FR33.3	The system shall link data received to the product reevaluation
FR33.4	The system shall capture all communication associated with the reevaluation
BR34	DPR shall coordinate risk assessment and risk mitigation
FR34.1	The system shall allow users to initiate risk assessments
FR34.2	The system shall flag products under risk assessment
FR34.3	The system shall track risk assessments
FR34.4	The system shall link data received to risk assessments
BR35	DPR shall have the ability to run standard and ad hoc reports
FR35.1	The system shall provide standard reports
FR35.2	The system shall provide ability to generate ad hoc reports
FR35.3	The system shall provide the ability to export data into personal productivity software products, such as Microsoft's Office Suite
BR36	DPR shall provide external communication and notices as required
FR36.1	The system shall automatically provide required notices (e.g. notice of decisions)
FR36.2	The system shall allow tracking of comments and their disposition
FR36.3	The system shall comply with CEQA requirements for the license/permit issuance
BR37	DPR shall have the ability to manage and track pesticide determination requests
FR37.1	The system will track determination requests and outcomes
FR37.2	The system will accept pesticide determination requests
FR37.3	The system will issue a pesticide determination disposition

ID	Requirement
Technical Requirement	
TR1	The system shall support secure, Internet access
TR2	The system shall comply with Code of Federal Regulations Section 508 and California Government Code Section 11135 guidelines for accessibility
TR3	The system shall provide, where appropriate, a listing of valid values at data entry (e.g., drop-down lists, pop-up windows, look-up tables)
TR4	The system shall allow authorized user (e.g., system administrator) to add, modify, or inactivate records
TR5	The system shall provide for multi-user access, according to group policy access rights, to all modules and functions within the system
TR6	The system shall validate all user-entered values based on business rules (e.g., mandatory fields, valid entries)
TR7	The system shall allow for completion of multiple system activities from a single action, where possible (e.g., by clicking a button, the system will add date, activity type, and other information as defined by DPR)
TR8	The system shall provide for intelligent form data entry, including completing keystrokes for data entry and skipping to the next entry
TR9	The system shall provide the ability to copy records forward during data entry
TR10	The system shall provide authorized users the ability to activate and deactivate user roles
TR11	The system shall provide a relational database management system compliant with DPR's enterprise database standards
TR12	The system shall archive and purge data based on business rules and industry best practices; archive process and database must comply with enterprise data architecture, internal audit, and security standards for DPR and the State of California
TR13	The system shall support a data dictionary that describes and maintains information on each data element including data element name and type, description of the data element, the format, and the preferred variations of each data element
TR14	The system shall provide extract, transform, and load (ETL) capabilities to migrate selected data from the production database to a separate database (e.g., an operational data store or data mart) for data analysis and reporting
TR15	The system shall provide the ability to export data into personal productivity software products, such as Microsoft's Office Suite, including Word and Excel to perform analyses, produce reports, and prepare files for mass mailings
TR16	The system shall use industry standard network protocols
TR17	The system shall utilize a table-driven, rules-based architecture to maximize system flexibility and minimize the need for code-level modifications to business logic, and to comply with changes in applicable federal and state law and regulations
TR18	The system shall provide the ability for configuration and customization of field labels on forms and menus, so that they are consistent with DPR terminology
TR19	The system shall store dynamic application parameters and settings to allow system administration staff the ability to make changes and have these changes immediately applied to the application without recompilation of the application's source code
TR20	The system shall generate record keys that have no semantic value [e.g., DPR now uses a "prodno" as a unique value]

ID	Requirement
Technical Requirement <i>(continued)</i>	
TR21	Comply with the DPR's IT architecture standards
TR22	The system shall allow authorized user to modify business rules to accommodate legislative, policy, and procedural changes
TR23	The system shall provide a minimum capacity for handling 40,000 registrations, renewals, and other actions per year, plus projected growth
TR24	The system shall support required interface with DPR's other systems, as specified by DPR, so that required information can be automatically extracted from the database of record, including but not limited to: product label database, licensing and certification database, pesticide use report database, and Fiscal Services and Business Operations Branch accounting database
TR25	The system shall allow for data import using industry-standard formats
TR26	The system shall comply with Departmental information security standards for web-based applications
TR27	The system shall provide lightweight directory access protocol (LDAP) and Active Directory support for internal user authentication and administration
TR28	The system shall provide multiple levels of security to accommodate role-based security administration, according to DPR defined user roles
TR29	The system shall provide the ability to create and assign user IDs and passwords for stakeholders, both internal and external
TR30	The system shall provide lock-out capability after a pre-defined number of unsuccessful user sign-on attempts
TR31	The system shall provide encryption, for both data in motion (and data at rest, where necessary), for data designated as confidential; all data stored and transmitted is classified and protected per guidelines stated in the California State Administrative Manual, Section 5300, and DPR standards (as documented by the Governor's Office of Information Security and Privacy Protection in Information Security Program Guide for State Agencies)
TR32	The system shall provide automatic logout of users when there has been no activity for a pre-defined period, maintaining transaction integrity
TR33	The system shall provide online help documentation that is indexed and searchable (i.e. alphabetical, topical, etc.)
TR34	The system shall provide online help that displays data element definitions for all user-accessible data elements
TR35	The system shall provide online, context sensitive help at the module, function, screen, and field level
TR36	The system shall generate an audit record for all records and transactions, including but not limited to the following values: operator ID, workstation ID, IP address, date, and time
TR37	The system shall prevent audit records from being physically deleted or altered, except as part of a system administration archival process
TR38	The system shall provide audit-tracking reports for user access, usage logs, and key data structures
TR39	The system shall archive and restore audit logs
TR40	The system shall provide online, web browser access 24X7, except during required maintenance and backups, or during unavailability due to off-hour batch processing
TR41	The system shall adhere to Cal EPA and DPR disaster recovery requirements
TR42	The system shall provide transaction processing control for 300 hundred concurrent authorized users without affecting system performance

ID	Requirement
Technical Requirement <i>(continued)</i>	
TR43	The system shall provide maximum 0.75 second transaction-level response time during normal DPR business hours
TR44	The system shall provide backup and recovery plans and procedures to comply with California State Administrative Manual, Section 5355 and DPR standards for operational recovery
TR45	The system shall conform to requirements outlined in AB 2408
TR46	The system shall provide a method for mass communication with all "registered" external stakeholders
TR47	The system shall provide an interface to manage external stakeholder user accounts
TR48	The system shall appropriately function with state approved sole-source vendors which will process credit card and EFT transactions
TR49	The system shall provide a method to allow external stakeholders to create user accounts without human intervention in a way that complies with DPR security policy
TR50	The system shall provide a generic method (web services) for internal and external applications to access product and product component data
TR51	The system shall provide the ability to scan in hard copy information (e.g. labels and scientific studies)
TR52	The system shall index scanned hard copy information
TR53	The system shall provide the ability to define user profile custom attributes

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Appendix A
Complexity Assessment

Project Name: PRDMS
 Technology Agency Project #: 3930-012
 Department: Department of Pesticide Regulation
 Revision Date: 2/12/14

Complexity Assessment

Business Complexity

Instructions: On a scale of .5 - low to 4-high (0 = N/A), rate each applicable attribute and compute the Business Complexity by dividing the total by the number of items rated above zero. [Notes: Business and technical complexity will be computed automatically in this worksheet, using the ratings you enter. Move your pointer over each attribute cell, marked with a red triangle, to see a definition of the attribute.]

Low Complexity	Business Attribute	High Complexity	Rating
0 1 2	3	4	
Static	Business rules	Changing	2
Static	Current Business Systems	Changing	2
Known and Followed	Decision Making Process	Not Known	1
Low	Financial Risk to State	High	1.5
Local	Geography	State Wide	1
Clear and Stable	High Level Requirements	Vague	1.5
Few & Routine	Interaction with Other Departments and Entities	Many and New	3
None	Impact to Business Process	High	3.5
Few & Straight Forward	Issues	Multiple & Contentious	2
High	Level of Authority	Low	1
Clear	Objectives	Vague	1
Established	Policies	Non-existent	2
Minimal	Politics	High	2.5
Familiar	Target Users	Unfamiliar	2
Experienced	Project Manager's Experience	Inexperienced	1.5
Experienced	Team	Inexperienced	2
Loose	Time Scale	Tight	2.5
Low	Visibility	High	3.5
	Business		
		Total:	35.5
		Complexity:	2.0

Project Name: PRDMS

Technology Agency Project #: 3930-012

Department: Department of Pesticide Regulation

Revision Date: 2/12/14

Complexity Assessment

Technical Complexity

Instructions: On a scale of 0-low to 4-high, rate each applicable attribute and compute the Technical Complexity by dividing the total by the number of items rated above zero. Use the definitions in the student notebook for clarity.

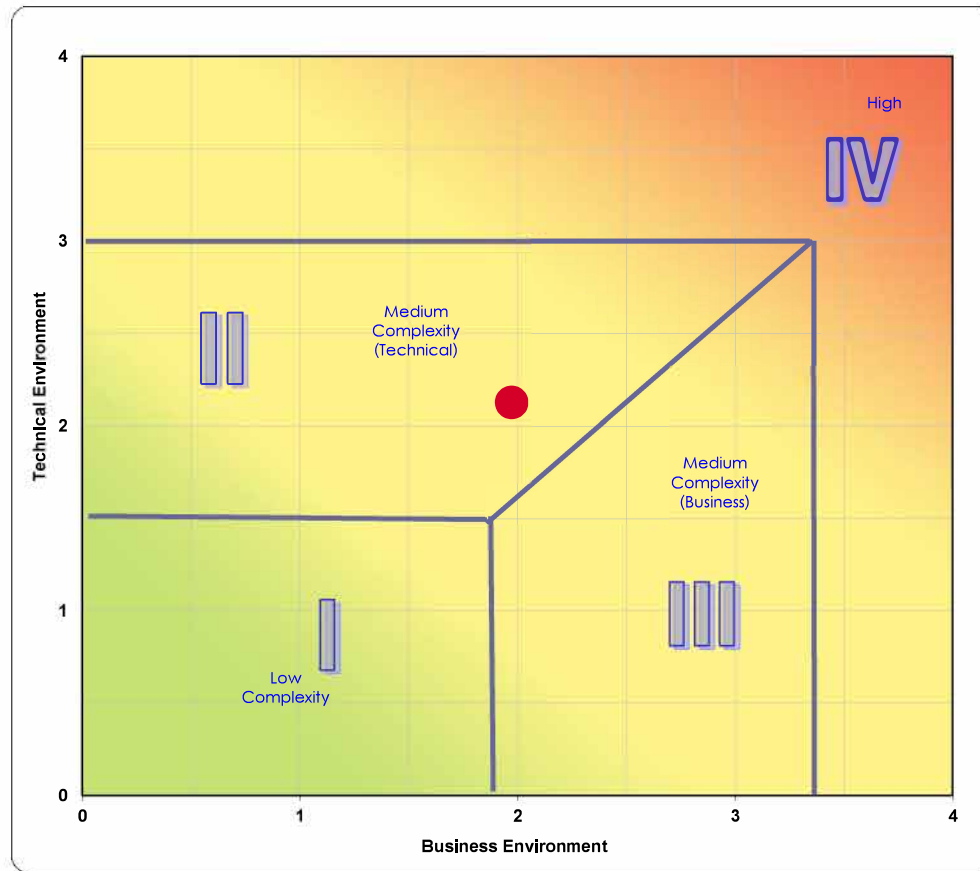
Low Complexity		Technical Attribute	High Complexity	Rating
0	1	2	3	
		Communications	Statewide	3.5
		Delivery Mechanism	New	1.5
		Geography	Statewide	0.5
		Hardware	New	1.5
		Level Of Integration	Tightly Integrated	3
		Networks (L/W)	New	1
		New Technology Architecture	Not in place	1
		Operations	24-hour, 7-day	4
		PM Technical Experience	Novice	2
		Scope Management Process	None	2
		Security	Tight	3
		Software	New	1.5
		Standards And Methods	None	2
		Team	Inexperienced	2
		Tolerance To Fault	Low	3
		Transaction Volume	High	2.5
			Total:	34
			Complexity:	2.4

Project Name: PRDMS
 Technology Agency Project #: 3930-012
 Department: Department of Pesticide Regulation
 Revision Date: 2/12/14

Complexity Assessment

Complexity Diagram

Instructions: Plot your project in the appropriate complexity zone.
 [Note: Your project will be plotted automatically in this worksheet, using the values computed in the previous tables.]



Scores	Business Complexity	<input type="text" value="2.0"/>
	Technical Complexity	<input type="text" value="2.1"/>

Project Name: PRDMS
 Technology Agency Project #: 3930-012
 Department: Department of Pesticide Regulation
 Revision Date: 2/12/14

Complexity Assessment

Suggested Project Manager Skill Set Guidelines

Complexity		Duration		Budget		Resources	
<input type="checkbox"/>	Zone 1	<input type="checkbox"/>	< 6 months	<input type="checkbox"/>	<\$500K	<input type="checkbox"/>	< 5
<input checked="" type="checkbox"/>	Zone II, Medium Zone III, Medium	<input type="checkbox"/>	< 1 year	<input type="checkbox"/>	<\$1M	<input checked="" type="checkbox"/>	<10
<input type="checkbox"/>	Zone II, High Zone III, High	<input checked="" type="checkbox"/>	>1 year; < 3 years	<input checked="" type="checkbox"/>	>\$1M; <\$5M	<input type="checkbox"/>	11e- 20
<input type="checkbox"/>	Zone IV	<input type="checkbox"/>	>3 years; <10 years	<input type="checkbox"/>	>\$5M; <\$100M	<input type="checkbox"/>	21e- 40
		<input type="checkbox"/>	>10 years	<input type="checkbox"/>	>\$100M	<input type="checkbox"/>	40+

PM Level: 2

Experience: 3 – 5 years as a key team member on a medium or large IT project or as a Project Manager on small or medium IT project. Technical experience commensurate with the proposed technology.

Professional Knowledge: Strong working knowledge of the CA-PMM, department's methodology, Software Development Life Cycle. Familiar with CA Budgeting, Procurement and Contracting processes.

Assess the complexity of the project periodically: every two - three months and/or at the conclusion of each phase

For Oversight Purposes:
Zone I = Low Criticality/Risk
Zones II and III = Medium Criticality/Risk
Zone IV = High Criticality/Risk



Appendix B

Stage 1 Business Analysis



Stage 1 Business Analysis

General Information

Agency or State Entity Name:

Pesticide Regulation, Department of

Organization Code:

3930

Name of Proposal:

Pesticide Product Registration Business Process Assessment and Design

Proposed Start Date:

January, 2015

Department of Technology Project Number:

3930-012

Submittal Information

Submission Date:

3/7/2014

Contact First Name:

Larry

Contact Last Name:

Wasson

Contact email:

larry.wasson@cdpr.ca.gov

Contact Phone:

(916) 324-5887

Business Sponsor and Key Stakeholders

Executive Sponsors

Title	First Name	Last Name	Business Program Area
Associate Director	Charles	Andrews	Pesticide Programs Division
Assistant Director	Marylou	Verder-Carlos	Pesticide Programs Division
Assistant Director	Anise	Severns	Administrative Services Division
Chief Information Officer and Project Director	Larry	Wasson	Office of Technology Services

Business Owners

Title	First Name	Last Name	Business Program Area
Branch Chief	Ann	Prichard	Pesticide Registration Branch
IT Manager	Michael	Wanser	Information Technology Branch, Application Development & Database Administration

Key Stakeholders

Title	First Name	Last Name	Business Program Area/Group	External
Associate Director	Charles	Andrews	Pesticide Programs Division	<input type="checkbox"/>

Assistant Director	Marylou	Verder-Carlos	Pesticide Programs Division	<input type="checkbox"/>
Assistant Director	Anise	Severns	Administrative Services Division	<input type="checkbox"/>
Chief Information Officer	Larry	Wasson	Office of Technology Services	<input type="checkbox"/>
Branch Chief	Ann	Prichard	Pesticide Registration Branch	<input type="checkbox"/>
IT Manager	Michael	Wanser	Information Technology Branch, Application Development & Database Administration	<input type="checkbox"/>
Branch Chief	George	Farnsworth	Enforcement Branch	<input type="checkbox"/>
Branch Chief	David	Duncan	Environmental Monitoring Branch	<input type="checkbox"/>
Branch Chief	Nan	Gorder	Pest Management and Licensing Branch	<input type="checkbox"/>
Branch Chief	Gary	Patterson	Medical Toxicology Branch	<input type="checkbox"/>
Branch Chief	Donna	Marciano	Product Compliance Branch	<input type="checkbox"/>
Branch Chief	Lisa	Ross	Worker Health and Safety Branch	<input type="checkbox"/>
PRB Employees	Various	Various	Employees working the PRB core processes	<input type="checkbox"/>
Registrants	Various	Various	Business entity registering a pesticide product for sale in California (e.g., pesticide product manufacturers Bayer, DuPont, BASF, Dow Chemical, etc.)	<input checked="" type="checkbox"/>
Applicants	Various	Various	Researcher, manufacturer, grower group, and other stakeholders	<input checked="" type="checkbox"/>
U.S. EPA	Various	Various	Office of Pesticide Programs	<input checked="" type="checkbox"/>
Other State Agencies	Various	Various	Pesticide intersections with various agency's responsibilities	<input checked="" type="checkbox"/>
Public	Various	Various	Environmental groups, schools, UC IPM, and others	<input checked="" type="checkbox"/>
County Agricultural Commissioners	Various	Various	All aspects of county pesticide enforcement	<input checked="" type="checkbox"/>

Business Analysis

1.1 Business Drivers

Financial Benefit:	<input checked="" type="checkbox"/> Increased Revenues
	<input checked="" type="checkbox"/> Cost Savings
	<input checked="" type="checkbox"/> Cost Avoidance
Mandate(s):	<input checked="" type="checkbox"/> State
	<input type="checkbox"/> Federal
Improvement:	<input checked="" type="checkbox"/> Better services to citizens
	<input checked="" type="checkbox"/> Efficiencies to program operations
	<input checked="" type="checkbox"/> Technology refresh

1.2 Statutes or Legislation

Statutes or Legislation: New statutes or potential legislation Not Applicable
 Changes to existing legislation

Bill Number: Chapter 584, Statutes of 2013 (AB 304)

Legal Code: Sections 14022, 14023, and 14024 of the Food and Agricultural Code

Additional Information: Pesticides: toxic air contaminant: control measures. Requires the Department of Pesticide Regulation to complete Toxic Air Contaminant risk mitigations within 2 years of problem being identified. This bill was enrolled and presented to the Governor September 19, 2013.
*** See FSR for additional statutes or legislation ***

1.3 Program Background and Context

As part of the California Department of Pesticide Regulation's (DPR's) regulation of pesticide sales and use in California, its PRB is responsible for the evaluation and registration of pesticides and certain devices. The PRB also processes exemptions from registration, tracks adverse effects, issues research authorizations, and coordinates reevaluations, and human health risk assessments and mitigations.

A PRB priority is efficient, effective and consistent service delivery with registrants and other stakeholders. As part of this RP² effort, DPR leadership and staff have defined the following Vision Statement: *To better serve our stakeholders, PRB leadership and staff are committed to an electronic, customer service focused, pesticide product registration program promoting effectiveness, efficiency, and quality.*

The PRB has five core registration program business processes:

- Register, amend, and renew pesticide products/devices
- Manage pesticide product label data, pesticide product labels, and scientific data
- Issue Research Authorizations (RAs)
- Receive and track adverse effects and make determinations
- Coordinate pesticide product(s) reevaluation, risk assessment, and mitigation programs.

PRB, as primary liaison with pesticide product registrants, corresponds with registrants regarding data requirements, health effects of pesticide determinations, labeling requirements, and final actions on registrations. PRB, with assistance of evaluation scientists within other DPR branches (i.e., Environmental Monitoring, Medical Toxicology, Worker Health and Safety, and Enforcement Branches), conducts a thorough evaluation to determine whether the pesticide endangers human health or the environment, and is effective for its intended use. PRB also prepares public notices, manages submitted data, oversees data call-ins on environmental fate and acute and chronic toxicology, coordinates the reevaluation process, maintains label files and the Registration Resource Center, receives and tracks registration and renewal fees and penalties, and provides information on registered pesticides and label instructions to pesticide enforcement agencies (e.g., other DPR branches, County Agricultural Commissioners, other State agencies) and the public.

In addition, PRB receives and processes additional data. For example, PRB assists the U.S. EPA in performing IR-4 reviews, analyzing residue studies for minor crops. PRB provides the evaluation reports to U.S. EPA using U.S. EPA's report format, processing about four to six reports a year. Additionally, PRB regularly logs correspondence with registrants and other stakeholders, including incoming public comments, letters of support from grower groups, outgoing correspondence regarding pesticide determinations (whether or not a product requires registration as a pesticide), public information requests, and other miscellaneous announcements.

1.4 Business Problem or Opportunity Summary

California has one of the most comprehensive and rigorous state pesticide regulation and enforcement programs. DPR's mission is to *"protect human health and the environment by regulating pesticide sales and use, and by fostering reduced-risk pest management."* The DPR regulates pesticides with its comprehensive program that encompasses not only the evaluation process of registering pesticide products, but also enforcement of pesticide sales and use, prevention of environmental contamination, licensing of applicators, and protection of workers,

consumers, endangered species, and the environment.

To effectively fulfill DPR's mission, there is a critical need for PRB to improve its business processes and supporting technology in order to meet State Mandates (e.g., AB 304, AB 101, AB 1011), as well as provide access to critical product and management information. The PRB plans to reduce manual processes and implement an integrated solution to better serve employees, registrants, and other stakeholders.

The DPR performed the *Pesticide Product Registration Business Process Assessment and Design* effort as part of RP² to evaluate the current PRB operations. During this effort, the project team analyzed the current operations of the PRB, and opportunities for improvement. Included in the process assessment efforts were research and information gathering, participation in approximately 20 team meetings and one-on-one interviews, and walk-throughs of the core business processes. The project team gathered key performance metrics for developing the baseline as well as to help build the case for change. As a result, the project team documented the current business processes, identified issues and improvement opportunities, developed a future state for improved business processes, and identified regulatory and policy implications.

The RP² project identified nine problems and/or opportunities. Each of these business problems are summarized below.

BP-1 PAPER-BASED, MANUAL-INTENSIVE REGISTRATION PROCESSES RESULT IN CUMBERSOME PROCESSING, BOTTLENECKS AND INEFFICIENCIES

PRB's current processes rely on paper-based submission of fees, registration applications, product renewals, scientific data studies, product labels, and other supporting documents. These paper-based submissions are extremely inefficient for staff and significantly increase the time it takes to make a registration decision on pesticide products in California. In 2012, DPR received 1,762 new pesticide product registration submissions, of which 1,726 were regular product registrations and 36 were new pesticide product submissions containing new active ingredients (AI). On average, it took 90 days to reach a final action for a 2012 regular product submission. For new active ingredient submissions received in 2010 that entered scientific evaluation, it took on average 531 days from submission to proposed decision. These timeframes do not meet DPR's goals.

Multiple issues exist in the paper-based, manually intensive processes. Below are illustrative challenges and examples:

- Tracking, managing, and storing large volumes of hard-copy documents is very cumbersome, time-consuming, and prone to lost or misplaced documentation. Documents and data studies may be lost or misplaced, resulting in increased processing time. As documents move through the registration process, many handoffs exist due to the current process of managing and tracking of all registration documents. In addition, hard-copy registration documents are stored in multiple places rather than in a centralized electronic location, which prevents quick access to needed registration product information. To note, the PRB paid approximately \$10,000 for storage space at the State Records Center for archived records in the past year. Annual storage costs increased almost \$800 between 2012 and 2013. PRB expects the annual storage costs to increase by the same rate.
- PRB currently cannot accept electronic payment of registration and renewal fees, and relies on a cumbersome, unsecured paper check processing process. Registrants must submit paper checks along with their registration submissions and renewal application forms. Checks arrive daily in the mail and reside in a processing location until staff can process the checks and submit them to the DPR Cashier. At times there may be up to a 15 day delay for check processing.
- PRB relies on 24 separate and disparate tracking systems and databases to log, index, manage, and track the work associated with PRB's core business processes. For example, with new product submissions, during the mail intake and indexing processes, employees from various PRB work units must manually log the mail received from registrants, enter key data elements from the registration application into DPR's Tracking database, and index key data from scientific studies submitted to support the application. Then after the product is licensed, staff code information from accepted hard-copy labels into DPR's Product Label database. Most of this activity is entered and tracked in separate database applications.
- In the current environment, scientific evaluation stations working on regular product registrations (excludes product registrations with new AIs) receive registration submissions sequentially after the previous station has completed its analysis of the submission. This sequential processing is due to hard copy submissions, along with the frequent need to reference additional studies that are archived off-site (requiring additional time for retrieval), all of which increases processing time. For example, in 2012, it took 48 days or more to complete a review in one station. Therefore, for submissions that required evaluation by two or more stations, the evaluation portion of the registration process is expected to take 96 days or more.

- Given the limitations of the current product/label system, conditionally registered products are not adequately tracked, and as a result may retain a conditional status for years, and may receive full registration in error. Conditional registration is intended to be a temporary status until a registrant completes certain specified data requirements. However, some conditionally registered products have been granted renewal of their conditional status for years without providing PRB with the additional data needed to grant or deny full registration status. In addition, conditionally registered products can be easily missed, overlooked, and improperly recorded in PRB's data systems as a result of human error, resulting in inconsistent tracking of the registration status (e.g., some products have full registration in the database but are conditional in the product file, or the reverse). Also, upon product renewal, a conditionally registered product may receive full registration in error when all conditions have not been satisfied (e.g., due to complex conditions, one condition may be partially met but not completely satisfied).

The lengthy registration and licensing process financially impacts registrants by delaying their ability to sell products in California until the registrant receives a product license from DPR. According to registrants, this issue is their number one concern with the current registration process. The delays also impact DPR's revenue stream since Mill Assessment Fees cannot be assessed until products are licensed and sold. For consumer pesticide products, the market is often driven by registrants' ability to place products in "big box" stores like Wal-Mart and Home Depot. Such stores only accept new products two times per year. Missing one of these two deadlines can be devastating for a consumer product pesticide company as it will have to wait another six months to try and get its product into the marketplace.

California's farmers and growers are also impacted by these delays since they cannot use a new pesticide until it is approved by DPR. The lengthy new product registration process can result in growers missing a product application window, resulting in crop loss due to pests that would be better controlled with a product pending registration. This product registration delay also can cause farmers to forgo planting a crop altogether because the product would not be available during the application period. In addition, the farming community often complains that neighboring producers (in other states) have an unfair advantage due to those states' quick acceptance of U.S. EPA approved products.

Reducing the average pesticide registration processing time by 30 days, results in additional time that the newly registered product is available for sale. It is estimated that, on average, by reducing the average registration time for a new product containing an active ingredient found in other registered products down from 90 days to 60 days can potentially increase total pesticide sales for the additional month of \$19.8 Million. (Pesticide products, newly registered between Q4 2011 and Q3 2012, totaled 1,318 products. Of these 1,318 products, 722 reported sales between Q1 2012 and Q4 2012. The average monthly reported sales for these 722 products totaled \$19,776,901, or \$27,392 per product. [1])

BP-2 HARD-COPY PRODUCT LABELS LIMIT THE ABILITY TO EVALUATE PESTICIDE PRODUCTS AND IMPACT STAKEHOLDERS IN THE FIELD NEEDING THE INFORMATION

The current process for submitting and storing pesticide product labels and label data requires registrants to submit six hard-copy labels, one of which, after completion of the registration process, is stored in filing cabinets in PRB's offices in Sacramento. Registrants are required to submit additional hard copies of labels if any information on the label changes, including minor modifications. One copy of each amendment to a label is also stored in DPR's filing cabinets.

Physical submission and storage of labels present myriad problems for PRB, including limiting public access to critical label data. Timely access to pesticide labels is especially important to: (1) registrants who need the ability to view the latest labels for all products currently registered with DPR; (2) Poison Control Centers in California that need to reference the most accurate and up-to-date product labels in emergencies; and, (3) consumers, growers and product end-users who need access to labels in the field. In addition, access to California registered pesticide labels would be extremely useful to product compliance and enforcement personnel during field inspections to ensure products are registered and being used and applied in accordance with the latest label specifications.

In addition, hard-copy product label submissions present significant bottlenecks in the pesticide product registration and label amendment processes. Working with hard-copy labels was identified by PRB staff in all units as being a major inefficiency in the current processes. Hard-copy labels take a long time to code, are difficult to search and access, and make technical evaluation and label comparisons a much slower, cumbersome, and potentially less accurate process.

The manual process to code product label data into the Product Label Database (PLD) after a product is licensed requires eight to twelve weeks to complete. The actual coding time varies, but is less than a week. The eight to twelve week wait is due to the backlog of labels waiting to be coded. During this delay, issues arise when inspectors

and other stakeholders need to look up information about the product, or if counties submit Pesticide Use Reports (PUR) for a product that is registered, but has incomplete label data in the PLD. Missing data could include critical information on restricted use, chemical formulation and approved application sites. Also, this data is critical to PUR reporting, validation, and use permitting.

As an example of the impact of hard-copy labels on stakeholders, the Worker Health and Safety Branch (WH&S) field's calls during pesticide related illness incidents ("episodes"), responding to approximately 70 episodes per year. One episode may affect one person to hundreds of people. The WH&S personnel needs to quickly access product label information and occasionally the Confidential Statement of Formulation (CSF), relaying the pesticide product information to hospital personnel (i.e., emergency room doctors). Medical professionals use the information to determine the appropriate course of treatment. Currently, medical professionals must contact DPR during normal business hours; WH&S personnel then must physically go to the Registration Resource Center to retrieve the hardcopy label and CSF, as applicable. This process significantly impacts the timeliness of critical information needed in emergency and poison control centers.

A second example of the impact to stakeholders; Product Compliance Branch auditors make copies of the label(s) registered to, or associated with, the entity (i.e., registrant, broker, or dealer) selected for audit. The auditor uses the hard-copy label to compare against the product labels identified in the field. The auditor may also need to contact the PRB while in the field to confirm the validity of a site's amended label. Often, the auditor must return to the field with the additional label information given the label was unavailable electronically at the location at the time of the audit.

BP-3 REGISTRANTS SUBMIT INCOMPLETE REGISTRATION AND LABEL AMENDMENT SUBMISSIONS

Registrants often submit incomplete new and amended product registration packages, which increase time lags in the registration process. DPR returns about 14 percent of registration submissions due to incomplete information. Registrants often submit packages that are missing information needed to properly evaluate requests. Submissions may be poorly organized, cite products not registered with DPR, omit cover letters describing proposed changes, contain labels that don't identify changes, or fail to provide supplemental documentation. Each of these issues makes the evaluation more lengthy and cumbersome. Regulatory Scientists must then contact registrants for more information or prepare a return package to send to the registrant.

In 2012, DPR returned 712 submissions to registrants who then had to resubmit revised packages and start the registration review process over again. Due to the high volume of applications, and PRB's policy of first-in, first-out processing, incomplete application packages may sit in the queue on the Regulatory Scientist's desk for 30 to 90 days without any action, to then be found incomplete upon initial review.

Similar issues exist with label amendment submissions from registrants. Often, registrants do not provide adequate documentation to support the label amendment request or send multiple label amendments (sometimes with a single cover letter) without detailing what is being provided or requested.

For minor label amendments (i.e., changes not requiring scientific data for support), neither statute nor regulations require registrants to submit a label amendment application or cover letter. In cases where limited or no information is provided, the Regulatory Scientist spends additional time to research and verify what is being amended on the label and often must compare the proposed label to prior DPR-accepted labels to identify the changes. Without a cover letter or adequate documentation, the Regulatory Scientist must call registrants to ask why they are submitting the label or may need to request additional documentation, adding additional delays in the processing time.

BP-4 INCONSISTENT WORK PRACTICES AND LACK OF STANDARDIZED PROCESS EXECUTION

From the employee survey, employees feel there are varying practices across PRB including inconsistencies in the way individuals perform their duties, conduct technical evaluations, and prepare and finalize submissions. Employees cite inconsistency in how processes are followed as one of the top three challenges they face in effectively and efficiently doing their jobs.

Anecdotally, employees cite differences in the way Regulatory Scientists execute the registration process, which leads to registrant frustration and processing delays. Similarly, employees note inconsistencies in the way supervisors or groups of Regulatory Scientists apply State regulations during the registration process. Examples include conditional letters not being forwarded consistently to Licensing, inconsistent application of amendment fees, and supervisors focusing on different factors when reviewing a completed package.

BP-5 DISPARATE, STAND-ALONE TRACKING SYSTEMS LIMIT VISIBILITY OF WORKLOAD PER STATION AND STAFF AND NO SINGLE DATA SOURCE EXISTS TO REGISTER PRODUCTS

Each of the five core business processes within PRB relies on numerous stand-alone systems and databases that are not fully integrated. This results in duplicate entry of similar and/or redundant information. Currently, DPR maintains 24 separate PRB systems including MS Access databases and complex macro-driven MS Excel spreadsheets. Each

scientific evaluation workstation maintains its own stand-alone tracking system to log and assign submissions for scientific evaluation. Most workstations use MS Excel, MS Access, or paper logs to track incoming submissions, assignments, and other scientific evaluation process information. The Regulatory Scientists commonly go to the individual workstation to check the package status and identify the assigned evaluation staff. Use of stand-alone systems also limits visibility of workload per station, staff, and other information that can be used to effectively manage the registration process, workloads, and backlogs.

The manual entry of information and product data can lead to input errors causing other processing or reporting errors. For example, if a product is incorrectly entered in the Product Label database, then Pesticide Use Reports (PUR) will be rejected by the system. These errors then need to be investigated and corrected.

BP-6 STAFF ARE NOT CONSISTENTLY TRAINED OR NEED MORE ONGOING TRAINING

PRB employees desire more effective and consistent training. Employees indicated that they should be better trained and informed not only on their own processes, but about all steps in the registration process. Staff noted that the lack of regular refresher courses for Regulatory Scientists may be partially responsible for inconsistencies in the way staff implement processes and policy/regulatory changes. An example is the prevalence of incomplete AB1011 (Assembly Bill 1011, Chapter 612, Statutes of 2005) searches that result in unnecessary routing of registration packages to evaluation stations.

Employees also cite inconsistencies in the way some senior and novice Regulatory Scientists process packages to be the result of past training practices where multiple trainers provided different or conflicting instructions to staff. PRB has recently consolidated training under a single trainer to address this issue.

In addition, there is limited/no training for supervisory or management staff that provide them with tools and techniques for organizational change management and managing employees' abilities to meet performance objectives.

Also, policy and procedure documentation may contain outdated material and is spread over various source documents. Procedures for Regulatory Scientists can be documented in policy procedure memos, branch memos (old), web documents, California Notices, various e-mails and the Regulatory Scientist Desk Manual (the Desk Manual is intended to be the final authority consolidating information from all other documentation sources). Intake through archiving procedures for support staff are documented in the Intake through Archiving manual and separate desk manuals for each station (i.e., intake, indexing, licensing). Evaluation Scientist stations do not have desk manuals. The resulting confusion about where to look for definitive guidance on policies, procedures and requirements contributes to inconsistencies in the way employees conduct their work.

BP-7 LACK OF COMMUNICATION

Employees reported lack of communication as one of the top challenges they face in performing their work effectively. They identified communication challenges between units within PRB, between PRB and other DPR branches, and between DPR and registrants.

Communication between PRB units:

- Employees placed heavy emphasis on fostering effective communication between Regulatory Scientists and Evaluation Scientists, and between all scientists and support staff. In particular, they believe better communication between Regulatory Scientists and Evaluation Scientists when conducting

AB 1011 label searches, as well as quick discussions of possible label candidates prior to routing of packages, could reduce unnecessary routing or misrouting of packages, which adds significant delays to the registration process.

- In general, employees desire better communication between all areas within the Branch (intake, coding, technical and scientific evaluation, Registration Resource Center, etc.). Also, employees desire information about the functions, workload and responsibilities of each area. Such information would make each area more aware of how the other areas operate and how areas impact one another, which could foster cross-functional efficiencies and process improvements. For example, if Regulatory Scientists knew exactly what the coders look for and what they code for, the coding process could be more efficient, (i.e., fewer unnecessary packages forwarded to coding).

Communication between PRB and other DPR Branches:

- Employees desire improved communication between PRB and other DPR Branches. Better communication would allow employees within each Branch to know what other branches do, how they do it, and how each fits into the Department's mission. Improved communication between Registration, Enforcement, and Product Compliance Branches leads to better coordination of activities. Branch employees need to learn and understand the primary concerns of other Branches and the interdependency of processes between Branches. For example, if coders knew what information was available to pesticide applicators, they could better recognize and prevent errors that could show up in the PUR.

Communication between PRB and Registrants:

- While communication between registrants and Regulatory Scientists is frequent and usually productive, it is typically on a case-by-case basis. More proactive, continuous communication with registrants through additional workshops, pre-registration meetings and online informational videos could help registrants better understand PRB’s processes. Also, this communication may result in more accurate submissions, and reduce returns and process delays.

BP-8 LACK OF PERFORMANCE MEASURES AND ACCOUNTABILITY

Currently in PRB, each core process lacks performance targets and standards to hold employees accountable. Also, given the numerous, disparate systems and databases, it is very difficult to obtain and provide quality management reports in a timely manner. Certain key information is currently not available, limiting management’s ability to monitor process performance metrics.

Given the manual, paper intensive processes, it is difficult to isolate and manage the various workflows and workloads. Related to the common theme of inconsistent work practices, employees cited the need for improved accountability, as well as adherence to standards and accepted performance objectives and time frames. Employees observed inconsistencies in the way others perform similar work with little accountability for accuracy and timeliness of the work products. Supervisors report there is a general inability to track staff productivity, backlog, and workflow. In addition, a lack of visibility in evaluation stations and inconsistencies in how Regulatory Scientists review labels and bridge data are cited as examples of lack of accountability across PRB. Although it is difficult to quantify the impact, it is reasonable to assume that these issues contribute to processing delays and reduced productivity from employees.

BP-9 LACK OF REWARDS, RECOGNITION AND FEEDBACK LINKED TO PROCESS PERFORMANCE

Currently, there are limited performance goals and metrics in place for each core business process. As part of their annual Individual Development Plans, employees currently do not have specific, measurable performance targets that link to the overall process performance.

Some employees in PRB cite the lack of motivating rewards and recognition for high performers. Some employees desire management to actively solicit and encourage feedback and ideas to improve the registration process, procedures, and policies. Employees suggested a formal procedure for submitting improvement ideas. Also, employees requested that there be greater educational, training and special project opportunities for motivated employees to allow them to advance beyond their current position and responsibilities.

[1] The calculation excludes quarters without reported product sales. The pesticide product sales amounts come from the registrants’, brokers’, and dealers’ quarterly report of pesticide sales.

1.5 Business Problems or Opportunities and Objectives Table

ID Problems and Opportunities

BP-1 Paper-based, manual-intensive registration processes result in cumbersome processing, bottlenecks and inefficiencies

ID Objective

O-1 **Improve data collection and integration, and develop electronic validation processes to ensure the accuracy, quality & completeness of registrants’ submissions**

Creating an electronic registration submission system that enforces robust data validation rules and imposes data format standards on registrants’ data at the time of submission can improve the quality, accuracy and completeness of data received from registrants. Data validation rules and standards that are integrated into the system would automatically screen registration information, flag missing or incomplete data, and require registrants to correct deficiencies prior to submitting requests for registration actions.

Metric	Baseline	Target	Measurement Method
% of submissions received via hardcopy versus electronic	100% submissions are paper-based	15% of submissions are submitted electronically by end of first year of implementation	Number and percentage of submissions received by method: electronic, Electronic Data Interchange (EDI), paper

ID Objective

O-3 Increase throughput while decreasing the time & effort to process registration submissions
 By developing a paperless, automated registration process, the burden of processing, tracking and archiving large volumes of paper documentation would be eliminated. Currently, a large number of person years (PYs) within the Branch manage hard-copy documents. With a paperless application submission process, these resources could be redirected to more high-value data management, analysis and evaluation activities that would help reduce backlog in these areas.

Metric	Baseline	Target	Measurement Method
Key process measures and targets for each major core process	90 days for regular submission	60 days for regular submission, by the end of the third year of implementation	Evaluation timeframe report

ID Problems and Opportunities

BP-2 Hard-copy product labels limit the ability to evaluate pesticide products and impact stakeholders in the field needing the information

ID Objective

O-2 Provide access to electronic product labels anytime and anywhere through the Internet/Intranet
 Electronic labels will allow all PRB and DPR staff to view and electronically compare labels – including prior versions of labels – rather than having to visually review and compare two hard copy labels side-by-side. Electronic labels would eliminate lost or missing labels and allow multiple staff to view labels simultaneously from their respective workstations or worksites. Overall, electronic label submission would greatly increase productivity across PRB processes and make it easier for staff to track label amendments and history. Also, approved electronic labels made available and accessible, through the Internet, will allow registrants, government agencies, Poison Control Centers, growers, consumers, enforcement or compliance personnel in the field, and other stakeholders to search, view, print, and download the most accurate and up-to-date product labels, as well as historic product labels, registered in the State.

Metric	Baseline	Target	Measurement Method
% of labels received via hardcopy versus electronic	100% submissions are paper-based	15% of label submissions are submitted electronically by end of first year of implementation	Number and percentage of product labels received by method: electronic, electronic data interchange (EDI), paper
Labels accessible online	1% California approved labels available online	100% of accepted labels submitted electronically are accessible online	Product labels accessible electronically

ID Problems and Opportunities

BP-3 Registrants submit incomplete registration and label amendment submissions

ID Objective

O-1 Improve data collection and integration, and develop validation processes to ensure the accuracy, quality & completeness of registrants' submissions

Creating an electronic registration submission system that enforces robust data validation rules and imposes data format standards on registrants' data at the time of submission can improve the quality, accuracy and completeness of data received from registrants. Data validation rules and standards that are integrated into the system would automatically screen registration information, flag missing or incomplete data, and require registrants to correct deficiencies prior to submitting requests for registration actions.

Metric	Baseline	Target	Measurement Method
# of incomplete submissions	712 incomplete submissions in 2012	90% of electronic submissions are complete, within the first year of implementation	Number of incomplete submission received by the end of the first year of implementation

ID Objective

O-3 Increase throughput while decreasing the time & effort to process registration submissions
 By developing a paperless, automated registration process, the burden of processing, tracking and archiving large volumes of paper documentation would be eliminated. Currently, a large number of person years (PYs) within the Branch manage hard-copy documents. With a paperless application submission process, these resources could be redirected to more high-value data management, analysis and evaluation activities that would help reduce backlog in these areas.

Metric	Baseline	Target	Measurement Method
Key process measures and targets for each major core process	90 days for regular submission	60 days for regular submission, by the end of the third year of implementation	Evaluation timeframe report

ID Problems and Opportunities

BP-4 Inconsistent work practices and lack of standardized process execution

ID Objective

O-4 Establish measurable process performance targets and accountability as a Best Practice
 To help achieve its goal of effectively managing the pesticide registration process in California, the PRB must adopt streamlined and efficient processes that meet reasonable timelines. PRB needs to define and implement process performance targets and key performance indicators. Those indicators must be quantifiable measurements that allow PRB management to measure achievement of its performance targets as well as identify problem areas and process bottlenecks to more effectively reduce and handle exception processes and backlogs. The new system should provide key metrics regarding day-to-day work to more effectively manage business processes and workflow monitoring. Once performance metrics can be established, the PRB can quantify accountability.

Metric	Baseline	Target	Measurement Method
Adherence to standardized work practices	100% manual workflows and processes	100% electronic workflows to assign, track, and manage work, also provide internal controls and validations with standardized business rules	Workflow metrics and reports

ID Objective

O-5 Improve registration, communication and staff coordination processes
 A key component to the entire registration process is effective communication and coordination between PRB staff, Department staff and registrants. Improving communication and coordination through flexible and configurable workflow automation is a key goal for the Branch. Automated workflow would automatically route work and necessary data to employees and notify registrants on key events/activities/requests/updates. An automated workflow also eliminates the need to physically route submissions between stations and branches.

Metric	Baseline	Target	Measurement Method
Adherence to standardized work practices	100% manual workflows and processes	100% electronic workflows to assign, track, and manage work, also provide internal controls and validations with standardized business rules	Workflow metrics and reports

ID Objective

O-7 Improve training and provide intelligent work tools for employees
 A critical aspect to improved operations is through standardized training in order to address staff concerns that non-standardized training across units leads to inconsistent process execution. They should clarify existing policy guidelines and procedures and communicate clear expectations that all employees must consistently follow Branch procedures when completing their work. The ability of the system to provide management reporting better allows management to identify training opportunities for specific staff groups as well as focused training for individuals. PRB will better be able to explore ways to engage employees in training curriculum tailored to their specific professional objectives. Similarly, PRB would better be able to investigate methods to improve accountability and adhere to established standards and accepted performance objectives and time frames, and, in turn, provide recognition for high-performing employees. Furthermore, PRB should provide process support for staff through the implementation of automated, intelligent work tools and systems that incorporate PRB's business rules and guide the user step-by-step through each process. Based on the task being completed and specific user input, intelligent work tools (e.g., self-help) would lead employees through the process, prompting them with next steps and requesting required information at relevant points until the work is completed. Additionally, such systems can provide robust, context-sensitive help tools based on the task currently in process and provide links or access to relevant supporting documentation and resources such as California and Federal laws and regulations.

Metric	Baseline	Target	Measurement Method
Online tools and self-help	Minimal tools currently exist	Critical information available online for each key processing step	Links to critical information in new system

ID Problems and Opportunities

BP-5 Disparate, stand-alone tracking systems limit visibility of workload per station and staff and no single data source exists to register products

ID Objective

O-6 Centralize (electronically) company profile information, pesticide label data, scientific studies data and supporting documents
 A single, centralized product registration system to capture, track, process and archive new registration

submissions, pesticide label data, scientific studies, and supporting documents would greatly improve efficiencies and facilitate data sharing across all five core processes. By consolidating the existing 24 systems and databases, a centralized system would provide numerous benefits, such as eliminating duplicate data entry in multiple stand-alone systems and eliminating the risk of data entry errors. Also, a company and product management component of a new system will help improve the quality of company profile data, contacts and products. A consolidated system also allows staff to view data simultaneously from their desktops, rather than having to physically check out the limited number of hard copies of scientific studies and product labels.

Metric	Baseline	Target	Measurement Method
Centralized data available and assessable online	Less than 20% of information available online	100% of information available to staff by the end of the first year of implementation	Availability of information online
Key process metrics available real-time	Historical data and reports are created several months later	100% of key process and management metrics available real-time	Workload and performance metrics report available on-demand

ID Problems and Opportunities

BP-6 Staff are not consistently trained or need more ongoing training

ID Objective

O-7 **Improve training and provide intelligent work tools for employees**
 A critical aspect to improved operations is through standardized training in order to address staff concerns that non-standardized training across units leads to inconsistent process execution. They should clarify existing policy guidelines and procedures and communicate clear expectations that all employees must consistently follow Branch procedures when completing their work. The ability of the system to provide management reporting better allows management to identify training opportunities for specific staff groups as well as focused training for individuals. PRB will better be able to explore ways to engage employees in training curriculum tailored to their specific professional objectives. Similarly, PRB would better be able to investigate methods to improve accountability and adhere to established standards and accepted performance objectives and time frames, and, in turn, provide recognition for high-performing employees.

Metric	Baseline	Target	Measurement Method
Online tools and self-help	Minimal tools currently exist	Critical information available online for each key processing step	Links to critical information in new system

ID Problems and Opportunities

BP-7 Lack of Communication

ID Objective

O-5 **Improve registration, communication and staff coordination processes**
 A key component to the entire registration process is effective communication and coordination between PRB staff, Department staff and registrants. Improving communication and coordination through flexible

and configurable workflow automation is a key goal for the Branch. Automated workflow would automatically route work and necessary data to employees and notify registrants on key events/activities/requests/updates. An automated workflow also eliminates the need to physically route submissions between stations and branches.

Metric	Baseline	Target	Measurement Method
Provide daily, weekly and monthly management reports with key information	Limited management reports currently available	Standard reports automatically generated and disseminated	Performance metrics reports (daily, weekly, and monthly)

ID Problems and Opportunities

BP-8 Lack of Performance Measures and Accountability

ID Objective

O-4 **Establish measurable process performance targets and accountability as a Best Practice**

To help achieve its goal of effectively managing the pesticide registration process in California, the PRB must adopt streamlined and efficient processes that meet reasonable timelines. PRB needs to define and implement process performance targets and key performance indicators. Those indicators must be quantifiable measurements that allow PRB management to measure achievement of its performance targets as well as identify problem areas and process bottlenecks to more effectively reduce and handle exception processes and backlogs. The new system should provide key metrics regarding day-to-day work to more effectively manage business processes and workflow monitoring. Once performance metrics can be established, the PRB can quantify accountability.

Metric	Baseline	Target	Measurement Method
Key process measures and targets for each major core process	90 days for regular submission	60 days for regular submission, by the end of the third year of implementation	Evaluation timeframe report

ID Problems and Opportunities

BP-9 Lack of Rewards, Recognition and Feedback Linked to Process Performance

ID Objective

O-4 **Establish measurable process performance targets and accountability as a Best Practice**

To help achieve its goal of effectively managing the pesticide registration process in California, the PRB must adopt streamlined and efficient processes that meet reasonable timelines. PRB needs to define and implement process performance targets and key performance indicators. Those indicators must be quantifiable measurements that allow PRB management to measure achievement of its performance targets as well as identify problem areas and process bottlenecks to more effectively reduce and handle exception processes and backlogs. The new system should provide key metrics regarding day-to-day work to more effectively manage business processes and workflow monitoring. Once performance metrics can be established, the PRB can quantify accountability.

Metric	Baseline	Target	Measurement Method
Individual development plans and performance linked directly to	0% of current Individual	100% of Individual Development Plans	Count of Individual Development Plans

process targets

Development Plans linked to process metrics and performance

link and cite personal goals that align with process goals, by the end of the third year of implementation

complete with performance metrics aligned with business process metrics

ID Objective

O-7 Improve training and provide intelligent work tools for employees

A critical aspect to improved operations is through standardized training in order to address staff concerns that non-standardized training across units leads to inconsistent process execution. They should clarify existing policy guidelines and procedures and communicate clear expectations that all employees must consistently follow Branch procedures when completing their work. The ability of the system to provide management reporting better allows management to identify training opportunities for specific staff groups as well as focused training for individuals. PRB will better be able to explore ways to engage employees in training curriculum tailored to their specific professional objectives. Similarly, PRB would better be able to investigate methods to improve accountability and adhere to established standards and accepted performance objectives and time frames, and, in turn, provide recognition for high-performing employees.

Metric	Baseline	Target	Measurement Method
Online tools and self-help	Minimal tools currently exist	Critical information available online for each key processing step	Links to critical information in new system

1.6 Strategic Business Alignment

Strategic Business Goals

Alignment

DPR Strategic Plan
Goal 1 – Protect People and the Environment

Goal 1 of DPR’s Strategic Plan focuses on assuring California’s environment is not adversely affected by pesticides and that all people are protected from unacceptable pesticide risks. The PRB plays a key role in assuring that pesticide products that are available for use in California do not pose an unacceptable risk. The proposed solution enables PRB to help the Department fulfill this goal by improving the evaluation process and disseminating information to other branches and external stakeholders that are responsible for product monitoring, enforcement, and emergency response activities.
The RP² would address problems BP-1, 2, 4, 5, and 7 stated in Sections 1.4 and 1.5, which is in alignment with the DPR’s Goal 1, and five associated objectives.

DPR Strategic Plan
Goal 2 –Advance Reduced-Risk Pest Management Systems

Goal 2 of DPR’s Strategic Plan focuses on advancing the research, development and adoption of effective pest management systems that reduce risks to people and the environment. The current manual-intensive pesticide registration business processes result in inefficiencies and lack of communication amongst key stakeholders. The proposed solution provides for access to centralized data, allowing various stakeholders to access and utilize the pesticide product information to perform various evaluations and analyses.
The RP² would address problems BP-1, 2, 4, and 5 stated

<p>DPR Strategic Plan Goal 3 –Enforce and Achieve Compliance</p>	<p>in Sections 1.4 and 1.5, which is in alignment with the DPR's Goal 2, and three associated objectives.</p> <p>Goal 3 of DPR's Strategic Plan focuses on maintaining and continuously improving strong and equitable compliance and enforcement programs to ensure people and the environment are not exposed to unacceptable pesticide risks. The proposed solution provides for the PRB to better perform registration activities; communicate requirements and status to registrants; disseminate information to stakeholders for enforcement; and readily provide access to pesticide registration data for ongoing data reviews.</p> <p>The RP² would address problems BP-2, 3, 6, and 7 stated in Sections 1.4 and 1.5, which is in alignment with the DPR's Goal 3, and three associated objectives.</p>
<p>DPR Strategic Plan Goal 4 –Ensure Environmental Justice</p>	<p>Goal 4 of DPR's Strategic Plan focuses on protecting all people in California, regardless of race, age, culture, income, or geographic location, from adverse environmental and health effects of pesticides. The RP² project will increase the PRB's ability to communicate with internal and external stakeholders, providing vital information regarding pesticides. In part, stakeholders groups will still receive communications regarding registrations, reevaluations, and other critical activities, allowing stakeholders the opportunity to respond.</p> <p>The RP² would address problems BP-2 and BP-7 stated in Sections 1.4 and 1.5, which is in alignment with the DPR's Goal 4, especially related to maintaining transparency and effectiveness in public participation through the use of advisory committees, workshops, and other forums.</p>
<p>DPR Strategic Plan Goal 5 – Continuously Improve Performance, Accountability, and Organizational Effectiveness</p>	<p>Goal 5 of DPR's Strategic Plan focuses on efficiently delivering programs by attracting and retaining a competent workforce, effective business processes, and use of current technology. As staff identified in the branch-wide survey, they desire increased and effective training, and consistency in processing submissions. The proposed solution promotes development and sustainment of highly skilled PRB staff that are valued and encouraged to grow professionally. The effort also supports the DPR's objectives to implement and maintain effective information system to support the program and accurately capture data that may be used to forecast trends, account for performance, and assess the ability to meet future program needs.</p> <p>The RP² would address problems BP-1, 2, 4, 5, 6, 8, and 9 stated in Sections 1.4 and 1.5, which is in alignment with the DPR's Goal 5, and seven associated objectives.</p>
<p>DPR Strategic Plan Goal 6 –Communication and Outreach</p>	<p>Goal 6 of DPR's Strategic Plan focuses on promoting an understanding and awareness of DPR programs, priorities, initiatives, and accomplishments through</p>

effective external communications, outreach, and public education. This proposed solution includes utilizing the DPR website and other media to convey pesticide information, including making key pesticide label information readily available so that household, and institutional and agricultural pesticide product users, specifically regarding safe, appropriate, and effective use.

The RP² would address problems BP-2 and 7 stated in Sections 1.4 and 1.5, which is in alignment with the DPR's Goal 6, and three associated objectives.