Approved by OMB[1]
Control No. 3150-0183
Expires 01/31/2020

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
QUESTIONNAIRE RESPONSE (10/7/19)

Reporting Period: October 10, 2015 – October 25, 2019

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer, if appropriate.

A. GENERAL

1. Please prepare a summary of the status of the State's or Region's actions taken in response to each of the open recommendations from previous IMPEP reviews.

[CDPH-RHB contacts: Ira Schneider/ John Fassell]

- *2015 IMPEP Recommendation: Develop and implement an action plan to complete pending SS&D transfer actions in a timely manner to ensure consistency and clarity in the licensing of the registered sources/devices across all jurisdictions.*

  An action plan was developed and implemented to transfer the nine remaining SS&D transfers in a timely manner by a pair of license reviewers. All transfer actions were completed by 11/8/16.

- *2015 IMPEP Recommendation: Develop and implement a procedure for reviewing the implementation of the SS&D manufacturer/distributor's quality assurance and quality control program commitments during an onsite inspection.*

  An inspection procedure was developed and first implemented in late 2015. To date, 17 of 21 active SS&D manufacturers/distributors have been inspected using the SS&D inspection procedure, with the remaining 4 to be inspected at their next routine inspection. An additional 6 inactive SS&D manufacturers/distributors will be inspected after the active SS&D manufacturers/distributors are inspected or when they reactivate their SS&D manufacturing/distribution. ***Attachment Q1*** *is a listing of SS&D manufacturers/distributors.*

B. COMMON PERFORMANCE INDICATORS

I. Technical Staffing and Training

2. Please provide the following organization charts, including names and positions:
   (a) A chart showing positions from the Governor down to the Radiation Control Program Director;

[1]Estimated burden per response to comply with this voluntary collection request: 53 hours. Forward comments regarding burden estimate to the Records Management Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0183), Office of Management and Budget, Washington, DC 20503. If an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

(b) A chart showing positions of the radiation control program, including management; and

[CDPH-RHB contact: Tony Andres]

*See **Attachment Q2***

(c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.

*The SS&D program is supervised by the Licensing Projects Unit (LPU) Senior HP within the Licensing Section, but utilizes additional Licensing staff (see **Attachment Q2** and Questionnaire item 30).*

CA does not have low level radioactive waste or uranium recovery programs.

3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, low-level radioactive waste, uranium recovery, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

Name	Position	Area of Effort	FTE%

[CDPH-RHB contacts: Tony Andres, Ira Schneider, John Fassell, Phil Scott]

*Radioactive materials program technical staff names, positions, and areas of effort are shown in the last four charts in **Attachment Q2** (Radiologic Health Branch, Licensing Section; Inspection, Compliance and Enforcement Section; and Strategic Planning and Quality assurance Section).*

The Radiologic Health Branch (RHB) chart shows the RHB program managers plus a full-time position funded by RHB in our state radiation laboratory for analyzing radiological samples. The Branch Chief's time is split approximately equally between RAM and X-Ray. The state laboratory position is devoted 100% to the RAM program.

The Radioactive Materials Licensing Section chart shows the RAM licensing technical staff (Medical Unit, Licensing Projects Unit, and Industrial & General License Unit) and technical support staff (Special Projects and Support Unit). These staff are devoted 100% to the RAM program.

The Inspection, Compliance & Enforcement Section, Radioactive Materials chart shows the RAM compliance technical staff and one support staff member (Mgmt. Services Technician Farm Saephan). These staff are devoted 100% to the RAM program. This chart also shows RAM technical staff in the Los Angeles County and San Diego County programs, which operate under contract to RHB to perform inspection and investigation activities within their respective counties. The technical FTE's funded by RHB in the two counties devoted to the RAM program are: 1) LA County - 1 supervisor and 3 inspector FTE and 2) SD County - 1 supervisor and 1 inspector FTE. The SD County supervisor performs RAM inspections in addition to supervisory duties, and the SD County inspector splits time between RAM and X-ray inspections.

The Strategic Planning & Quality Assurance Section shows other technical and support staff involved in the RAM program. The Radiological Assessment Unit is devoted 100% to RAM. The Regulations Unit is devoted to both RAM and X-ray on an approximately equal basis. The Enforcement and Compliance Unit is devoted predominantly to X-ray.

Emergency response for RAM is part of the HP inspectors' job duties. Emergency preparedness for nuclear power plants is located in a separate Branch within the California Department of Public Health (CDPH). RAM technical staff are called upon on as needed to participate in nuclear power plant emergency preparedness exercises, which amounts to approximately 1% of the total RAM inspector and reviewer time.

CDPH does not have low level radioactive waste or uranium recovery programs.

No consultants were used in the RAM program during the IMPEP period.

4. Please provide a listing of all new professional personnel hired into your radioactive materials program since the last review, indicate the date of hire; the degree(s) they received, if applicable; additional training; and years of experience in health physics or other disciplines, as appropriate.

[CDPH-RHB contacts: Tony Andres, Ira Schneider, John Fassell]

New Staff since October 10, 2015:

Tracy Jue – Associate HP (Licensing)
April 2018
B.S., Health Physics
10 years Environmental Management Branch previous experience in CDPH

Patrick Fassell – Junior HP (Licensing)
August 2018
B.S., Nano Engineering/Marine Biology
No previous HP experience

Bradley Loomis - Associate HP (Radiological Assessment)
April 2019
B.S., Applied Physics
6 years of X-ray enforcement/investigation previous experience in RHB

Davood Aboudarda – Associate HP (Inspection)
December 2017
B.S. Physics/App Math
4 years X-ray licensing/Registration previous experience in RHB

Gregg Cohn – Associate HP (Inspection)
December 2016
B.S., Health Physics
30 years previous experience in RAM/X-ray at AS (FL – RAM and X-ray), nuclear power plant, universities (RSO) and RHB (X-ray) programs

Carlin Harkness – Assistant HP (Inspection)
June 2017
B.S., Chemistry
No previous HP experience

Ana Casaje – Associate HP (Inspection, LA County)
January 2017
B.S., Radiologic Technology
10 years of X-ray experience with LA County

Tracy Au – Associate HP (Inspection, LA County)
October 2018
B.S., Radiologic Technology
9 years of X-ray Experience with LA County

Truyen Nguyen – Health Program Specialist I (Regulations)
November 2016
No degree (working on Business undergraduate degree)

Zyra Baron Health Program Specialist I (Regulations)
October 2018
B.A/B.S. Nursing

5. Please list all professional staff who have not yet met the qualification requirements for a radioactive materials license reviewer or inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements.

[CDPH-RHB contacts: Ira Schneider, John Fassell, Rob Greger]

All license reviewers and inspectors are qualified to perform a minimum of one type of license review/inspection, and some license reviewers and inspectors are qualified to perform multiple types of license reviews/inspections. Training for additional types of license review/inspection areas are pursued on an as available/needed basis to allow for current and future needs. We progress most license reviewers and inspectors through the full range of license reviewer or inspection qualifications.

*See **Attachment Q5** for inspection-specific qualification status and refresher training status.*

License reviewer-specific qualification status and refresher training status are as follows.

All technical Licensing staff work under the supervision of a Senior Health Physicist who oversees their work product. Informal on-the-job training is used extensively to allow reviewers and inspectors to be productive if formal training is delayed. As classes are announced, RHB sends staff to formal training as space is made available to us, and as out-of-state travel is authorized by the state. RHB remains interested in bringing NRC training to the State of California, since we have such a large professional staff and authorization for out-of-state travel can be an issue irrespective of the funding source.

License reviewers are assigned to specific types of licensing reviews, rather than being all-purpose reviewers. The training required for particular types of license reviewers is defined in our training procedure. During the training process, their work is closely reviewed by a qualified reviewer or supervisor. Training needs for each license reviewer

are evaluated each year and the individual is nominated to attend NRC course(s) deemed as reviewer core course(s). In lieu of attending the NRC course(s) each reviewer can attend an equivalent course or undergo on-the-job training (OJT) for the specific core material for which they had not yet had the opportunity to attend the NRC course. OJT is given by a core qualified peer reviewer or the core qualified supervisor. The work assignments of license reviewers who are not yet considered fully qualified are limited to selected licensing matters within their licensing unit for which they have demonstrated proficiency through on-the-job training.

Required refresher training during the IMPEP period has been successfully completed for the first half of the IMPEP period; however, due to extenuating circumstances, one license reviewer has not yet successfully completed the refresher training requirements for the second half of the IMPEP period.

The following license reviewers require the additional training shown to meet our full qualification requirements for the types of licenses they are assigned to review.

<u>Medical, Academic and Pharmacy Licensing Unit:</u>

Brian Goode
Transportation (applied for on-line class)
Jennifer Granger
Transportation (applied for on-line class)
Tracy Jue
Sealed Source and Device Evaluation

<u>Industrial Licensing Unit:</u>

Robert Custodio (supervisor)
H-315 Irradiator Technology
Rajwant Bedi
H-315 Irradiator Technology
Prem Gambhir
H-315 Irradiator Technology
Beverly Hill
H-315 Irradiator Technology
Scott Landry
H-315 Irradiator Technology
NRC Course for Sealed Source and Device Evaluations
Kevin Quach
G-109 Licensing Practices and Procedures
H-305 Safety Aspects of Industrial Radiography
John Rexroth
H-315 Irradiator Technology

<u>Licensing Project Unit:</u>

Kristina De Leon
H-315 Irradiator Technology
Thomas Moore
H-315 Irradiator Technology
Vandana Kohli
H-315 Irradiator Technology
Patrick Fassell
Transportation

H-315 Irradiator Technology
Mina Goeders
H-315 Irradiator Technology

Large Scale Decommissioning:

Debora Vail
Decommissioning of RAM Facilities
RESRAD
Jennifer Grainger
Decommissioning of RAM Facilities
Brain Goode
Decommissioning of RAM Facilities
MARSSIM
Jennifer Cho
Decommissioning of RAM Facilities
MARSSIM
Carol Rexroth
Decommissioning of RAM Facilities
Tracy Jue
Decommissioning of RAM Facilities
Scott Landry
Decommissioning of RAM Facilities
MARSSIM
RESRAD
Kevin Quach
Decommissioning of RAM Facilities
MARSSIM
RESRAD
Patrick Fassell
MARSSIM
RESRAD

6. Identify any changes to your qualification and training procedure that occurred during the review period.

[CDPH-RHB contacts: Ira Schneider, Rob Greger]

There have been no Licensing changes to qualification/training procedures.

Inspection changes to qualification/training procedures were made regarding:

- *Clarification of the need for 24 hours refresher training per each 24-month period of IMPEP cycle*
- *Changes to reflect transition from IC Orders to Part 37*

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7. Please identify the technical staff that left your radioactive materials program during the review period and indicate the date they left.

CDPH-RHB contact Tony Andres/Ira Schneider/John Fassell

Steve Hsu (Supervising HP, licensing) December 2016 (retired)

Ron Rogus (Senior HP, licensing) – September 2019 (retired)

Victoria Brandt (Associate HP, RAU) December 2016 (resigned)

Jeff Wong (Associate HP, RAU) November 2018 (retired)

Roger Lupo (Senior HP, RAU) December 2018 (retired)

James Thomas (Associate HP, RAU), October 2019 (retired)

Eugene Forrer (Associate HP, inspection) – April 2016 (resigned)

Donelle Krajewski (Associate HP, inspection) – September 2016 (retired)

Kenneth Furey (Associate HP, Inspection) – October 2019 (retired)

*Tanya Ridgle (Associate HP, inspection, LA County) – 2017 (reassigned)**

*Joji Ortego (Associate HP, inspection, LA County) – 2019 (reassigned)**

Corine Amato (Health Program Specialist I, Regulations) – April 2016 (retired)

Leo Spencer (Associate HP, Regulations) – December 2016 (retired)

Brandy Caldeira (Health Program Specialist I, Regulations) – December 2016 (vacated)

** Still with LA County and available to occasionally assist in RAM work*

8. List any vacant positions in your radioactive materials program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

[CDPH-RHB contact: Tony Andres]

Licensing (1 Supervisor):
Senior Health Physicist; officially vacated September 2019 – recruitment in progress.

Inspection, Compliance, & Enforcement RAM (1 Inspector):
Associate Health Physicist; officially vacated position October 2019 – Program is reviewing duty statement.

Strategic Planning & Quality Assurance (1 Manager):
Supervising Health Physicist; officially vacated December 2016 – Program is reviewing duty statement.

Radiological Assessment Unit (3 HPs):
Associate Health Physicist; position vacated September 2019 – Program is reviewing duty statement.
Associate Health Physicist; position vacated November 2018 – Recruitment in progress
Associate Health Physicist; position vacated October 2019 – Program is reviewing duty statement .

Regulations (1 HP):
Associate Health Physicist; officially vacated December 2016 – Program is reviewing duty statement.

Licensing (2 Special Projects and Support technical support positions):
Program Technician II; officially vacated July 2019 – Program is reviewing duty statement
Associate Government Program Analyst; officially vacated December 2016 – Program is reviewing duty statement.

9. For Agreement States, does your program have an oversight board or committee that provides direction to the program and is composed of licensees and/or members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.

[CDPH-RHB contact: Gonzalo Perez]

Not at present. We had a Nuclear Medicine Council that provided oversight of our medical activities, but that group has not been active for in excess of 10 years.

II, Status of Materials Inspection Program

10. Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC's Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: license category or licensee name and license number, your inspection interval, and rationale for the difference.

[CDPH-RHB contacts: Ira Schneider, John Fassell, Rob Greger]

None

11. Please provide the number of routine inspections of Priority 1, 2, and 3 licensees, as defined in IMC 2800 and the number of initial inspections that were completed during each year of the review period.

[CDPH-RHB contact: Rob Greger]

Number of Routine Priority 1, 2, & 3 Inspections (11/10/15-~10/1/19):

2015	*Priority 1 = 9*	*Priority 2 = 16*	*Priority 3 = 26*
2016	*Priority 1 = 29*	*Priority 2 = 87*	*Priority 3 = 81*
2017	*Priority 1 = 29*	*Priority 2 = 67*	*Priority 3 = 69*
2018	*Priority 1 = 23*	*Priority 2 = 84*	*Priority 3 = 93*
2019	*Priority 1 = 24*	*Priority 2 = 67*	*Priority 3 = 65*

Number of Initial Inspections Completed (11/10/15-10/1/19)

2015 = 14
2016= 32
2017 = 35
2018 = 34

Total Priority 1-3 + Initial Inspections Completed (11/10/15-10/1/19):

2015 = 65
2016= 229
2017 = 200
2018 = 234

2019 = 29 *2019 = 185*
Total = 913

Note- The 2019 #s will increase somewhat with additional completion results from September, and later with the October inspections.

12. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees and initial inspections that were conducted overdue.

At a minimum, the list should include the following information for each inspection that was conducted overdue during the review period:

(1) Licensee Name
(2) License Number
(3) Priority (IMC 2800)
(4) Last inspection date or license issuance date, if initial inspection
(5) Date Due
(6) Date Performed
(7) Amount of Time Overdue
(8) Date inspection findings issued

[CDPH-RHB contacts: John Fassell, Rob Greger]

Overdue priority 1-3 + initial inspections for the period 10/10/19-10/25/19 is expected to be 10, which is approximately 1% of the total priority 1-3 + initial inspections conducted over that period.

*See **Attachments Q12***

13. Please submit a table or computer printout that identifies any Priority 1, 2, and 3 licensees and initial inspections that are currently overdue, per IMC 2800. At a minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection. Also include your plan for completing the overdue inspections.

CDPH-RHB contact: Rob Greger

No priority 1, 2, or 3, or initial inspections are anticipated to be overdue as of October 25, 2019.

14. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and indicate the number of reciprocity inspections of candidate licensees that were completed each year during the review period.

CDPH-RHB contact: Rob Greger]

CANDIDATE RECIPROCITY INSPECTIONS (only those not inspected previous year)

Priority 1 – 3	*2015*	*2016*	*2017*	*2018*	*2019 (to 10/1)*
#. Worked in CA	*18*	*17*	*19*	*15*	*11*
# Inspected	*7*	*8*	*9*	*5*	*3*
% Inspected	***38.9%***	***47.1%***	***47.4%***	***33.3%***	***27.3%***
Priority 5 – 6					

#. Worked in CA	*6*	*9*	*15*	*20*	*17*
#. Inspected	*1*	*3*	*8*	*5*	*2*

III. Technical Quality of Inspections

15. What, if any, changes were made to your written inspection procedures during the reporting period?

[CDPH-RHB contact: Rob Greger]

Inspection procedures changes were made regarding:

- *Safety culture*
- *Pre-licensing visits*
- *Incorporate 9/12/17 changes to NRC Inspection Manual 2800*
- *Vacating installations guidance*

16. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

Inspector Supervisor License Category Date

[*CDPH-RHB contact: Rob Greger]*

*See **Attachment Q16***

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17. Describe or provide an update on your instrumentation, methods of calibration, and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available throughout the review period?

[CDPH-RHB Contact: John Fassell].

RHB maintains an ample supply of calibrated survey instruments to support inspectors in the field. Calibrations and repairs of all instruments are provided through a contract with a California licensed calibration service provider (Occupational Services, Inc.).

Each inspector has the following survey instruments/detectors available to them:

- *Energy compensated GM or ion chamber*
- *Pancake GM probe*
- *Low energy NaI (Tl) probe (thin)*
- *High energy NaI(Tl) probe (1x1)*
- *Alpha scintillation probe*
- *Beta scintillation probe (optional)*
- *Micro R meter*
- *Wipe counter (located in each inspection office)*
- *Portable multi-channel analyzer (MCA)*

Since the portable MCAs are only used for qualitative identification, they are not routinely calibrated. All other survey instruments are calibrated annually.

IV. Technical Quality of Licensing Actions

18. How many specific radioactive material licenses does your program regulate at this time?

[CDPH-RHB Contact: Ira Schneider]

As of October 1, 2019, California administers 1708 radioactive materials licenses.

19. Please identify any major, unusual, or complex licenses that were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.

[CDPH-RHB Contact: Ira Schneider]

UCLA - Lic # 1335 – Viewray
UCLA – Lic # 1335 – Broadscope renewal
Sutter (Sacramento) – Lic # 2964 - ICON GSR
UC Davis – Lic # 1345 – Broadscope renewal
UCSF – Lic # 1725 – Broadscope renewal
**MP Mine Operations (MPMO); formerly Molycorp - Lic # 3229 – Complex Decommissioning*
***Chevron Environmental Management - Lic # 7747 – Unusual License*

**MP Mine Operation is an unusual license. The licensee is a rare earth mining and processing site that initiated bankruptcy in mid-2015. Tens of thousands of tons of unsealed radioactively contaminated materials (mostly radium and thorium) are located at several staging areas. Some buildings, tanks, and piping are radioactively contaminated. The site is subject to multiple regulatory jurisdictions. The bankruptcy, which was followed closely by LPU staff and the RHB attorney, and which took significant LPU and legal staff resources, resulted in an ownership change to MPMO. Licensing staff did two onsite inspections, and a scoping survey was conducted in 2018. Currently, a critical issue is the legal analysis of proposed on-site mixing and burial of radium and source material as well as the funding amount of MPMO's DFP.*

***Chevron is an unusual license. Chevron is a radioactively contaminated area in California and is located several miles from MPMO. Like the MPMO site, the Chevron site also has radium and source material. There are thousands of tons of this unsealed radioactive material. RAU performed a scoping survey in 2018. Currently, a critical issue is the legal analysis of proposed on-site burial of these materials as well as the funding amount of the needed DFP.*

20. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

[Contact: Ira Schneider]

None

21. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

[CDPH-RHB Contact: Ira Schneider]

*See **Attachment Q21***

22. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

[CDPH-RHB Contact: Ira Schneider]

*See **Attachment Q22** for list of renewal applications pending for one year or more.*

Reasons for license renewal backlog:

At the time of the 2015 IMPEP, Licensing was still recovering from the effects of a previous state worker furlough program. The average loss of available FTE over the furlough program duration (approximately 5 years) was approximately 10%. During that period we deemed it more important to address license amendment requests than license renewals, which resulted in a backlog of 209 renewals at the time of the 2015 IMPEP. Subsequent to the 2015 IMPEP, we have been able to reduce the renewal backlog to the current 128 number. The current renewal backlog would have been reduced further but for the redirecting of Licensing staff to an extensive survey of Hunters Point in response to citizen and local government concerns. This project resulted in the loss of approximately 1 FTE for Licensing. Licensing had projected being caught up with the renewal backlog within three years of the 2015 IMPEP; however, due to the Hunters Point staff redirection, as well as the original Licensing action plan to reduce the backlog not being as successful as anticipated, the backlog remains at 128.

Action plan to reduce license renewal backlog:

A new plan was implemented that assessed workload, redirected resources and flattened fluctuations in future renewal processing while maintaining maximum resource utilization. Routine Licensing workloads were forecast out to a four-year period in order to help guide the redeployment of resources in the most effective and efficient manner. Additionally, Licensing will utilize information technology to redesign the renewal process to minimize process inefficiencies. At the current licensing pace, with no further significant disruptions to RML operations, we anticipate the backlog to be significantly reduced within approximately 2 years.

V. Technical Quality of Incident and Allegation Activities

23. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

Licensee Name	License #	Date of Incident/Report	Type of Incident

[CDPH-RHB Contact: Rob Greger]

None to our knowledge

24. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

[CDPH-RHB Contact: Rob Greger]

Only non-substantial changes were made to our incidents and allegations reporting procedures.

C. NON-COMMON PERFORMANCE INDICATORS

I. Compatibility Requirements

25. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.

[CDPH-RHB Contact: Phil Scott]

a) Radiation Control Law (Health & Saf. Code, §§114960 et seq.)

b) Radiation Protection Act of 1999 (Health & Saf. Code, §§114650 et seq.)

c) Containment of Radioactive Materials (Health & Saf. Code, §§114705 et seq.)

d) No legislation relating to activities subject to IMPEP was enacted or amended during the review period.

26. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

[CDPH-RHB Contact: Phil Scott]

The Radiation Control Regulations are not subject to a "Sunset" or equivalent law.

27. Please review and verify that the information in the enclosed State Regulation Status (SRS) sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them. If legally binding requirements were used in lieu of regulations and they have not been reviewed by NRC for compatibility, please describe their use.

[CDPH-RHB Contact: Phil Scott]

*See **Attachment Q27** (State Reg Status-07302019)*

28. If you have not adopted all amendments within 3 years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

[CDPH-RHB Contact: Phil Scott]

All proposed regulations must be approved by CDPH' Office of Regulations (CDPH-OR) and by a separate California state agency, the Office of Administrative Law (OAL). Please see the following attached documents, which describe the procedures followed by the two offices:

*1. CDPH Rulemaking Process Map Flowchart – See **Attachment Q28-1** (CDPH-Flowchart)*
*2. CDPH Regulatory Process Steps **– See Attachment Q28-2** (RegulatoryProcessSteps)*
*3. CDPH Office of Regulations and Hearings Action Plans – See **Attachments Q28-3A and Q28-3B** (RegActionPlan and EmergencyActionPlan)*
*4. How to Participate in the Rulemaking Process (from Office of Administrative Law) – See **Attachment Q28-4** (HowToParticipate)*

The following is a list of other state laws that must also be considered during regulation promulgation:

- *Public Records Act*
- *Information Practices Act*
- *Bagley-Keen Open Meeting Act*
- *State Records Management Act*
- *Government Code, §§17500-17613*
- *State Building Standards Law*
- *Suspension of statutes, rules and regulations during state of emergency*

A copy of the above identified regulations and laws are available on request.

II. Sealed Source and Device (SS&D) Evaluation Program

29. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of sources and devices issued during the review period. The table heading should be:

SS&D Registry Number	Manufacturer, Distributor or Custom User	Product Type or Use	Date Issued	Type of Action

[CDPH-RHB Contact: Ira Schneider]

*See **Attachment Q29***

30. Please include information on the following questions in Section A, as they apply to the SS&D Program:

[Contact: Ira Schneider]

SS&D Technical Staffing and Training –

See responses to Questions 2-9
Additionally, the following individuals have performed SS&D work in the current IMPEP period:
Ron Rogus: Level 2 reviewer

John Fassell: Level 2 reviewer
Hugh Alsworth: Level 2 reviewer
Kristina Deleon: Level 2 reviewer
Vandana Kohli: Level 2 reviewer
Mina Goeders: Level 2 reviewer
Kevin Quach: Level 1 reviewer
Patrick Fassell: in training

Technical Quality of Licensing Actions –

See responses to Questions 18-22.
Additionally, there are 23 active SS&D licensees, with 206 active SS&Ds.

Technical Quality of Incident and Allegation Activities –

See responses to Questions 23-24.

III. Low-level Radioactive Waste Disposal Program

31. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

Not applicable to CDPH/RHB.

IV. Uranium Recovery Program

32. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

Not applicable to CDPH/RHB

Attach Q1
Licensed SS&D Manufacturers/Distributors (9/25/2019)

Active Licensees

1. License # 1777 SS&D program inspected 1/7/19
2. License #1509 SS&D program Inspected 9/10/19
3. License # 0017 SS&D program inspected 10/29/18
4. License #1100 SS&D program inspected 12/5/16
5. License #1288 SS&D program NOT inspected Inspection due date 1/21/20
6. License # 1389 SS&D program inspected 1/15/18
7. License # 1451 SS&D program inspected 10/3/19
8. License # 1673 SS&D program inspected 12/28/18
9. License # 2229 SS&D program inspected 10/26/18
10. License # 2290 SS&D program inspected 7/8/19
11. License # 7873 SS&D program inspected 11/9/17
12. License # 3755 SS&D program inspected 6/28/17
13. License # 3775 SS&D program inspected 10/23/17
14. License # 4147 SS&D program NOT inspected Inspection due date 6/29/20
15. License # 5497 SS&D program inspected 10/16/18
16. License # 6621 SS&D program NOT inspected Inspection due date 2/12/20
17. License # 6663 SS&D program NOT inspected Inspection due date 3/23/20
18. License # 7362 SS&D program inspected 12/28/17
19. License # 7947 SS&D program inspected 2/21/19
20. License # 7972 SS&D program inspected 12/10/15
21. License # 6875 SS&D program inspected 5/2/19

Future Licensees

License # 7924 not issued yet

Inactive Licensees

License # 3925 Inspected 6/7/19 No SSD manufacturing per Item 24 on checklist
License # 0441 Inspected 6/7/19 No SSD manufacturing per Item 24 on checklist
License # 4143 Inspected 6/7/19 No SSD manufacturing per Item 24 on checklist
License # 0145 Inspected 6/7/19 No SSD manufacturing per Item 24 on checklist
License # 1025 Inspected 1/30/18 No SSD manufacturing per Item 24 on checklist
License # 7845 No longer manufactures the SSD

Attachment Q5 - ICE QUALIFICATION STATUS CURRENT (Updated 10/7/19)

NAME	Start mo/y	PRE REQ	BASIC	Gauge Minor	MED 100-300	MED 400, 600	NON-MED	IC	IND RAD	WELL LOG	POOL IRR	BROAD SCOPE	DECOMM
Hewadikaram, Nika	8/00	OK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes
Furey, Ken	11/86	OK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes
Mekuria, Ephrime	2/07	OK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes
Cohn, Gregg	12/16	OK	Yes	Yes	Yes	Yes	Yes	Yes	**No**	**No**	**No**	Yes	**No**
Aboudarda, Davood	12/17	OK	Yes	Yes	Yes	Yes	Yes	Yes	**No**	**No**	**No**	**No**	**No**
Oesterle, Don	6/96	OK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes
Harkness, Kathi	5/06	OK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes
Taylor, Andrew	1/06	OK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes
Rook, Alan	11/10	OK	Yes	Yes	**No**	Yes	Yes	Yes	Yes	Yes	**No**	**No**	Yes
Harkness, Carlin	6/17	OK	Yes	Yes	**No**	**No**	**No**	**No**	**No**	**No**	**No**	**No**	**No**
Day, Jeff	10/10	OK	Yes	Yes	Yes	Yes	Yes	Yes	NA	NA	NA	Yes	Yes
Miko, Tom	9/11	OK	Waived	Yes	Yes	Yes	Yes	Yes	NA	NA	NA	Yes	Yes
Casaje, Ana	1/17	OK	Yes	Yes	Yes	Yes	Yes	**No**	NA	NA	NA	**No**	**No**
Au, Tracy	10/18	OK	Waived	**No**	Yes	**No**	**No**	**No**	**No**	**No**	**No**	**No**	**No**
**Ortego, Joji	5/05	OK	Yes	Yes	Yes	Yes	Yes	Yes	NA	NA	NA	Yes	Yes
**Ridgle, Tanya	2/12	OK	Yes	Yes	Yes	Yes	Yes	Yes	NA	NA	NA	Yes	Yes
Yonemitsu, Ron	?/0?	OK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	NA	NA	**No**
Tawatao, James	10/11	OK	Yes	**No**	Yes	**No**	**No**	**No**	**No**	NA	NA	NA	**No**
Greger, Rob	7/98	OK	Yes	Yes	Yes	Yes	Yes	Yes	**No**	**No**	Yes*	Yes	Yes

Retired/Resigned during IMPEP period: G Forrer (4/16); D Krajewski (9/16), Ken Furey (10/19) *lack training course **J Ortego and T. Ridgle reassigned but available for occasional inspections/investigations

FORMAL TRAIING COURSES for above qualification categories:
Basic inspector qualification - Inspection Procedures (G-108), Transportation of Radioactive Materials (H-308); OSHA Hazmat
Gauge/Minor qualification - None (although vendor portable gauge course desirable)
Medical (35.100, 35.200, 35.300, 35.500) – Diagnostic and Therapeutic Nuclear Medicine (H-304)
Other Medical (35.400, 35.600, 35.1000) – Brachytherapy, Gamma Knife, and Emerging Technologies (H-313)
IC (Increased Controls) - Materials Control and Security Systems and Principles (S-201)
Industrial Radiography - Industrial Radiography (H-305)
Well Logging - Well Logging (H-314)
Pool Irradiators – Irradiator Technology (H-315)
Broad Scope - Environmental Monitoring (H-111), Advanced Health Physics (H-201). **[H-201 requires completion of Fundamental Health Physics Self-Study Course (H-122S) ≥ 30 days prior to H-201 course.]**
Decommissioning – MARSSIM (H-121), Radiological Surveys in Support of Decommissioning (ORAU)
Root Cause Workshop (G-205)

PRE-REQUISITE TRAINING (optional based on individual):
Introductory Health Physics (H-117), and/or Fundamental Health Physics I & II (H-122), and/or fundamental Health Physics III (H-123), and/or Gollnick

SUPPLEMENTAL TRAINING COURSES (optional):
Air Sampling (H-119), Internal Dosimetry and Whole Body Counting (H-312), RESRAD (H-410), RESRAD-OFFSITE (H-411), Visual Sampling Plan (H-500), MARSAME (H-120), Health Physics Topics (H-401), Licensing Practices and Procedures (G-109), Respiratory Protection (H-311),

REFRESHER TRAINING (required both 1st and 2nd half of 4-year IMPEP cycle)
Any of the above FORMAL or SUPPLEMENTAL training courses (does not have to be in addition to training courses taken for qualification) can be used to meet the refresher training criterion of 24 hours training per 24 months.
Refresher training can consist of: 1) NRC sponsored technical training; 2) State sponsored technical training; 3) webinars sponsored by NRC, States, or vendors; 4) external training courses provided by vendors or universities; 5) lectures given at professional organizations; 6) State developed presentations on subjects related to health and safety, security or regulation of radioactive materials; 7) directed self-study; or 8) other training approved by the ICE Senior and Supervising Health Physicist.

REFRESHER TRAINING (24 hours required every 2 years per FSME-13-043, IMC 1248, STC-15-069)

	First 2 Yrs of IMPEP Cycle 10/15-9/17		Last 2 Yrs of IMPEP Cycle 10/17-9/19	
NAME	**Training**	**# Hours**	**Training**	**# Hours**
Hewadikaram, Nika				
Furey, Ken	Pre-licensing, Radium, Medical (2), SLO reactor effluents, and inspection procedure 87132 brachytherapy webinars; Diablo Canyon IPX, RAM Meeting	38.5	T&E radiopharmaceuticals and Type B packages webinars; NRC Cyber security; Mare Island Urban Shield EX	27
Mekuria, Ephrime	Webinars, Diablo Canyon EP, etc	77.5	Civil Support Team evaluation exercise; Lu-177 and national materials program webinars; NRC video Part 71 QA, Mirion 2-day tech seminar	24.5
Cohn, Gregg	H-313	40	H-121, H-304, H-314	120
Aboudarda, Davood	Not Qualified – started 12/17	NA	G-108, S-210, H-308	120
Oesterle, Don				
Harkness, Kathi	XRF, Diablo Canyon IPX	62.5	Part 37, Mo-99, LLRW, Lu-177, GM Pancake, QA/QC Beam Size webinars; CTOS	29.5
Taylor, Andrew	Pre-licensing, Part 37, Non-Military Ra-226, Y-90, Mo-99, & Safety Culture webinars; RAM Meeting in Sacto	26.5	Lu-177, national matrls program, SLO, & Part 35 1/14/19 revisions webinars, CTOS	27
Rook, Alan	H-304, Diablo Canyon IPX	40	National matls program, waste conference, extended storage, Part 71 QA, Part 35.300, Part 37, & Part 35 Jan 2019 changes, AgS compatibility, MD 5.6 and 5.9, IP 87132 webinars; HAZMAT driver	24
Harkness, Carlin	Not Qualified – started 6/17	NA	H-308, H-117S, G-205, H-122S, H-122 Lab, H-111, S201, CTOS	286.5
Day, Jeff				
Ortego, Joji	Part 37, Brachytherapy Med Events, & Mo-99 webinars; DHS secondary screener RIID; DNDO backpack	29	H-111, FEMA Radiological Accident Assessment Concepts	80
Miko, Tom	RAM meeting, CTOS	24	H-115, G-109, DOT refresher; Part 35 rev & draft SA-10 rev webinars	~100
Casaje, Ana	DHS secondary screener RIID, DHS personal radiation detector, DNDO backpack; Brachytherapy Med Events and	36.5	H-111, H-115, H-117, G-205	200

	Mo-99 webinars			
Ridgle, Tanya	RAM Meeting, DHS RERO	56	FEMA Rad Assessmt & REP. NNSA Alarm Resp	48
Yonemitsu, Ron	Medical brachytherapy events webinar, Coastal Warrior mass decontamination, RAM Meeting	25	Procedure 87132 brachytherapy webinar, HPS Radiological Surveying	42
Tawatao, James	H-304	40	HPS Radiological Surveying	40

CTOS is Counter Terrorism Operational Support organization training (part of NNSA).

SUPPLEMENTAL TRAINING

NAME * [Root Cause required]	* Root Cause G-205	Air Sampling H-119	Internal Dosimetry H-312	RESRAD H-410	RESRAD OFFSITE H-411	HP Topics H-401	VSP H-500	MARSAME H-120	Licensing G-109	Respiratory Protection H-311	Other (footnote and explain)
Hewadikaram, Nika	Yes								Yes		
Furey, Ken	Yes								Yes		
Mekuria, Ephrime	Yes							Yes	Yes		
Cohn, Greg	Yes		In progress						Yes		
Aboudarda, Davood	Yes		< Oct						Yes		
Oesterle, Don	Yes	Yes	Yes	Yes	Yes		Yes		Yes		
Harkness, Kathi	Yes	Yes	Yes	Yes					Yes		
Taylor, Andrew	Yes			Yes	Yes			Yes			
Rook, Alan	Yes										
Harkness, Carlin	Yes										
Day, Jeff	Yes	Yes	Yes	Yes	Yes			Yes			
Ortego, Joji	Yes	Yes	Yes	Yes	Yes		Yes	Yes			
Tom Miko	Yes	Yes							Yes		
Casaje, Ana	Yes										
Tanya Ridgle	Yes	Yes	Yes	Yes							
Tracy Au	Yes										
Yonemitsu, Ron	Yes										
James Tawatao	Yes										
Greger, Rob	Yes	Yes	Yes	Yes	Yes			Yes		Yes	

Supervisors shown in bold TR completed Root Cause 4/25-29/16. *Records not necessarily complete except for Root Cause (G-205)

ATTACHMENT Q12
OVERDUE INSPECTION STATUS (2019 IMPEP) Rev 10/7/19

The IMPEP Fully Satisfactory criteria for overdue inspections is <10% conducted overdue (including the 0 that were overdue at the time of the 2015 IMPEP). RHB's goal is to be below 5%. Priority 1-3 routine inspections and all initial inspections are counted in determining if the criteria is met.

Note: Determine OD inspections by checking "Regional Reports": 1) "Inspected after Overdue" list; 2) "Projected Overdue Inspections as of" list; and 3) "Unclosed Inspections" listing. Determine # of inspections conducted by checking: "Performance Reports" 1) "Inspection Count" report for "Priority 1-3" [DO NOT PRINT DUE TO SIZE]; 2) "Inspection Count" report for Priority Other" [DO NOT PRINT DUE TO SIZE]; and 3) "Inspection Count-Open Inspections" reports.

Note: Commencing 9/12/17 NRC Manual Chapter 2800 was modified to allow an OD extension of ±50% instead of ±25%, except that the OD extension is not to exceed 1 year. Also initial inspections can be extended from 1 year to 18 months if use of RAM has not commenced w/i 1 year. RAM2000_fe has not been successfully updated to reflect these changes. Per 2/13/19 email, R Erickson stated new OD criterion would be used for the entire IMPEP period.

Overdue Routine Priority 1-3 and Initial Inspections - at Time of 2015 IMPEP

(These inspections, if any, counted against us for the 2015 IMPEP, and will count against us again in the 2019 IMPEP)

	License #	Licensee	Priority	Ovderdue Date	Fieldwork Date	Days Overdue
RHB-N	None					
RHB-S	None					
LA Cty	None					
SD Cty	None					

OD at time of 2015 IMPEP = 0

Overdue Routine Priority 1-3 and Initial Inspections - 2015 (Starting 10/10)

In order to achieve the <5% overdue status, the following numbers of new overdue inspections (i.e., not including the 0 carryover overdues from the last IMPEP period) must not exceed: 3/yr each for RHB-N and RHB-S, 2/yr for LA County and 1/yr for SD County (over 4 years = 36 +0 starting OD ÷ ~1000 insp = ~3.6%).

		Oct	Nov	Dec	YTD Tot
RHB-N	# 1-3+I Insp	8	10	8	26
	# Insp. Conducted OD	**0**	**0**	**0**	**0**
	Licensee, Lic #, Pri, Days and Reason OD				
RHB-S	# 1-3+I Insp	6	8	16	30
	# Insp. Conducted OD	**0**	**0**	**0**	**0**
	Licensee, Lic #, Pri, Days and Reason OD				
LA Cty	# 1-3+I Insp	3	3	0	6
	# Insp. Conducted OD	**0**	**0**	**0**	**0**
	Licensee, Lic #, Pri, Days and Reason OD				
SD Cty	# 1-3+I Insp	1	0	2	3
	# Insp. Conducted OD	**0**	**0**	**0**	**0**
	Licensee, Lic #, Pri, Days and Reason OD				
Totals	# 1-3+I Insp	18	21	26	65
	# Insp. Conducted OD	0	0	0	0
	% OD for Month	0.0%	0.0%	0.0%	**0.0%**
	Cummulative # OD	**0**	**0**	**0**	
	Cummulative # Insp	18	39	65	
	Cummulative % OD w/0 from last IMPEP	**0.0%**	**0.0%**	**0.0%**	

EOY PERFORMANCE	**RHB-N**	**Goal**	**Actual**	**RHB-S**	**Goal**	**Actual**	**LA-Cty**	**Goal**	**Actual**	**SD-Cty**	**Goal**	**Actual**
IMPEP Years 0-0.25		0.75	0.00		0.75	0.00		0.50	0.00		0.25	0.00

Overdue Priority 1-3 and Initial Inspections - 2016

In order to achieve the <5% overdue status, the following numbers of new overdue inspections (i.e., not including the 0 carryover overdues from the last IMPEP period) must not exceed: 3/yr each for RHB-N and RHB-S, 2/yr for LA County and 1/yr for SD County (over 4 years = 36 +0 starting OD ÷ ~1000 insp = ~4.6%).

		Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	YTD Tot
RHB-N	# 1-3+I Insp	7	5	7	4	3	8	7	5	8	10	8	6	78
	# Insp. Conducted OD	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
	Licensee, Lic #, Pri, Days and Reason OD													
RHB-S	# 1-3+I Insp	5	16	5	9	6	11	11	5	6	7	10	4	95
	Conducted OD	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
	Licensee, Lic #, Pri, Days and Reason OD													
LA Cty	# 1-3+I Insp	1	3	1	6	0	1	3	1	5	6	8	1	36
	# Insp. Conducted OD	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**0**	**2**
	Licensee, Lic #, Pri, Days and Reason OD	Oct: College Medical Center-Childrens Hospital Long Beach (0908); Pri 3; Prev FW 9/26/12; OD 9/26/16; FW 10/6/16; 10 days OD; Reason OD; Miscommunication by Inspection staff regarding scheduling of inspection. Nov: Providence Health System (1258); Pri 2; Prev FW 8/21/13; OD 8/19/16; FW 11/17/16; 3 mo OD; Reason OD: Priority changed fm 3 to 2 on 12/28/16 without verifying with ICE that OD would not occur. The priority change reset the OD date from 5/21/17 to 2/21/16 causing instantaneous OD.											
SD Cty	# 1-3+I Insp	3	4	0	1	2	0	3	0	1	2	1	2	19
	# Insp. Conducted OD	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**
	Licensee, Lic #, Pri, Days and Reason OD	Jan: General Dynamics - National (0684); Pri 1; Prev FW 12/10/13; OD 6/10/15; FW 1/21/16; 7+ mo OD; Reason OD; priority changed from 2 to 1 on 10/6/15 w/o verifying with ICE that OD would not occur. The priority change reset the OD date from												
Totals	# 1-3+I Insp	15	25	12	14	11	19	21	10	15	19	19	12	192
	# Insp. Conducted OD	1	0	0	0	0	0	0	0	0	1	1	0	3
	% OD for Month	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	5.3%	5.3%	0.0%	**1.6%**
	Cummulative # OD	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**2**	**3**	**3**	
	Cummulative # Insp	80	105	117	131	142	161	182	192	207	226	245	257	
	Cummulative % OD w/ from last IMPEP	**1.3%**	**1.0%**	**0.9%**	**0.8%**	**0.7%**	**0.6%**	**0.5%**	**0.5%**	**0.5%**	**0.9%**	**1.2%**	**1.2%**	

EOY PERFORMANCE	**RHB-N**	**Goal**	**Actual**	**RHB-S**	**Goal**	**Actual**	**LA-Cty**	**Goal**	**Actual**	**SD-Cty**	**Goal**	**Actual**
IMPEP Years 0-1.25		3.75	0.00		3.75	0.00		2.50	2.00		1.25	1.00

Overdue Priority 1-3 and Initial Inspections - 2017

In order to achieve the <5% overdue status, the following numbers of new overdue inspections (i.e., not including the 0 carryover overdues from the last IMPEP period) must not exceed: 3/yr each for RHB-N and RHB-S, 2/yr for LA County and 1/yr for SD County (over 4 years = 36 +0 starting OD ÷ ~1000 insp = ~3.6%).

		Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	YTD Tot
RHB-N	# 1-3+I Insp	8	11	7	10	5	5	5	6	8	6	8	9	88
	# Insp. Conducted OD	**0**	**0**		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
	Licensee, Lic #, Pri, Days and Reason OD													
RHB-S	# 1-3+I Insp	9	9	2	5	1	10	5	7	5	6	8	3	70
	# Insp. Conducted OD	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
	Licensee, Lic #, Pri, Days and Reason OD													
LA Cty	# 1-3+I Insp	3	2	2	3	3	1	1	3	0	3	1	4	26
	# Insp. Conducted OD	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
	Licensee, Lic #, Pri, Days and Reason OD													
SD Cty	# 1-3+I Insp	1	1	2	1	3	0	3	0	2	1	2	0	16
	# Insp. Conducted OD	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**1**
	Licensee, Lic #, Pri, Days and Reason OD	Jul: Prime Healthcare Services (2483): Priority 2; Prev FW 1/15/14; OD 1/15/17; FW 7/18/17; 6 mo OD; Reason OD: Priority changed fm 3 to 2 on 3/8/17 w/o verifying with ICE that an OD would not occur. The priority change reset the OD date from											
Totals	# 1-3+I Insp	21	23	13	19	12	16	14	16	15	16	19	16	200
	# Insp. Conducted OD	0	0	0	0	0	0	1	0	0	0	0	0	**1**
	% OD for Month	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.5%**
	Cummulative # OD	**3**	**3**	**3**	**3**	**3**	**3**	**4**	**4**	**4**	**4**	**4**	**4**	
	Cummulative # Insp	278	301	314	333	345	361	375	391	406	422	441	457	
	Cummulative % OD w/ from last IMPEP	**1.1%**	**1.0%**	**1.0%**	**0.9%**	**0.9%**	**0.8%**	**1.1%**	**1.0%**	**1.0%**	**0.9%**	**0.9%**	**0.9%**	

EOY PERFORMANCE	**RHB-N**	**Goal**	**Actual**	**RHB-S**	**Goal**	**Actual**	**LA-Cty**	**Goal**	**Actual**	**SD-Cty**	**Goal**	**Actual**
IMPEP Years 0-2.25		6.75	0.00		6.75	0.00		4.50	2.00		2.25	2.00

Overdue Priority 1-3 and Initial Inspections - 2018

In order to achieve the <5% overdue status, the following numbers of new overdue inspections (i.e., not including the 0 carryover overdues from the last IMPEP period) must not exceed: 3/yr each for RHB-N and RHB-S, 2/yr for LA County and 1/yr for SD County (over 4 years = 36 +0 starting OD ÷ ~1000 insp = ~4.6%).

		Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	YTD Tot
RHB-N	# 1-3+I Insp	7	5	9	9	12	13	6	9	3	7	8	6	94
	# Insp. Conducted OD	0	0	0	0	0	0	0	0	0	0	0	0	**0**
	Licensee, Lic #, Pri, Days and Reason OD													
RHB-S	# 1-3+I Insp	4	8	4	6	9	12	7	6	8	7	10	12	93
	# Insp. Conducted OD	0	0	0	0	0	0	0	0	0	0	0	0	**0**
	Licensee, Lic #, Pri, Days and Reason OD													
LA Cty	# 1-3+I Insp	3	2	4	1	2	3	1	6	3	4	4	3	36
	# Insp. Conducted OD	0	0	0	0	0	0	0	0	0	0	0	1	**1**
	Licensee, Lic #, Pri, Days and Reason OD	Dec: Centerlake Medical Group (8087): Priority 2; Prev FW 10/21/15; OD 10/21/18; FW 12/12/18; 53 days OD; Reason Overdue: Priority changed fm 5 to 2 on 5/29/18, w/o informing ICE The priority change reset the OD date from 10/21/21 to 10/21/18, but the license mistakenly showed priority 3, which appeared to make the OD date 10/21/19. The inspection was performed 12/12/18,											
	Licensee, Lic #, Pri,													
SD Cty	# 1-3+I Insp	3	2	2	1	0	1	1	0	0	1	1	0	12
	# Insp. Conducted OD	0	0	0	0	0	0	0	0	0	0	0	0	**0**
	Licensee, Lic #, Pri, Days and Reason OD													
Totals	# Insp	17	17	19	17	23	29	15	21	14	19	23	21	235
	# Insp. Conducted OD	0	0	0	0	0	0	0	0	0	0	0	1	**1**
	% OD for Month	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	4.8%	0.4%
	Cummulative # OD	**4**	**4**	**4**	**4**	**4**	**4**	**4**	**4**	**4**	**4**	**4**	**5**	
	Cummulative # Insp	474	491	510	527	550	579	594	615	629	648	671	692	
	Cummulative % OD w/0 from last IMPEP	**0.8%**	**0.8%**	**0.8%**	**0.8%**	**0.7%**	**0.7%**	**0.7%**	**0.7%**	**0.6%**	**0.6%**	**0.6%**	**0.7%**	

EOY PERFORMANCE	**RHB-N**	**Goal**	**Actual**	**RHB-S**	**Goal**	**Actual**	**LA-Cty**	**Goal**	**Actual**	**SD-Cty**	**Goal**	**Actual**
IMPEP Years 0-4		9.75	0.00		9.75	0.00		6.50	3.00		3.25	2.00

Overdue Priority 1-3 and Initial Inspections - 2019 (through October 25)

In order to achieve the <5% overdue status, the following numbers of new overdue inspections (i.e., not including the 0 carryover overdues from the last IMPEP period) must not exceed: 3/yr each for RHB-N and RHB-S, 2/yr for LA County and 1/yr for SD County (over 4 years = 36 +0 OD ÷ ~1000 insp = ~3.6%).

		Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct (to 10/25)	Nov	Dec	YTD Tot
RHB-N	# Insp	8	7	14	10	9	6	4	11	1				70
# Insp. Conducted OD		0	0	0	0	0	0	0	0	0	0			**0**
Licensee, Lic #, Pri, Days and Reason OD														
RHB-S	# Insp	4	4	6	10	12	15	7	11	6				75
# Insp. Conducted OD		0	0	1	0	0	0	0	0	0	1			**2**
Licensee, Lic #, Pri, Days and Reason OD		Mar: Simonmed Imaging (8247): Priority 5 (Initial); Issued 3/9/18; OD 3/10/19; FW 3/12/19; 3 days OD; Reason OD: Scheduled week before OD, but RSO unavailable that week, done following week.												
Licensee, Lic #, Pri, Days and Reason OD		Oct: Top Shelf-Growers Choice (8227): Priority 5 (Initial); Issued 2/15/18; OD 2/15/19; FW 10/7/19; 8 mo OD; Reason OD: Mistakenly coded to nonexistent Region 5; therefore didn't show up on any Region's OD list.												
LA Cty	# Insp	0	3	3	5	3	1	2	3	1				21
# Insp. Conducted OD		0	0	0	0	0	0	0	2	0	0			**2**
Licensee, Lic #, Pri, Days and Reason OD		Aug: Shared Imaging (8196): Priority 5 (Initial); Issued 2/21/18; OD 2/21/19; FW 8/12/19; 6 mo OD; Reason OD: Mistakenly coded to SD Cty instead of LA Cty, and communication breakdown between Counties.												
Licensee, Lic #, Pri, Days and Reason OD		Aug: City of Glendale (8218): Priority 5 (Initial); Issued 2/21/18; OD 2/21/19; FW 8/16/19; 6 mo OD; Reason OD: Mistakenly coded to SD Cty instead of LA Cty, and communication breakdown between Counties.												
Licensee, Lic #, Pri, Days and Reason OD														
SD Cty	# Insp	2	1	3	1	1	0	2	4	1				15
# Insp. Conducted OD		0	0	0	1	0	0	0	0	0	0			**1**
		Apr: Pipeline Therapeutics (8243): Priority 5 (Initial); Issued 4/4/18; OD 4/4/19; FW 4/24/19; 20 days OD; Reason OD: Scheduled for week became OD, but RSO unavailable that week, done 3 weeks later when RSO available.												
Licensee, Lic #, Pri, Days and Reason OD														
Totals	# Insp	14	15	26	26	25	22	15	29	9	0			181
# Insp. Conducted OD		0	0	1	1	0	0	0	2	0	1			**5**
% OD for Month		0.0%	0.0%	3.8%	3.8%	0.0%	0.0%	0.0%	6.9%	0.0%	#DIV/0!			2.8%
Cummulative # OD		**5**	**5**	**6**	**7**	**7**	**7**	**7**	**9**	**9**	**10**			
Cummulative # Insp		706	721	747	773	798	820	835	864	873	873			
Cummulative % OD w/12 from 2011 IMPEP		**0.7%**	**0.7%**	**0.8%**	**0.9%**	**0.9%**	**0.9%**	**0.8%**	**1.0%**	**1.0%**	**1.1%**			

PERFORMANCE	**RHB-N**	**Goal**	**Actual**	**RHB-S**	**Goal**	**Actual**	**LA-Cty**	**Goal**	**Actual**	**SD-Cty**	**Goal**	**Actual**
IMPEP Years 0-4		12.00	0.00		12.00	2.00		8.00	5.00		4.00	3.00

Priority 1-3 and Initial Inspections Overdue at time of 2019 IMPEP = 0	
RHB-N Pending OD Licensee, Lic #, Pri,	0
RHB-S Pending OD Licensee, Lic #, Pri,	0
LA Cty Pending OD Licensee, Lic #, Pri,	0
SD Cty Pending OD Licensee, Lic #, Pri,	0

Attachment Q16 - INSPECTOR ACCOMPANIMENTS (2016-2019)

updated 10/4/19

Over the IMPEP period, accompaniments should, as reasonably achievable, include the various types of inspections for which the inspector is qualified.

If inspector is qualified for IC, accompaniments should include an IC inspection at least every other year.

For “Doc Done”, “Yes” indicates the accompaniment has been documented and the documentation is available in the supervisor’s files (the inspector should also have a copy).

2016

Region	Inspector	Accompanied by	License Category (IC?)	Date	Doc Done
North RHB	E. Mekuria	J. Fassell	Non-Medical +IC (0017)	4/8/16	Yes
		K. Furey*	Radiographer +IC (4424)	11/15/16	Yes
	K. Furey	J. Fassell	Medical (2017)	10/4/16	Yes
	K. Hewadikaram	J. Fassell	Non-Medical +IC (0017)	4/8/16	Yes
South RHB	D. Krajewski	D. Oesterle	Radiography + IC (8080)	1/13/16	Yes
		D. Oesterle	Radiography +IC (8120)	1/21/16	Yes
		D. Oesterle	Gauge (6545)	2/25/16	Yes
		D. Oesterle	Medical (7425)	3/11/16	Yes
	K. Harkness	D. Oesterle	Medical (1709)	2/24/16	Yes
		D. Oesterle	Gauge (6686)	12/28/16	Yes
	A. Taylor	D. Oesterle	Medical (6924)	3/3/16	Yes
		D. Oesterle	Non-Medical (2473)	8/18/16	Yes
		D. Oesterle	Medical (7470)	8/19/16	Yes
	A. Rook	D. Oesterle	Gauge (4788)	4/22/16	Yes
LA County	T. Miko	J. Day	Medical (0277)	2/5/16	Yes
		J. Day.	Medical (8153)	8/24/16	Yes
	J. Ortego	J. Day	Medical (2365)	2/16/16	Yes
		J. Day	Broad Medical (1949)	11/29/16	Yes
	T. Ridgle	J. Day	Industrial (0078)	4/7/16	Yes
SD County	R. Yonemitsu	J. Fassell	Medical (6224)	12/29/16	Yes
	J. Tawatao	R. Yonemitsu	Medical (0719)	12/20/16	Yes

* Acting supervisor

2017

Region	Inspector	Accompanied by	License Category (IC?)	Date	Doc Done
North RHB	E. Mekuria	N. Hewadikaram	Broad Academic (0676)	07/17/17	Yes
	K. Furey	N. Hewadikaram	Radiography +IC (4424)	12/21/17	Yes

	G. Cohn	N. Hewadikaram	Medical (7373)	05/30/17	Yes
South RHB	K. Harkness	D. Oesterle	Non-Medical (8156)	1/21/17	Yes
			Gauge (6128)	3/18/17	Yes
			Gauge (3931)	4/26/17	Yes
	A. Taylor	D. Oesterle	Medical (7547)	2/7/17	Yes
			Radiography +IC (8120)	2/8/17	Yes
			Radiography +IC (4182)	2/9/17	Yes
	A. Rook	D. Oesterle	Radiography +IC (6571)	9/18/17	Yes
	C. Harkness	D. Oesterle	Not qualified to inspect	--	--
LA County	T. Miko	J. Day	Broad Medical (0404)	2/2/17	Yes
	A. Casaje	J. Day	Medical (7422)	4/6/17	Yes
SD County	R. Yonemitsu	J. Fassell	Non-Medical (8161)	10/5/17	Yes
	J. Tawatao	R. Yonemitsu	Medical (7944)	1/25/17	Yes

* Acting supervisor

2018

Region	Inspector	Accompanied by	License Category (IC?)	Date	Doc Done
North RHB	E. Mekuria	N. Hewadikaram	Non-Medical +IC (0017)	10/24/18	Yes
		N. Hewadikaram	Broad Scope +IC (1725)	12/18-19/18	Yes
	K. Furey	N. Hewadikaram	Medical (7735)	10/3/18	Yes
	G. Cohn	N. Hewadikaram	Broad Scope +IC (1725)	12/13,18,19/18	Yes
	D. Aboudarda	N. Hewadikaram	Gauge (8183)	2/2/18	Yes
		N. Hewadikaram	Medical (7180)	05/24/18	Yes
South RHB	K. Harkness	D. Oesterle	Medical (2591)	12/11/18	Yes
			Well Logging (5489)	12/12/18	Yes
	A. Taylor	D. Oesterle	Non-Medical +IC (1777)	11/29/18	Yes
	A. Rook	D. Oesterle	Well Logging (6386)	8/3/18	Yes
		D. Oesterle	Radiography + IC (3951)	8/14/18	Yes
	C. Harkness	D. Oesterle	Gauge +PLV (8275)	10/9/18	Yes
LA County	T. Miko	J. Day	Radiopharmacy (5143)	1/4/18	Yes
	A. Casaje	T. Ridgle*	Non-Medical (3317)	10/3/18	Yes
	T. Ridgle	J. Day	Radiopharmacy (5143)	1/4/18	Yes
SD County	R. Yonemitsu	J. Fassell	Non-Medical (3953)	9/18/18	Yes
	J. Tawatao	R. Yonemitsu	Medical (8061)	11/28/18	Yes

* Acting supervisor

2019

Region	Inspector	Accompanied by	License Category (IC?)	Date	Doc Done

North RHB	E. Mekuria	N. Hewadikaram	Radiography +IC (8204)	10/7/19	Yes
	K. Furey	N. Hewadikaram	Radiography +IC (4424)	2/21/19	Yes
	G. Cohn	N. Hewadikaram	Gauge (6431)	10/4/19	Yes
	D. Aboudarda	N. Hewadikaram	Medical (6082)	3/5/19	Yes
South RHB	K. Harkness	D. Oesterle	Medical (0211)	8/13/19	Yes
		D. Oesterle	Radiography +IC (6313)	9/9/19	Yes
	A. Taylor	D. Oesterle	Medical (7092)	9-12-19	Yes
	A. Rook	D. Oesterle	Radiography +IC (8080)	8/14/19	Yes
	C. Harkness	D. Oesterle	Gauge (8261)	5/22/19	Yes
LA County	T. Miko	J. Day	Broad Academic +IC (0359)	1/17/19	Yes
	A. Casaje	J. Day	Medical (7560)	2/7/19	Yes
		J. Day	Medical (7757)	4/17/19	Yes
	T. Au	J. Day	Medical (6525)	3/1/19	Yes
SD County	R. Yonemitsu	J. Fassell	Non-Medical +IC (5951)	10/10/19	Yes
	J. Tawatao	R. Yonemitsu	Medical (7403)	8/21/19	Yes

* Acting supervisor

Attachment Q21 (rev 10/9/19)

Licensing Written Procedures/Policy Changes/Additions

Delinquent License Fees and Referrals for Enforcement Actions

Determining Inspection Priorities for Radioactive Materials Licensing

Evaluation of Quarterly TLD Results

Feedback to RML from ICE

Germanium-68/Gallium-68 Generators—Financial Assurance and Decommissioning Funding Requirements

Information Security

Licensing Fees Charged for Temporary Job Sites

Pre-Licensing Guidance

Procedure to Obtain and Draw on Financial Instruments

Returned Mail Correspondence

Risk-Significant Radioactive Material Checklist and Guidance

Attachment Q22 (rev10/9/19)
Pending License Renewals - Greater than One Year

Unit	Lic #	Licensee	Docket Number	Date Received	Action Type
M	1725		17251/11/2006TR	1/11/2006	TR
M	0307		03075/31/2006TR	5/31/2006	TR
M	0676		06765/31/2007TR	5/31/2007	TR
M	1338		13381/12/2009TR	1/12/2009	TR
M	0404		04046/24/2009TR	6/24/2009	TR
M	0417		04178/15/2011TR	8/15/2011	TR
M	7074		70744/6/2012TR	4/6/2012	TR
M	0517		05172/22/2012TR	5/10/2012	TR
M	0250		02506/1/2012TR	6/1/2012	TR
M	1434		143411/14/2012TR	11/14/2012	TR
M	0060		00602/7/2013TR	2/7/2013	TR
M	0134		01343/15/2013TR	3/15/2013	TR
I	7191		71917/2/2013TR	7/2/2013	TR
I	0801		080111/4/2013TR	11/4/2013	TR
M	1336		133612/24/2013TR	12/24/2013	TR
M	7261		72611/21/2014TR	1/21/2014	TR
I	7357		735710/3/2014TR	10/3/2014	TR
I	5863		586312/9/2015TR	12/9/2015	TR
I	0306		030612/11/2015TR	12/11/2015	TR
P	7558		75584/21/2016TR	4/21/2016	TR
P	5827		58274/29/2016TR	4/29/2016	TR
P	7540		75407/19/2016TR	6/28/2016	TR
P	6073		60737/5/2016TR	7/5/2016	TR
P	1100		11009/6/2016TR	9/6/2016	TR
I	2878		28789/13/2016TR	9/13/2016	TR
I	6286		62869/19/2016TR	9/19/2016	TR
I	6089		608911/4/2016TR	11/4/2016	TR
P	1155		115512/5/2016TR	12/2/2016	TR
I	6109		610912/6/2016TR	12/6/2016	TR
P	6268		626812/9/2016TR	12/9/2016	TR
P	5066		506612/12/2016TR	12/12/2016	TR
P	4690		46902/13/2017TR	2/13/2017	TR
P	6666		66662/14/2017TR	2/14/2017	TR
P	5319		53194/17/2017TR	4/17/2017	TR
I	7501		75014/25/2017TR	4/25/2017	TR
P	4032		40325/3/2017TR	5/3/2017	TR
P	5254		52545/5/2017TR	5/5/2017	TR
P	1103		11035/11/2017TR	5/11/2017	TR

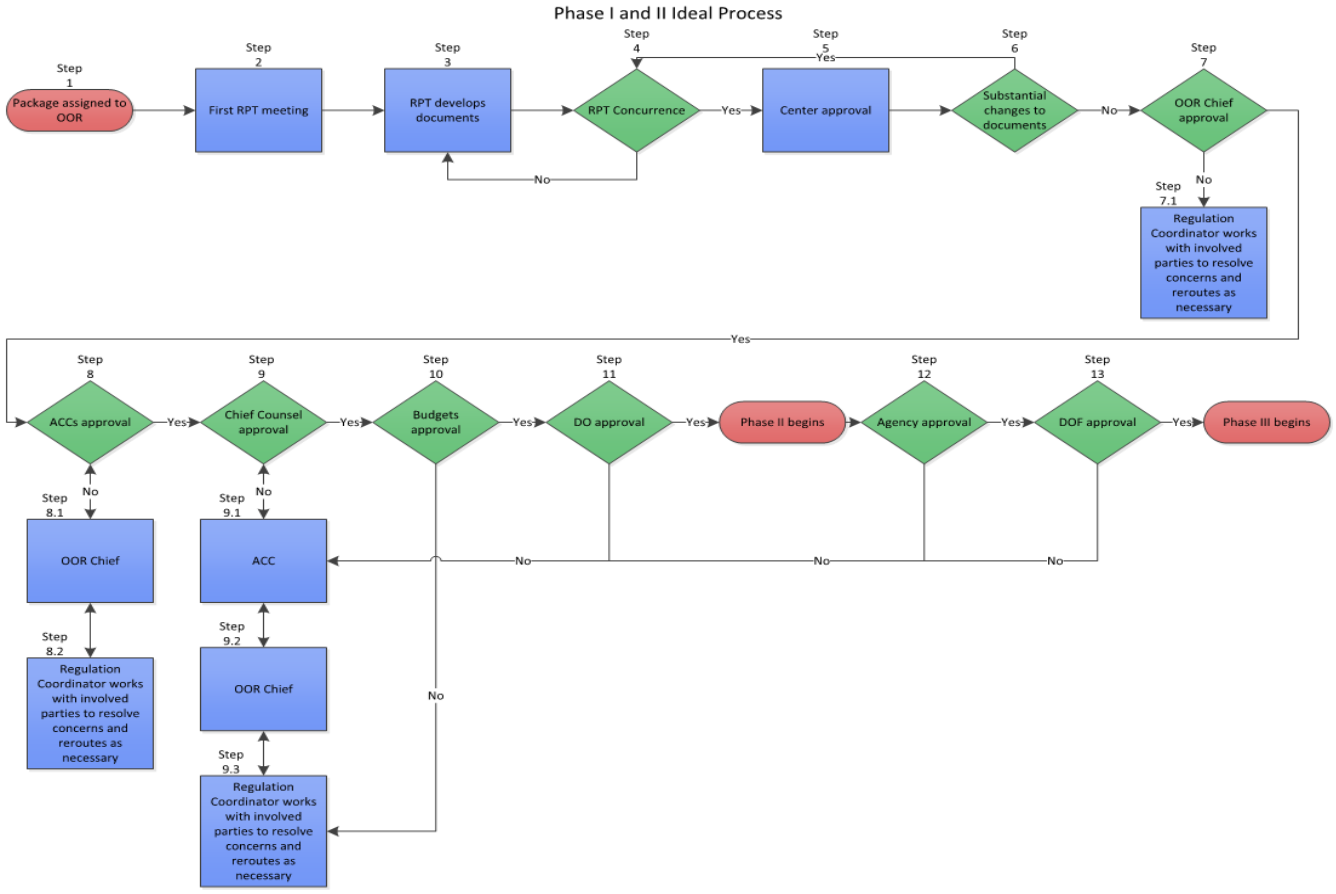
Unit	Lic #	Licensee	Docket Number	Date Received	Action Type
P	0218		02185/18/2017TR	5/18/2017	TR
I	5328		53287/5/2017TR	7/5/2017	TR
I	3049		30497/10/2017TR	7/10/2017	TR
I	2700		27008/15/2017TR	7/10/2017	TR
I	2563		25637/13/2017TR	7/13/2017	TR
I	7621		76217/17/2017TR	7/17/2017	TR
I	5334		53348/7/2017TR	8/7/2017	TR
P	0113		01138/8/2017TR	8/8/2017	TR
I	6431		64318/16/2017TR	8/16/2017	TR
P	4618		46188/16/2017TR	8/16/2017	TR
P	3925		39258/22/2017TR	8/22/2017	TR
P	0204		02049/8/2017TR	9/8/2017	TR
P	7668		76689/12/2017TR	9/12/2017	TR
I	6449		64499/25/2017TR	9/25/2017	TR
I	2777		277710/6/2017TR	10/6/2017	TR
I	7667		766710/9/2017TR	10/9/2017	TR
P	5155		515510/10/2017TR	10/10/2017	TR
I	0503		050310/12/2017TR	10/12/2017	TR
I	7676		767610/17/2017TR	10/17/2017	TR
I	5017		501710/19/2017TR	10/19/2017	TR
I	5098		509810/30/2017TR	10/30/2017	TR
I	7634		763411/1/2017TR	11/1/2017	TR
P	6831		683111/6/2017TR	11/6/2017	TR
I	6326		632611/6/2017TR	11/6/2017	TR
I	5775		577511/13/2017TR	11/13/2017	TR
I	7641		764111/14/2017TR	11/14/2017	TR
I	5544		554411/15/2017TR	11/15/2017	TR
I	6329		632911/20/2017TR	11/17/2017	TR
I	4948		494811/21/2017TR	11/21/2017	TR
P	2290		229011/22/2017TR	11/22/2017	TR
P	6299		629912/15/2017TR	12/15/2017	TR
P	6504		650412/19/2017TR	12/19/2017	TR
I	5262		52621/8/2018TR	1/8/2018	TR
P	0190		01901/24/2018TR	1/24/2018	TR
I	5411		54111/30/2018TR	1/30/2018	TR
I	7686		76861/31/2018TR	1/31/2018	TR
I	6313		63132/5/2018TR	2/5/2018	TR
P	6371		63712/13/2018TR	2/13/2018	TR
I	6349		63492/13/2018TR	2/13/2018	TR
I	6370		63702/23/2018TR	2/23/2018	TR

Unit	Lic #	Licensee	Docket Number	Date Received	Action Type
I	4721		47212/23/2018TR	2/23/2018	TR
I	2010		20102/23/2018TR	2/23/2018	TR
I	5456		54562/26/2018TR	2/26/2018	TR
I	7692		76922/27/2018TR	2/27/2018	TR
I	5192		51923/1/2018TR	3/1/2018	TR
P	4144		41443/13/2018TR	3/13/2018	TR
P	4143		41433/13/2018TR	3/13/2018	TR
P	0777		07773/19/2018TR	3/19/2018	TR
I	7697		76973/22/2018TR	3/22/2018	TR
I	3789		37893/22/2018TR	3/22/2018	TR
P	2419		24193/27/2018TR	3/27/2018	TR
I	5591		55914/2/2018TR	4/2/2018	TR
I	4288		42884/3/2018TR	4/3/2018	TR
I	6369		63694/5/2018TR	4/5/2018	TR
I	4377		43774/6/2018TR	4/6/2018	TR
I	1014		10144/16/2018TR	4/16/2018	TR
I	5623		56234/18/2018TR	4/18/2018	TR
P	1364		13645/8/2018TR	5/8/2018	TR
P	6659		66595/11/2018TR	5/11/2018	TR
I	7703		77035/14/2018TR	5/14/2018	TR
I	4414		44145/14/2018TR	5/14/2018	TR
P	6154		61545/17/2018TR	5/17/2018	TR
I	6149		61495/18/2018TR	5/18/2018	TR
I	3880		38805/23/2018TR	5/23/2018	TR
P	4177		41775/31/2018TR	5/31/2018	TR
M	6245		62456/4/2018TR	6/4/2018	TR
I	6148		61486/4/2018TR	6/4/2018	TR
I	0782		07826/4/2018TR	6/4/2018	TR
I	5657		56576/12/2018TR	6/12/2018	TR
I	6520		65206/15/2018TR	6/15/2018	TR
P	7721		77216/19/2018TR	6/19/2018	TR
P	3914		39146/21/2018TR	6/21/2018	TR
I	5642		56426/22/2018TR	6/22/2018	TR
I	6523		65236/27/2018TR	6/27/2018	TR
I	0109		01097/3/2018TR	7/3/2018	TR
P	7728		77287/11/2018TR	7/11/2018	TR
P	2877		28777/11/2018TR	7/11/2018	TR
P	2229		22297/30/2018TR	7/30/2018	TR
P	5311		53118/1/2018TR	8/1/2018	TR
I	5671		56718/10/2018TR	8/10/2018	TR

Unit	Lic #	Licensee	Docket Number	Date Received	Action Type
P	6545		65458/13/2018TR	8/13/2018	TR
I	6448		64488/30/2018TR	8/30/2018	TR
P	1777		17779/4/2018TR	9/4/2018	TR
I	5539		55399/10/2018TR	9/10/2018	TR
I	7732		77329/14/2018TR	9/14/2018	TR
P	5933		59339/18/2018TR	9/18/2018	TR
I	7719		77199/18/2018TR	9/18/2018	TR
I	6430		64309/19/2018TR	9/19/2018	TR
I	3252		32529/25/2018TR	9/25/2018	TR
I	4498		44987/24/2017TR	7/24/2017	TR

APPENDIX D: RPT FLOWCHARTS AND PROCESS BREAKDOWN

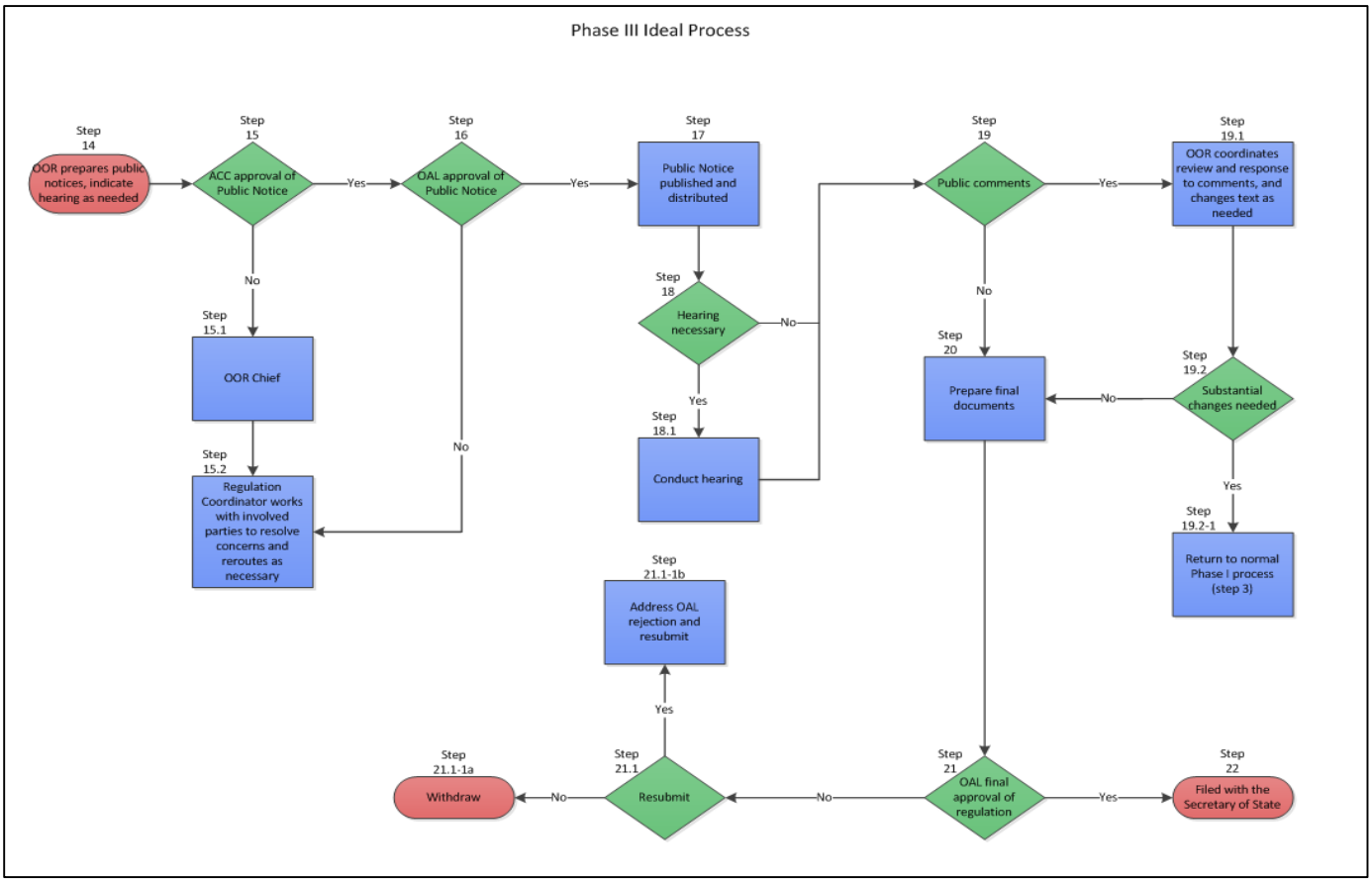
Regular Rulemaking Process Phases I and II: Creation and Approval



Process Breakdown

Step	Description	Roles
1	Package assigned to OOR	OOR Chief, OOR Coordinator
2	First RPT Meeting	OOR Coordinator, Program Staff, Program Budgets Staff, OLS Attorney
3	Reg. Text, ISOR, ID, fiscal documents developed.	OOR Coordinator, Program Staff, Program Budgets Staff, OLS Attorney
4	RPT Concurrence	OOR Coordinator, Program Staff, Program Budgets Staff, OLS Attorney
5	Center Approval	Program Chief, Program Staff
6	Changes needed	OOR Coordinator, Program Staff, Program Budgets Staff, OLS Attorney
7	Manager approval	OOR Chief
8	ACC Approval	OOR Chief
9	Chief Counsel Approval	OOR Chief
10	Budget Approval	Program Budgets Staff
11	Director's Office Approval	Director
12	Agency Approval	Agency Chief
13	Department of Finance (DOF) Approval	DOF Chief

Regular Rulemaking Phase III: Submission to OAL



Process Breakdown

Step	Description	Roles
14	Public Notice Prepared	OOR Coordinator
15	ACC Approval	OOR Chief
16	OAL Approval of Public Notice	OOR Coordinator
17	Public Notice Published and Distributed	OOR Coordinator
18	Hearing (if applicable)	OOR Coordinator
19	Public Comments Received	OOR Coordinator, Program Staff, OLS Attorney, OOR Chief, Program Chief
19.1	Public Comments Reviewed	OOR Coordinator, Program Staff, OLS Attorney, OOR Chief, Program Chief
19.2	Substantial Changes Needed	OOR Coordinator, Program Staff, OLS Attorney, OOR Chief, Program Chief
20	Final Documents Prepared	OOR Coordinator
21	OAL Approval of Final Documents	OOR Coordinator
21.1	Resubmission	OOR Coordinator
21.2	Withdrawal	OOR Coordinator
22	Filed with Secretary of State	OOR Coordinator

RPT PHASE I, PART 1: DRAFTING THE REGULATORY PACKAGE

Preparing to Draft the Package

Once the need for a regulatory package has been determined, the state agency responsible for promulgating the regulation (Program) must consider several details before beginning their collaboration with OOR. Program may wish to seek stakeholder engagement or create an outline to help guide their efforts. Concurrence by the Center Deputy Director is required before Program can formally submit a regulation package to OOR.

The Regulations Writer

At the beginning of the RPT process, Program assigns a regulations writer for the package. Usually, the regulations writer is Program Staff or Program's OLS House Counsel, but may sometimes be a Regulations Writing Attorney (RWA) or other personnel depending on the specific regulation. Program may always consult with OOR for help on selecting their regulations writer.

Determining the Goal

Before drafting any regulatory documents, it may be helpful for Program to consider the following questions:

- What prompted the creation of the regulations? Why are they needed?
- What is the regulatory goal? Will the regulations:
  - Implement a new program?
  - Develop a new process or procedure?
  - Update or require new standards or criteria?
  - Make specific or interpret legislative direction?

Statutory Authority

Does the Department have statutory authority to accomplish its goal? For example:

- Has a federal or state law been enacted permitting this goal?
- Has a court decision required this goal?
- Will the regulations fit within the scope of state and federal statute, into the existing legal framework of these statutes?

Program should consult with their assigned House Counsel on these and other legal authority questions.

Economic Impact

Will the regulations have a potential adverse economic impact on California business enterprises and individuals?

Are the regulations considered "Major Regulations" (regulations that have an economic impact (+ or -) on California business enterprises and individuals in an amount exceeding $50 million over the course of one fiscal year)?

Are there any fiscal constraints to accomplishing the regulatory goal? For example:

- Are there costs to the State and/or federal funds?
- Are there costs that will affect the regulated community?
- Would a Budget Change Proposal be necessary?

Controversy

Are there any high profile or controversial issues surrounding the regulatory goal? For example:

- Is there a significant new policy or change in policy being implemented?
- Is there a segment of people this proposal will negatively affect?

Outlining the Proposal

Based on past experience, it may be helpful for Program to draft an outline of their proposal to help guide them in achieving their regulatory goals. While this is not an APA requirement, the following items are important to identify and consider—and several must be included in Program's initial transmittal memo to OOR:

- A list of each regulatory section proposed to be adopted, amended, or repealed, and each provision (objective, requirement, or standard) of the regulation.
- The timelines, aspirational dates, and priorities for the package.
- A description of the legal authority and objective for each section of the regulation.
- A determination of the statutes, court decisions, or other provisions of law that are being implemented, interpreted or made specific by the regulation.
- A determination of the existing statutory and CCR requirements, internal standards, and procedural requirements that may apply to the matters covered by the proposed regulations.
- If establishing a new program, procedure, or process, an outline of each step that the regulated community must meet to be in compliance.
- A determination of any legal, economic, fiscal, or controversial issues to be addressed.
- A determination of how state and federal law will interact, if applicable. Will state regulations need to be at as stringent or more stringent that federal law/regulations? etc.
- A determination as to whether state regulations can diverge from the federal law or rules (consult with House Counsel as necessary).
- Relevant factual information to be relied upon in proposing the regulations.
- An identification of any documents to be incorporated by reference though the proposed regulations, as well as any documents already incorporated by the existing version of the regulations.

Stakeholder Engagement

As early as possible, the state agency initiating the proposal should consult with any relevant stakeholders (trade associations, other state agencies, advocacy groups, etc.) to determine the potential impact of the proposal on the regulated community. Conducting stakeholder engagement early in the development process may help mitigate potential problems down the road and lead to a more streamlined process.

Additionally, the APA requires the Department to consult with the regulated public (affected parties) involving complex proposals, or on a large number of proposals that cannot be easily reviewed during the comment period. *(Gov. Code § 11346.45)*. (This does not apply when the Department is implementing federal law and regulations for which there is little or no discretion for the state to vary.)

It is Program's responsibility to:

- Schedule the time and place of their stakeholder meeting(s);
- Provide and set up any needed equipment (WebEx, conference call lines, etc.);

- Moderate and guide the proceedings in a timely and orderly manner.

Stakeholder engagement should occur before the publication of the notice. The 45-day public comment period and/or public hearings held after the notice do not satisfy the requirements of Government Code section 11346.45. Additionally, Program must provide documentation in the ISOR and rulemaking file of involvement in the regulation development process by regulated parties and task forces or advisory groups *(Gov. Code § 11346.45)*.

If a statute requires that regulations proposed by the Department undergo review, consultation, and/or approval of an advisory group or another agency, any written notes/comments as a result of this interaction should be included in the initial package submitted to OOR if at all possible.

If the Department did not or cannot consult with the regulated public, it must document in the rulemaking file why it did not do so.

Beginning the RPT Process

Step 1: Package Assigned

The development stage of the regulation package is initiated when the Center Deputy Director submits a formal transmittal memo or email for the regulatory proposal to OOR's Chief of Regulations. The beginning date of the regulation process is based on the assignment of the regulation packages on the Department's Pending Assignment List to OOR.

The transmittal memo or email:

1) Lists the sections of the state statutes (and year enacted), or court cases that the regulations are intended to implement, interpret, or make specific.
2) Lists relevant federal statutes and regulations.
3) Specifies statutory authority.
4) Summarizes the intent and objectives of the regulatory proposal.
5) If not mandated by statute, summarizes the decision to pursue regulatory changes.
6) Discusses relevant policy issues.
7) Discusses fiscal impact of the proposal (costs or savings).
8) Discusses any potential adverse economic impact.
9) Discusses any anticipated controversies.
10) Lists any parties in support or opposition.
11) Lists the regulated parties. (Who will be affected?)
12) Lists any parties consulted.
13) States any statutory or court-prescribed deadline by which the regulations must be adopted.
14) Provides sign-offs by all affected managers, particularly if the proposal affects more than one program.

Program should be ready to start the regulation process by the start date listed on the Pending Assignment List and be prepared to set up the initial RPT meeting. OOR will contact Program to give the go-ahead to start the process, and will provide Program with a Department of Public Health (DPH) tracking number.

Step 2: Assembling the RPT

It is Program and OOR staff's responsibility to assemble the RPT and conduct the initial meeting. The Program staff member should set up the initial RPT meeting by emailing the RPT members with an calendar invite that includes any relevant documentation, information, or background about the proposal.

Step 3: The Initial RPT Meeting

The objective of the initial RPT meeting is to provide an overview of the RPT process and to make sure each team member knows what activities they are responsible for. Initial timelines and "aspirational dates" should be finalized by the end of this meeting.

Note: An flowchart providing an overview of the RPT process, Phases I and II, as well as flowcharts detailing the steps in promulgating emergency, Section 100, and File and Print regulations may be found in Appendix D: RPT Flowcharts and Process Breakdown.

Step 4: Developing the Regulatory Documents

Once the initial RPT meeting has been held, the regulations writer collaborates with the other members of the RPT to create the documents that make up a regulatory proposal. These documents are the:

1) Informational Digest (ID);
2) Regulation Text;
3) Initial Statement of Reasons (ISOR);
4) Standard Form (Std.) 399; and
5) Cost Estimating Methodology (CEM) (for regular regulations) or Standard Regulatory Impact Analysis (SRIA) (for major regulations).

Additionally:

- The OOR Coordinator uses information provided by Program to create the Notice of Proposed Action (notice).
- Program and OOR each generate their own regulations mailing lists which must also be included in the regulatory package.

The required contents of the regulatory documents are discussed in further detail in the following sections.

REGULATION TEXT

The regulation text is the language of the regulatory proposal formatted to distinguish between existing regulatory language and the language as it is proposed to be amended, adopted, or repealed *(Gov. Code, §11346.2, subd. (a)(3)).* Existing language may be copied from the California Code of Regulations online to form the basis of the proposed text.

Tips:

- Past regulation writers have found it useful to draft the text simultaneously with the ISOR, ensuring consistency between the two documents.
- The complete duplication of existing regulatory text in the regulation text document is not required unless it is necessary for comprehension. However:
  - OAL usually reviews existing language in order to assess the proposal for clarity, consistency, accuracy, or context; and
  - The affected public may consider it more transparent if existing language is wholly reproduced so that they can compare and contrast the proposed changes with what is currently in code.
  - When determining whether to include all the existing text, keep in mind space/length issues. It may be more efficient to simply note: "No proposed changes" for long, un-amended sections.
  - ***However***, issues of brevity should be weighed against the need for clarity. If a subdivision or paragraph of a regulatory section is being amended, as much of the overarching section must be faithfully reproduced as is necessary for clarity/ comprehension, even if the section has no proposed changes. In other words, if paragraph (3) of subdivision (a) is the only portion of subdivision (a) being amended, it is probably wise to include paragraphs (1) and (2) for context.

Organization

The following details should be considered when organizing and developing the regulation text.

Subject Order

Subject matter should be arranged in the anticipated order by which persons directly affected by the regulations will encounter the various subjects. For example, regulations implementing a "client services program" could logically be arranged as follows:

Article 1, Definitions
- Section 50000 – Beneficiary
- Section 50005 – Client
- Section 50010 – Eligibility
- Section 50015 – Services

Article 2, Client Eligibility for Services
- Section 50020 – Income Requirements
- Section 50025 – Age Requirements
- Section 50030 – County Residency Requirements

Article 3, Client Application and Enrollment for Services
- Section 50035 – Client Application Requirements
- Section 50040 – Departmental Application Review Criteria

Section 50045 – Departmental Application Review Timeframes
Article 4, Service Provider Requirements
Section 50050 – Educational Requirements
Section 50055 – Experience
Section 50060 – Training Requirements
Section 50065 – Licensure and Certification Requirements
Article 5, Sanctions for Violations
Section 50070 – Client Violations
Section 50075 – Service Provider Violations
Article 6, Fair Hearing Process
Article 7, Appeal Rights

When amending or adopting regulatory language, provisions, or sections, the regulations writer should review the current version of the regulation in the CCR to determine the best structure. For example, new definitions should be located in the existing "Definitions" article. If implementing a new benefit, the new language should be located in the chapter, article, or section that includes all other benefits. If new chapters or articles are needed, the regulations writer should consult with the OOR Coordinator.

Definitions

Unfamiliar or uncommon words that would not be immediately obvious to the regulated population must be clearly defined. These definitions are typically listed alphabetically in the regulation under a separate article entitled "Definitions." These definitions then apply to the other articles within the chapter.

Definitions should not be interspersed throughout the regulations. However, in some cases a definition is imbedded within a regulatory section and applies ***only*** to the meaning of the word as used in that section.

In addition, definitions must be consistent with existing terms, ideas, and references used within the regulation text. They should ***not***:

1) Contain program requirements or standards; or
2) Include the term being defined within the definition itself.

Section Numbering

Where possible, new section numbers should be assigned in intervals. This allows space for the adoption of other sections in the future. OAL recommends assigning section numbers in increments of no less than five (e.g., Section 50000, 50005, 50010, 50015). Using the above example under Subject Order, a definition for the term "benefit" could easily be adopted as section 50003 at a later time.

If an existing section is given a new number without changing any of the regulatory language, this is considered a change without regulatory effect because it merely re-designates the number of the section *(CCR, tit. 1, § 100).* Questions about re-designation may be addressed to the OOR Coordinator.

Other Affected Sections

When proposing to adopt, amend or repeal a regulation, the impact on other regulatory sections should be evaluated. Do other sections need to be amended or repealed accordingly? For

example, when updating a term or its definition, all sections using that term should be evaluated and amended accordingly. Or, if a section is re-designated, all sections referencing the re-designated section should be amended accordingly.

APA Standards

The proposed regulation text must comply with the six standards of the APA.

Clarity

(Gov. Code, §§ 11349, subd. (c) and 11349.1, subd. (a)(3); CCR, tit. 1, § 16)

The regulation text should be written such that persons directly affected can understand it. (See also: Administrative Procedure Act (APA), Clarity.)

The following publications recommended by OAL and OLS may help with crafting clear regulatory and legal documents:

- Legal, Legislative, and Rule Drafting in Plain English (2005) by Martineu and Salerno
- The California Style Manual (Fourth Edition, 2000) by Edward. W. Jessen (This is the preferred style manual of OLS, particularly for citations.)

In addition to being comprehensible, regulations must be subject to only one reasonable and logical interpretation. For example, if there is a conflict between the proposed regulation text and the description of the effect of the regulation, this discrepancy may create a clarity issue and be grounds for OAL disapproval *(CCR, tit. 1, § 16 subd. (a)(2) and Gov. Code, § 11349.1, subd. (b)).* To avoid this, it may be helpful to compose the regulation text and the ISOR concurrently.

At a minimum, the following considerations should be kept in mind when composing the regulatory text:

- Language should be consistent with the Department's description of the effect of the regulation;
- Any terms/definitions should be familiar to those directly affected by the regulation. (If terms may be interpreted differently, a specific definition or reference to an existing definition in regulation or statute should be provided);
- Correct grammar, punctuation and spelling should be used;
- Formatting should be easily understood by the regulated population; and
- Citations to other laws, regulations or published materials should be provided so that those directly affected by the regulation may easily identify the intended requirements.

Effectively meeting the APA clarity standard means that the regulations will be interpreted the same way by all the affected parties. For example:

- By the Department employee who explains the regulation to the public;
- By the county employee who applies the regulation when assisting a beneficiary;
- By the private individual or business person required to follow the regulation; and
- By the attorney or judge called upon to interpret the regulation in a legal proceeding.

Examples of regulation text that does not meet the clarity standard:

- *"The applicant shall use forms prescribed by the Department."*

In this example, the type of forms and the circumstances under which they should be used is unclear and overly broad, leading to multiple interpretations by different populations.

- *"At the Department's discretion."*

  In this example, it is unclear what specifically in meant by "the Department's discretion." The Department's discretion by what authority? A citation to an applicable/enforceable standard/law/regulatory provision etc. should be provided.

- *"Notwithstanding other provisions of law."*

  This example is vague and overbroad. Other provisions of state law? Federal law? This would be confusing to a reasonable member of the regulated population.

- *"The cost shall not be unreasonably high."*

  Specific costs should be provided based on the needs and governing standards/laws, etc. of the program.

- *"As determined by the Department."*

  What will be determined by the Department and under what authority?

Additionally, and in a similar vein, OAL has advised OOR that the following commonly used vocabulary words are often considered a "red flag" for disapproval:

- *Reasonable*
- *Sufficient*
- *Noncompliance*
- *Unusual*
- *Excessive*
- *Adequate*
- *Suitable*

Nonduplication
(Gov. Code, § 11349, subd. (f) and 11349.1, subd. (a)(6); and CCR, tit.1, § 12.)
Under the APA, a regulation may not serve the same purpose as a state or federal statute or another regulation. A regulation that duplicates a statute or regulation "serves the same purpose" as that statute or regulation. However, duplication ***is*** acceptable when necessary to satisfy the clarity standard (e.g., adopting a definition of a term that is already defined in statute).

Any overlap or duplication of a statute or regulation must be identified and justified in the rulemaking record *(CCR, tit. 1, § 12)*. This is typically done in the ISOR. In the regulations text, a citation to the duplicated statute or regulation should be included in the reference note at the end of the applicable section. (See also: The Administrative Procedure Act (APA), Nonduplication.)

Consistency
(Gov. Code, §§ 11342.2, 11349, subd.(d), and 11349.1, subd.(a)(4).)

A regulation shall not conflict with other existing provisions of law (i.e., U.S. Constitution, federal statutes and regulations, the California Constitution, state statutes and regulations, or court decisions. See also: Regulations Under the Administrative Procedure Act (APA),The Hierarchy of Law). Whenever, by the express or implied terms of any statute, the Department has authority to adopt regulations to implement, interpret, make specific, or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute, and reasonably necessary to effectuate the purpose of the statute *(Gov. Code, § 11342.2)*. Other potential consistency issues may arise in relation to conformity with administrative hearings, remedies, and due process requirements contained in the APA, as well as state and federal law.

A court will determine if a state statute is in conflict with federal law or regulation and not valid, and/or if a state law or regulation is unconstitutional.

An OLS Attorney should be consulted when the Department proposes to implement standards or requirements that may differ from what is required by law. (See also: The Administrative Procedure Act (APA), Consistency.)

Necessity

(Gov. Code, §§ 11342.2, 11349, subd. (a), 11349.1, subd. (a)(1), and CCR, tit. 1, §§ 10 and 11.)

Each provision of a regulation must be based in reason and supported by an explanation as to why it is necessary. Necessity is demonstrated in the ISOR, however, the APA necessity standard should be kept in mind when composing the regulatory text. Are the Department's amendments or revisions necessary to effectuate the intent of the proposal? (See also: The Administrative Procedure Act (APA), Necessity.)

Authority

(Gov. Code, §§ 11342.1, 11346.2, subd. (a)(2), 11349, subd. (b), 11349.1, subd. (a)(2), and CCR, tit. 1, § 14.)

A regulation must include citation(s) of the appropriate statute(s) granting the Department its rulemaking authority (i.e., the provisions of law which permit or obligate the Department to adopt, amend, or repeal regulations). These authority citations are included in the "Note" area located at the end of each regulatory section. Authority citations remain when a section is repealed. When listing the authority citations, each section number shall be listed individually and in numerical order. The use of ranges (such as Sections 50000-51000) or et seq. (such as Section 51000 et seq.) is to be avoided.

If there are conflicts or discrepancies, federal law supersedes state law. (See also: The Hierarchy of Law.)

Express or Implied

A statutory delegation of rulemaking authority may be express or implied.

With express rulemaking authority, the cited statute expressly permits or obligates the Department to adopt, amend or repeal regulations:

> ***Example:*** Welfare and Institutions Code section 14312: *"The director shall adopt all necessary rules and regulations to carry out the provisions of this chapter. In adopting such rules and regulations, the director shall be guided by the needs of eligible persons as well as prevailing*

practices in the delivery of health care on a prepaid basis..."

With implied rulemaking authority, the cited statute grants a duty or power to the Department but does not specifically state the Department's authority to adopt, amend or repeal regulations necessary, in order to achieve the purpose for which the power was granted:

> ***Example:*** Welfare and Institutions Code Section 14132.41, subdivision (a): *"Services provided by a certified nurse practitioner shall be covered under this chapter to the extent authorized by federal law, and subject to utilization controls. The department shall permit a certified nurse practitioner to bill Medi-Cal independently for his or her services. If a certified nurse practitioner chooses to bill Medi-Cal independently for his or her services, the Department shall make payment directly to the certified nurse practitioner."*

However, whether it has express or implied rulemaking authority, the Department cannot alter, amend or enlarge the scope of the power conferred upon it. To be effective, each regulation adopted must be within the scope of authority conferred and in accordance with standards prescribed by other provisions of law *(Gov. Code, § 11342.1).*

If Program has questions about their authority or anticipates a potential conflict between their regulatory proposal and the state or federal law, they should contact their assigned OLS House Counsel.

Additional Authority Information

As a result of the California Public Health Act of 2006 the Department of Health Services split into two separate departments: the Department of Health Care Services (DHCS) and the California Department of Public Health (the Department). As a result, all regulation packages related to Health Care Services (under CCR titles 22 and 17), must address the Department's name change by citing Health and Safety Code Section 20 in the authority note.

> ***Example of how to amend the Authority Note:***
>
> *Note: Authority cited: Section 20, Health and Safety Code; and sections 10725 and 14124.5, Welfare and Institutions Code. Reference: Section 14124.91, Welfare and Institutions Code; and 42 USC 1396(A)(1).*

(See also: The Administrative Procedure Act (APA), Authority.)

Reference

(Gov. Code, §§ 11346.2, subd. (a)(2), 11349, subd. (e), and 11349.1, subd. (a)(5); and CCR, tit. 1, § 14.)

A regulation must include reference citations (i.e., the statutes, court decision or other provision of law that the regulation implements, interprets and/or makes specific). These citations establish the statutory basis for the regulation. Every regulation includes reference citations in the "Note" area located at the end of the regulation. Reference citations remain when a section is repealed.

An entire chapter or group of statutes should not be cited unless they are being implemented, interpreted, or made specific. When listing the reference citations, each section number must be listed

individually and in numerical order. Avoid the use of ranges (such as Sections 50000-51000) or et seq. (such as Section 51000 et seq.).

Reference citations can also be authority citations. For example, Welfare and Institutions Code section 14105, subdivision (a) is used as both an Authority and Reference citation for regulations involving Medi-Cal Rates. It reads in relevant part: "The director shall prescribe the policies to be followed in the administration of this chapter, may limit the rates of payment for Health Care Services, and shall adopt any rules and regulations as are necessary for carrying out, but are not inconsistent with, the provisions thereof."

Note: A regulation cannot be written to alter, amend, enlarge or restrict its underlying statute. Additionally, a regulation cannot be written to override any statute or conflict with other provisions of law.

Grammar and Style Issues

Keep it Short

Keep each section focused on one identified objective. Too much information in a single sentence may be harder for the reader to understand. It may be better to separate such run-on sentences into shorter sentences or even separate them into another section or subsection.

Use Only Necessary and Simple Words

Words or terminology should be necessary, simple and familiar to the affected community. Avoid complicated or technical terminology unless essential to the meaning of the sentence.

For clarity, use the same terminology consistently. Avoid using different words, phrases, or terms that mean the same thing (i.e., "authorized representative," "representative," "person authorized to file an application") interchangeably.

Make it Easy to Follow

The regulation should be written in a clear and straightforward manner.

> ***Example:*** *"Section 99999. Requirements for Enrollment.*
> *As a condition of enrollment, an applicant or provider shall:*
> *(a) Meet the Standards of Participation specified in Chapter 7 of Part 3 of the Welfare and Institutions Code, and Division 3, Title 22, California Code of Regulations;*
> *(b) Be certified by the Department to participate in the Medi-Cal program; and*
> *(c) Submit, to the Department, a completed application package specified in subsection 12(c), below."*

Use Mandatory Actions

Statements indicating mandatory actions should use the word "shall" rather than "should," "may," or even "must" or "will." (For example: "The physician shall administer….") A discretionary act as implied by the term "may," for example, is unenforceable.

Avoid Intent or Informational Language

Intent and/or information statements have no legal effect but merely telegraph the scope or intended

results of a regulation. For example*: "This subsection provides processes for beneficiary eligibility."*

Explanations of regulatory scope and intent should be reserved for the ISOR and/or the Informative Digest. Avoid general, speculative, or descriptive statements or opinions in the regulation text.

Verb Tense

In general, regulations should be written in the present tense. Using future tense would be incorrect because a regulation "speaks" to the present time.

> ***Example:*** *"The applicant shall meet the standards of participation…."*
>
> ***Not:*** *"The applicant will have to meet the standards of participation…."*

Gender

Use gender-neutral language. Avoid words like "he," "she," "his," and "hers" unless the gender is pertinent to the regulation. Use singular nouns, plural nouns, or pronouns wherever appropriate (i.e., applicant, physician, providers, beneficiaries, or they, them or their).

Active Voice

Regulations should be written in the active voice (i.e., the subject provides the action).

> ***Example****: "A dispensing optician shall have a permit as a registered …."*
>
> ***Not****: "It is required that a dispensing optician have a permit as …."*

Third Person

Deal with subjects objectively rather than by speaking from the writer's point of view (first person) or by addressing the reader (second person).

> ***Example****: "A dispensing optician shall have a permit as a registered …. "*
>
> ***Not****: "We require that a dispensing optician have a permit as a registered …. "*

Parallel Construction

Use parallel grammatical construction. Lack of parallelism is most noticeable in lists that include sentences and sentence fragments, nouns, infinitives and participles.

The following examples illustrate parallel construction and are listed in order of preference for their use in regulations:

The objectives shall be:

All nouns*: "Achievement of …." Implementation of …." Minimization of …."*

OR

All participles: *"Achieving …." Implementing …." Minimizing …."*

OR

All infinitives: *"To achieve …." To implement …." To minimize …."*

Do not mix:

Noun: *"Achievement of …."*
Participle: *"Implementing …."*
Infinitive: *"To minimize …."*

Double Negatives

For clarity purposes, avoid double negatives.

> ***Example**: "A provider shall be licensed a minimum of 5 years, in order to qualify for preferred provider status."*
>
> ***Not**: "No provider shall not be licensed for less than 5 years, in order to qualify for preferred provider status."*

Circular Definitions

Do not use the word being defined in its definition.

> ***Example**: "Business address means the physical location, identified by a street number, street name, suite number or room number, city, state and nine-digit zip code, where services are delivered to clients."*
>
> ***Not**: "Business address means the address where the business is located."*

Regulatory Content Issues

Definition vs. Process

Do not incorporate a process into a definition. When defining a term, the definition should explain "who" or "what" not "how."

> ***Example**: "Provider" means any individual, partnership, provider group, association, corporation, institution, or entity, that provides services, goods, supplies, or merchandise, directly or indirectly, to a Medi-Cal beneficiary, and that has been enrolled in the Medi- Cal program."*

In the above example, the definition for provider describes who or what a provider is and what a provider does. However, it avoids listing the requirements on how to become a provider, which involves process.

> ***Not**: "Provider means any individual, partnership, provider group, association, corporation, institution, or entity that:*
> *(1) Meets the standards of participation in Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code;*
> *(2) Is certified by the Department;*
> *(3) Is licensed by the Department*
> *(4) Submits a Medi-Cal Provider Agreement (DHCS 9999, Rev. 5/04) and Medi-Cal Disclosure Statement (DHCS 9998, Rev 5/04);*
> *(5) Has an established place of business …."*

While the above example lists the requirements to become a provider, it does not define the term itself. The requirements or steps for becoming a provider should be incorporated into their own specific regulatory section.

Objective vs. Subjective

Write to express objective rather than subjective concepts.

> ***Example****: "The applicant shall complete 10 courses…"*
>
> ***Not****: "The applicant shall complete the required number of courses."*

Regulate the Public, Not the Department

A regulation should be written to require an action or compliance from the regulated public.

> ***Example****: "The applicant shall submit to the Department a completed application, which includes a signature of the applicant in ink."*
>
> ***Not****: "The Department shall require the applicant to submit a completed application signed in ink."*

The second example is not enforceable, since the Department would not sanction itself for not complying with the regulation.

An exception to this rule is when the regulations involve an application process.

> ***Example****: "The Department shall respond to the provider within 30 days of receipt of the provider's request to appeal a termination from the Medi-Cal program."*

Do not impose requirements on the regulated public or the Department that are unenforceable by the Department or other affected parties, or are not intended to be enforced. If there is any uncertainty as to the enforcement of a proposed regulation, please contact the Regulations Coordinator or the OLS Attorney/House Counsel.

Retroactive or Prospective Requirements

Avoid retroactively applied requirements or prospective requirements, unless specifically authorized by the program's underlying statute.

Language to Avoid

Avoid:

- Confusing series of exceptions such as: "Notwithstanding any other provision…"
- Vague and unclear phrases such as: "Including but not limited to, " "appropriate," "sufficient," "applicable," "timely," or "as necessary."
- Phrases such as "required by law." Instead, cite the law (statute or regulation or both).
- Redundant expressions or "lawyerisms" which are words or phrases characteristically used by lawyers or people trying to sound like lawyers. For example: "said," "whereas," "hereby," "further," or "provided that."

References to "the Department"
Refer to the Department of Public Health as "Department" instead of "CDPH" throughout all the documents in the regulation package.

Verifying Regulatory Content
Ensure that the regulation text is not in conflict with state or federal laws or regulations and that section numbers reflect/track with what is currently in the CCR.

It is also important to remember that regulation text must be consistent with the description of its effect as described in the corresponding section of the ISOR.

Printer's Instructions
Printer's instructions are the first line at the top of the page and describe the action (amend, adopt, or repeal) to be taken for a specific regulatory section. (See also: Appendix B: Example of Regulation Text Document.)

The following is a brief explanation of adopt, amend, repeal, and re-designate:

Type of Regulatory Action	**Acceptable printer's instructions**
Amend	Amend Section 51515 to read:
Adopt	Adopt Section 53032 to read as follows:
Repeal	Repeal Section 59998:
Re-designate	Re-designate Section 51000.1 to 51000.1.1:

Formatting Issues

- Begin each regulatory section on a new page. All sections should be contained in a single Word document.
- Double space the regulation text.
- Indent the first line of every section, subsection, paragraph, and subparagraph five spaces. All other lines begin flush with the left margin. (It may be helpful to deactivate the auto-format function in Word.)
- Use strikeout (~~strikeout~~) to indicate deleted text. If an entire regulatory section is being repealed, all text is shown in strikeout, except the title and the authority and reference note, which remains in print in the CCR.
- Use underline (underline) to indicate newly proposed regulation text. If an entire regulatory section is proposed for adoption, all text is shown in underline, including section number, title, and the authority and reference note.
- Use the following system to number and reference regulations consisting of more than one subsection:
    - Section 99999

- Subsection
- Paragraph
- Paragraph
- Subparagraph
- Subparagraph
- Subsection
- Paragraph
- Paragraph
- Subsection

As a general rule, a regulation should be organized so that there are (at least) two of every category level (i.e., two subsections, two paragraphs, two subparagraphs, etc.) Therefore, if the regulation is structured such that there is a subsection (a), there must be (at least) a subsection (b), or if there is a subparagraph (1), there must be (at least) a subparagraph (2). In other words, you cannot have a subsection (a) without a subsection (b), or a paragraph (1) without a paragraph (2).

Authority and Reference Note

The authority and reference note is the Department's interpretation of its regulatory power to adopt, amend, or repeal a particular regulation. It appears at the end of every regulatory section and should be consistently formatted.

Formatting the Note

- Use single-spacing.
- Use underline to indicate newly added authority and reference sections or citations.
- Use strikeout to indicate deleted authority and reference sections or citations (deletions can occur when updating or correcting). However, if a regulation is repealed, the authority and reference note is not repealed and is not shown in strikeout.
- List each section number individually and in numerical order. Avoid using ranges (such as sections 50000-51000) or et seq. (such as section 51000 et seq.).
- If amending a currently in-print section that does not have an authority and reference note, add the appropriate note and show the addition in an underline.

Incorporation by Reference

(CCR, tit. 1, § 20)

Incorporation by reference means the method whereby a regulation makes provisions of another document part of that regulation by referencing the other document. The document incorporated by reference is not printed in the CCR, but a detailed reference to this document, including the title and date of publication, is present in the regulation text. Incorporating a document by reference gives the incorporated document the same effect and force of law as if the whole document were printed in the CCR.

Incorporation by reference can be used when a regulation mandates the use of a specific form or mandates compliance with a set of published standards that would otherwise be cumbersome, unduly expensive, or impractical to print in the CCR. Since a document incorporated by reference is essentially a regulation, that document shall meet all six of the APA standards. However, if a state statute or other applicable law specifically requires the adoption or enforcement of the incorporated material, then the incorporated material is not subject to OAL review for compliance with APA

standards.

Requirements

Pursuant to CCR, Title 1, section 20, when a document is incorporated by reference, the following information shall be included in the regulation text:

- A statement that the document or portion of the document is incorporated by reference.
- The document title.
- The form number (if applicable). (Forms should go through a forms management process before the regulation package is submitted to OOR for review. Please contact the Department's Forms Management Program to get a number for the form if one is not already assigned.)
- The date of publication or issuance (if applicable).
- The page or section numbers (if not incorporating the entire document).
- The availability of the document.

Prospective Incorporation by Reference

Materials cannot be prospectively incorporated by reference unless permitted by statute. For example: if a set of standards is updated or if a form is altered, any subsequent amendments of the document (such as updating a set of standards of care, or the addition of a new field to a form) are not automatically covered through incorporation by reference. The regulatory section must be amended through the regulatory process each time the document incorporated by reference is amended and/or has a new publication or new revision issued.

The exception to this is if statute authorizes prospective incorporation by reference. For example, if the statute includes language such as: "The providers shall meet the standard of acceptable quality, as established by the California Dental Association Guidelines for the Assessment of Clinical Quality and Professional Performance, Copyright 1995, Third Edition, as periodically amended." *(Welf.& Inst. Code, § 14123, subd. (f).)*

Example of language for a form incorporated by reference:

"The applicant or provider, when required pursuant to subsection (a), shall complete the "Medi-Cal Provider Group Application," DHCS 6203 (Rev. 12/00), hereby incorporated by reference."

Example of language for standards incorporated by reference:

#1*: "DHCS's Manual of Criteria for Medi-Cal Authorization (Jan. 1, 2008), hereby incorporated by reference in its entirety."*

#2*: "The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services, Sixth Edition (2013) herein incorporated by reference in its entirety."*

Additional Information

- Program must submit the current and/or revised version of any forms incorporated by reference to OOR with the rulemaking package.
- Program must also submit all forms mentioned within the sections affected by the regulation proposal to OOR, even if the form is not being incorporated or revised through the particular regulatory action.

- Program should plan sufficient lead time to work with the Forms Management Program if revisions are required on forms incorporated by reference.
- Printer's instructions, authority and reference notes, and page headers are not needed for incorporations by reference.
- If a form incorporated by reference collects personal data, the provisions of Civil Code, section 1798.17 must be followed (Program may consult their assigned OLS House Counsel as necessary).
- The Informative Digest must identify all documents incorporated by reference (title, form
- #, date of publication) (See: Informative Digest (ID), below, and CCR, tit. 1, § 20, subd. (c)(3)).
- The ISOR and Final Statement of Reasons (FSOR) must include specific information pertaining to documents incorporated by reference, specifically, a demonstration that it would be too cumbersome, unduly expensive, or otherwise impractical to publish the document in the CCR, and a demonstration that the document was made available upon request directly from the Department, or was reasonably available to the affected public from a commonly known or specified source. (See: Initial Statement of Reasons (ISOR) and Preparing the Final Statement of Reasons (FSOR), below, and CCR, tit. 1, § 20, subd. (c)(1) and (2).)
- If a document is incorporated by reference through a 15-day public availability the document must be identified by title and date of publication in the 15-day public availability notice.

Regulations Involving Application Processes or Forms

Application Processes

When writing regulations for an application process (e.g., permits, enrollment, etc.) be sure to include the process and procedures to be followed by both the Department and the applicant. Each step of the process must be addressed in order to establish the responsibilities of each party, the timeframes within which to complete specified actions, and the criteria that will be applied during the application review.

These requirements were once part of the Permit Reform Act of 1981, formerly located in Government Code section 15376. The Permit Reform Act has since been repealed (effective January 2004). However, from a clarity standpoint, the OOR still recommends adhering to the main requirements of this Act.

The following requirements and examples are based on past experience and practice with Department regulations.

Requirements

The regulations shall specify the following requirements, as applicable, and include others as required:

- State a time period, dating from the receipt of the application, within which the Department is required to inform the applicant, in writing, that the application is either complete and accepted for filing, or is deficient - and include any further specific information that may be required.
- State a time period, dating from the filing of a completed application, within which the Department must reach a decision regarding the application (i.e., approval or denial).
- Specify any additional steps in the process, including the timeframes within which specific

actions must be taken.
- Specify the criteria the Department uses to reach either an approval or disapproval decision regarding the application.

Examples of Regulatory Language for Forms

Example #1:

(a) Starting from the date the Department receives an application, the applicant shall be informed within thirty (30) calendar days whether the application is complete and accepted for filing, or whether the application is deficient. If deficient, the Department shall issue an application deficiency notice specifying what specific information is needed.

(b) The applicant shall, within forty-five (45) calendar days from the date on the Department's application deficiency notice, resubmit a complete application. The resubmitted application shall include any additional information specified on the Department's application deficiency notice.

(c) Starting from the date a completed application is received, the Department shall make a decision whether to approve or disapprove the application within ninety (90) calendar days.

Example #2:

(a) At least twenty (20) business days prior to the effective date of the action, the Department shall mail the provider a written notice of the proposed action. The Department shall send this notice by certified mail to the most recent business address on record and shall indicate the reasons for such action, and shall include a copy of the charges and material upon which the action is based and an explanation of the right to respond either verbally or in writing to a Departmental representative at an informal hearing. Persons convicted in a court of law are not eligible for the informal hearing process.

(b) The informal hearing shall be held at a location designated by the Department. The provider must submit a request for an informal hearing within fifteen (15) business days of receipt of the notice of the effective date of an action to suspend or revoke his or her certificate. The Department shall conduct the informal hearing within five business days of receipt of a timely request for a hearing.

Note: These recommendations also apply to regulations that specify a process, such as an appeals process.

Department Forms

There are three ways to promulgate the requirements of a form through regulation:
- Incorporate the form by reference within the proposed regulation text;
- Include all the elements of the form within the regulation text; or
- Include the image and the content of the form within the regulation text.

Necessity must be provided in the ISOR for each element of information and each requirement on the form, including any instructions.

(See also: Exemptions from the APA, Forms Exemption.)

INITIAL STATEMENT OF REASONS (ISOR)

The Initial Statement of Reasons (ISOR) document explains and justifies the need for each adoption, amendment, or repeal in a regulatory proposal. It establishes the proposal's regulatory intent and necessity, and identifies the material the Department has relied on in proposing regulatory action. *(Gov. Code, §11346.2, subd.(b).)* The courts may later rely on the ISOR if litigation is involved regarding the validity or the interpretation of the regulation.

Note: Please see Appendix C: OOR Templates for OOR's current ISOR template or download the ISOR template online at the Office of Regulations Intranet .

Summary of Proposal

(Gov. Code, §11346.2, subd. (b)(1).)
The ISOR begins with a brief summary explaining what prompted the creation of the regulation, why the regulation is necessary, and generally, what the regulation would do. This summary references the state and/or federal law granting the Department and/or Program the authority to develop rules and regulations in the given subject area, along with any existing or new legislation or court decision upon which the regulatory proposal is based. In other words, this portion of the ISOR should discuss what provisions of law are being implemented, interpreted, or made specific. Reference citations should be consistent with those cited in the "Note" section at the end of each regulatory section and should conform to the California Style Manual (CSM). (See: Additional Resources for a link to the CSM online.)

(See also: Gov. Code, §§ 11346.5, subd. (a)(2) (Authority/Reference), and 11346.5, subd. (a)(3) (Informative Digest).

Background or Summary of Existing Laws and Regulations

While not required by the APA, this section is generally included in the ISOR to facilitate reader comprehension and expedite the Department's review process. The background section mentions any relevant laws or regulations affected by the regulatory proposal, says how the proposal will affect those laws, and states why regulations are needed to support the regulatory purpose.

Policy Statement Overview

(Gov. Code, § 11346.2, subd. (b)(1).)
This section of the ISOR states the problem the Department hopes to address with the proposed regulation, and should help the reader understand the need for action. It consists of the "Problem Statement," followed by a summary of the broad objectives or goals of the proposal. (See Appendix C: OOR Templates, Initial Statement of Reasons for an example of OAL's preferred formatting for this section.)

Benefits

(Gov. Code, § 11346.2, subd. (b)(1).)
A list of the regulation's anticipated benefits must be included in the ISOR. These benefits may include monetary benefits and/or nonmonetary benefits (such as the protection of public health and safety, worker safety, or the environment, the prevention of discrimination, the promotion of fairness or social equity, etc.) (See Appendix C: OOR Templates, Initial Statement of Reasons for an example of OAL's preferred formatting for this section.)

Discussion of Each Regulatory Provision
(Gov. Code, § 11346.2, subd. (b)(1).)
Under the APA, the ISOR must identify each regulatory section proposed to be adopted, amended, or repealed, and provide the necessity and rationale for each change. (See Appendix C: OOR Templates, Initial Statement of Reasons for an example of OAL's preferred formatting for this section.)

If a section contains numerous subsections, paragraphs, or subparagraphs, each one of these must be acknowledged in the discussion. Where applicable, the discussion of each proposed regulation shall include the following:

- A statement of the specific purpose and rationale of each section adopted, amended, or repealed.
- The reason(s) why the change is necessary to carry out the purpose and intended effect of the change.

Other considerations:

- If the adoption or amendment of a regulation mandates the use of specific technologies or equipment, include the reasons why such mandates or prescriptive standards are required, and any alternatives considered, including the required consideration of performance standards *(Gov. Code, § 11346.2, subd. (b)(4) and (5)(A)).*
- If the provision is controversial, it may be helpful to restate/reaffirm legal authority underlying the regulation text.
- If businesses are required to submit reports or any other written information, explain the need for each such report or written information. Any proposed regulation that imposes a reporting requirement on businesses must be accompanied by a finding that the report requirement is necessary for the health, safety, or welfare of the people of the State of California *(Gov. Code, §§ 11346.3, subd. (d) and 11346.5(a)(11))*.

Please see also: CCR, Title 1, section 10 (Necessity) for further guidance as to purpose and rationale.

Documents Relied On
(Gov. Code, § 11346.2, subd. (b)(3).)
The ISOR must identify any study, report, letter, memorandum, document, or other information or material that the Department relied upon during the creation of the regulatory proposal. This information should be compiled as a list using CSM citation style (see Additional Resources). In general, such citations include the author, title, publication date, and pertinent page number(s).

Examples of documents relied on include:

- Written recommendations from stakeholder groups;
- Articles from medical, scientific or other professional journals;
- Correspondence (including email correspondence);
- Legal actions (i.e., lawsuits, writs, or court orders);
- Technical, theoretical, or empirical studies or reports.

Documents relied on must be available to the public in the rulemaking file *(Gov. Code, § 11347.3,*

subd. (b)(7)). Therefore, OOR requests that **two** copies of each material relied upon be included with the regulation package when submitted OOR. If the material relied upon is web-based, the regulation package should provide the URL where the material may be accessed.

Note: For copyrighted material please consult with the OOR Coordinator or OLS House Counsel.

Alternatives Considered

(Gov. Code, § 11346.2, subd. (b)(5)(A)-(C).)

The ISOR must include a description of reasonable alternatives to the regulation and the Department's reasons for rejecting those alternatives. Reasonable alternatives may include alternatives proposed as less burdensome and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the authorizing statute or other law being implemented or made specific by the proposed regulations. Why is the proposed regulation the best standard among the alternatives considered? This information is usually compiled under the heading "Reasonable Alternatives Considered."

Supporting information backing up the determination that there are no reasonable alternatives to the regulations should be provided. For example: the regulation is mandated by federal or state law, is the most effective and least burdensome means to implement a statutory policy or other provision of law, etc. *(Gov. Code, § 11346.9, subd. (a)(4).)*

In cases where a regulation would mandate the use of specific technologies or equipment, or prescribe specific actions or procedures, the imposition of performance standards shall be considered as an alternative *(Gov. Code, § 11346.2, subd. (b)(5)(A)).* Government Code section 11346.2 subdivision (b)(4) also provides that any prescriptive standard or mandate to use specific technology or equipment, be accompanied by a statement as to why the standard or mandate is required.

Additionally, the ISOR should identify any reasonable alternatives rejected that would have lessened any adverse impact on small business, and should provide the reasons for such a rejection *(Gov. Code, § 11346.2, subd. (b)(5)(B)).* (See also, Statements of Determination, below).

Note: It is not necessary to artificially create alternatives in order to comply with this provision. Additionally, there is no need to discuss unreasonable alternatives, such as unlawful alternatives. *(Gov. Code, § 11346.2, subd. (b)(5)(C).)*

Economic Impact Assessment or Standardized Regulatory Impact Analysis

(Gov. Code, § 11346.3, subd. (a)(3).)

For non-major regulations: The ISOR must address the impact of the proposed regulation upon the following:

1) The creation or elimination of jobs in the state.
2) The creation or elimination of businesses within the state.
3) The expansion of businesses currently doing business in the state.
4) The benefits of the regulation to the health and welfare of California's residents, worker safety, and the environment.

In addition, Program must prepare a Cost Estimating Methodology (CEM) to accompany the ISOR. (Please see Economic and Fiscal Documents, below for further information.)

For major regulations: The ISOR must address how the proposed regulations will impact the following:

1) The creation or elimination of jobs in the state.
2) The creation or elimination of businesses within the state.
3) The competitive advantages or disadvantages for businesses currently doing business in the state.
4) The incentives for innovation in products, materials, or processes.
5) The benefits of the regulations, including but not limited to, benefits to the health, safety, and wellbeing of California's residents, worker safety, and the state's environment and quality of life.

In addition, Program must prepare a Standardized Regulatory Impact Analysis (SRIA). (Please see Economic and Fiscal Documents, below.)

Note: Programs should consult with OOR if a major regulation is anticipated.

For no anticipated impact: If no significant economic impact is identified, the following statement may be used in the ISOR:

> *"The Department has determined that the proposed regulatory action would have no significant direct economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states because [reason why there is no impact]."*

Statements of Determination

The specific statements of determination that the ISOR must address may be different or non-existent depending on the specific regulatory package.

Mandated Use of Specific Technologies, Equipment, Actions, or Procedures

If the regulation mandates the use of specific technologies, equipment, actions, or procedures, Program must:

1) Consider a performance standard as an alternative;
2) Explain why the agency believes the mandate or prescriptive standard is required; and
3) Explain the reason for using a prescriptive vs. performance standard.

Determination of Significant Adverse Economic Impact on Business

This portion of the ISOR should state the facts, evidence, and documentation that Program is relying on to support an initial determination that the regulation will have no significant adverse economic impact on businesses.

Involvement with Affected Parties

The ISOR should document the involvement of any regulated parties, task forces, or advisory groups that the state agency engaged with during the regulation development process. Additionally, in the course of developing the proposal and prior to the publication of the initial public notice, the APA requires the Department to consult with the regulated public involving complex or multi-package

proposals that cannot be easily reviewed during the comment period. This does not apply when the Department is implementing federal law and regulations for which there is little or no discretion *(Gov. Code, § 11346.45)*. This public involvement must take place prior to the publication of the notice.

If the Department does not or cannot consult with the regulated public, it must document why it did not do so in the ISOR. Statute requires that the reasons for noncompliance be stated with reasonable specificity. However, this APA requirement is not subject to judicial or OAL review.

APA Standards

The ISOR must comply with the six standards of the APA.

Necessity

(Gov. Code, §§ 11342.2, 11349, subd. (a),11349.1, subd. (a)(1), and CCR, tit. 1, §§ 10 and 11.)

The purpose of each regulatory provision must be stated with an explanation of why the provision is reasonably necessary to effectuate the purpose of the statute *(Gov. Code, § 11342.2).* If one subsection (i.e., subsection (a)) of a regulation includes three requirements (i.e., (a)(1), (a)(2), and (a)(3)), each must be justified separately to meet the necessity standard. This justification should include a brief explanation of the necessity for any non-substantial changes. If a regulation is necessary to maintain consistency with other regulations, the link between the cited regulations must be established.

Even if a regulatory provision is specifically mandated by statute or a court order, the ISOR shall still include an explanation of why the regulation is necessary to accomplish the purpose of the statute or court order. CCR, title 1, section 11 provides that the necessity standard is met in this mandated type of situation when the "record demonstrates that the specific provisions adopted in the regulation are mandated by a California statute or other applicable law."

Clarity

(Gov. Code §§ 11349, subd. (c) and 11349.1, subd. (a)(3); and CCR, tit. 1, § 16)

The ISOR must clearly explain the purpose and necessity for each regulatory change. If there is a conflict between the language of the proposed regulation and the description of the effect of the regulation, this creates a clarity problem and grounds for OAL disapproval *(CCR, § 16, subd. (a)(2)).* To avoid this situation, it may be helpful to compose each section of regulation text along with its corresponding justification in the ISOR. As with the Regulations Text, the ISOR must be written clearly enough to be understood by the regulated population.

Consistency

(Gov. Code, § 11342.2, 11349, subd. (d), and 11349.1, subd. (a)(4).)

In order to satisfy the consistency standard, the proposed regulation cannot conflict with other provisions of law (i.e., federal and state statutes and regulations). If a proposed regulation is necessary to maintain consistency with other regulations or statutes, this should be established by citing the relevant regulation or statute.

In some very limited cases the proposed regulations may differ from what is authorized under law. In such cases, Program must consult with the OLS Attorney/House Counsel. In order to meet the consistency standard, the ISOR should include a discussion that points out the difference between the Department's proposal and what is authorized by law, and should provide justification for the

Department's position. For example, if the Department proposes to implement a more stringent standard than what is required by federal law, the ISOR should explain how the Department's proposal differs from federal law, and should provide the authority and rationale for a more stringent standard.

Nonduplication
(Gov. Code, §§ 11349, subd. (f) and 11349.1, subd. (a)(6); and CCR, tit. 1, § 12.)
The nonduplication standard requires that a regulation not serve the same purposes as a state or federal statute or regulation *(Gov. Code, § 11349, subd. (f)).* This occurs where a regulation either repeats or rephrases in whole or in part a state or federal statute or regulation *(CCR, tit. 1, § 12, subd. (a)).*

For duplication of federally mandated regulations, the nonduplication standard is satisfied if the 45-day public notice states that the federally mandated regulation is being proposed, and cites where an explanation of the provisions of the regulation can be found. See Government Code sections 11346.2, subdivision (c), 11346.9, subdivision (c), and CCR, title 1, section 12, subdivision (b)(2) for further information.

For duplication mandated or authorized by law, the nonduplication standard is satisfied if a statement in the rulemaking file identifies the statute or regulation overlapped or duplicated and identifies the provision of law mandating or authorizing the overlap or duplication. See CCR, title 1, section 12, subdivision (b)(3) for further information.

Exceptions to APA Nonduplication Standard
Exceptions to the APA nonduplication standard are allowed under the following circumstances:

When Needed to Meet the Clarity Standard
In this situation, two requirements must be met in order to satisfy the nonduplication standard:
1) Any state or federal statute or regulation which is overlapped or duplicated by the proposed regulation must be identified.
2) The overlap or duplication must be justified.

In this scenario, a statement identifying the overlap/duplication must be included in the ISOR, and the overlapped/duplicated statute or regulation must also be cited in the authority or reference note at the end of the regulatory section. Additionally, an explanation justifying the necessity of the overlap or duplication must be provided to satisfy the clarity standard. This justification must provide information establishing that duplication/overlap is necessary to provide the requisite amount of clarity to the regulated population.

When Adopting or Amending Regulations Mandated by Federal Law Pursuant to Government Code Section 11346.9, subdivision (C)
In this situation, the Department adopts or amends a regulation mandated by federal law or regulations, the provisions of which are identical to a previously adopted or amended federal regulation. The Department shall be deemed to have complied with this section if a statement to the effect that a federally mandated regulation or amendment to a regulation is being proposed, together with a citation to where an explanation of the provisions of the regulation can be found, is included in the public notice (prepared pursuant to Gov. Code, § 11346.5). However, the Department must fully comply with Government Code Chapter 3.5, commencing with section 11340, with respect to any

provisions in the regulation which the Department proposes to adopt or amend that are different from the corresponding provisions of the federal regulation.

When Duplication is Mandated or Authorized by Another Provision of Law
In this situation, a statement must be included in the ISOR that:

1) Identifies the overlap/duplication with the other relevant provision of law. (The overlapping/duplicated statute or regulation should also be cited in the authority or reference note at the end of the regulatory section.)
2) Identifies the federal or state law requiring the overlap/duplication. This statement should set forth the applicable provision of law in a citation style which clearly identifies the statute or regulation and provides the information necessary to locate the full text of the statute or regulation. The mandating or authorizing provision of law should also be cited in the Authority and Reference note at the end of the regulatory section.

Grammar and Style Issues

Verb Tense
For non-emergency proposals use the present tense. For example: *"The proposed regulation amends requirements for…"*

Because emergency regulations actually go into effect before the public notice is published, the present or present perfect tense should be used. For example: *"This emergency regulation amends or has amended Section 51003…."*

Active Voice/Parallel Construction
Write the ISOR in the active voice (i.e., the subject provides the action) and provide parallel construction for paragraphs and the sentences. (See Regulation Text, Grammar and Style Issues, Parallel Construction for more information.) The ISOR must flow as a document read on its own, and its content must coincide with the regulation text.

Avoid Circular or Empty Statements or Explanations
Statements such as the following **do not** satisfy the necessity standard:

- *"A definition for 'provider' is proposed for adoption to clarify its meaning."*
- *"The application process is being adopted so that the public will know what rules to follow."*

Policy statements, speculation, or conjecture, without stating a reason or basis, do not constitute "substantial evidence of the need for a regulation" *(CCR, tit.1, § 10, subd. (b)(2)).*

Formatting
The ISOR should be single-spaced. When discussing each regulatory section proposed to be amended, each discussion point should follow the order in which the regulation text is presented in the existing regulation.

Incorporation by Reference Issues

(CCR, tit. 1, § 20.)

As previously discussed, incorporating a document by reference gives the document the same effect and force of the law as if the entire document were printed in the CCR. Therefore, the APA necessity standard also applies to materials incorporated by reference. The ISOR must include an explanation of necessity for **each regulatory element of an incorporated document, or each standard incorporated by reference.** This includes any instructions that are part of a form.

Specifically, the ISOR must explain:

- The authority, purpose and necessity for new or revised material incorporated by reference. (For example, if the incorporated material is a set of standards, explain the need for each standard and why one set of standards was chosen over another set of standards (if applicable)).
- The purpose and need for each field on any form incorporated by reference. (e.g.: Why must the information requested by the form be reported/collected, etc.?)
- The necessity of collecting any personal data on a form incorporated by reference (if applicable) in relation to the provisions of Civil Code, section 1798.17(consult with OOR and House Counsel as necessary).
- The necessity for each standard or requirement on a form (unless expressly exempt from the APA by statute).

Additionally, the Department must demonstrate that the material incorporated by reference is:

- Available to the affected public from a commonly known or specified source or is available, upon request, from the Department. (If the document is not available from a commonly known source and cannot be obtained from the Department, the ISOR and Notice of Proposed Action should indicate how to get a copy.)
- Too cumbersome, unduly expensive, or otherwise impractical to publish in its entirety in the CCR. (This is one of the main reasons to incorporate something by reference in the first place.)

Form and Application Issues

Style Guidelines for Forms Incorporated by Reference

When writing about forms in the ISOR, typically the form name, number, and date are underlined. The form name, number and revision date must also be included in the proposed Regulation Text.

Justification for Application Processes

When writing regulations to establish a "process," the following components should be kept in mind:

1) Timeframes
2) Step-by-step procedure; and
3) Approval criteria.

The purpose and necessity for these components must be established in the ISOR.

Timeframes

For any proposed timeframes established by the regulatory package, the ISOR should address how these timeframes were selected (for example, are they based on timeframes for a similar applications

process?). It may also be helpful to break down the timeframes and explain what actions would be occurring during that time.

> ***Example:*** *"The Department determined that a thirty-day processing time is necessary in order to allow time for adequate review of the provider application. The thirty-day processing time includes the following steps:*
>
> *"Five days – Assignment to appropriate unit.*
> *Five days were allowed for review and assignment to the appropriate unit. When the Department receives a provider application, it is opened, reviewed, logged in a tracking database and routed to the correct unit for review. (Different units handle different types of provider applications, for example, one unit handles dental providers, another unit handles physician providers, etc.)*
>
> *"Ten days – Analyst evaluation of application completeness.*
>
> *"Five days – Additional/secondary review, if necessary.*
>
> *"Five days – Prepare response to applicant (includes draft response and management approval).*
>
> *"Five days – Department mailroom handling.*

Step-by-step procedure

Each step of any applications process must be explained and justified in the ISOR. For instance, using the example above, the ISOR should explain why each of the proposed steps is critical to the process.

Approval criteria

Each criterion considered when reviewing an application for approval should be specified in the regulation and justified in the ISOR. The ISOR should explain why the Department believes it is necessary to meet the application criteria. For example, are these criteria for approval based on widely accepted standards such as the American Dental Association or Clinical Laboratory Improvement Amendments? Does meeting the criteria ensure accreditation?

Fees and Rates

If the regulation is setting or revising a fee or a rate, the ISOR must describe how the specific dollar amount was determined. In many cases legislation requires fees to be equivalent to the cost of providing a service, so a cost-revenue analysis should be included in the estimated fiscal impact statement portion of the ISOR.

INFORMATIONAL DIGEST (ID)

The Informational Digest (ID) provides a summary of the regulatory proposal for inclusion in the Notice of Proposed Action (notice). *(Gov. Code § 11346.5, subd. (a)(3).)* It is similar to the ISOR and, in some cases, can be directly duplicated from that document, however, it is intended to be a higher level overview, providing a snapshot of the regulatory proposal that the ISOR will then expand upon. The information provided in the ID is usually the regulated public's first encounter with the details of the regulatory package.

Note: Please see Appendix C: OOR Templates, Informational Digest for OOR's current ID template, or download the template online at the Office of Regulations Intranet site.

Summary of Proposal
Similar to the ISOR, this section of the ID briefly summarizes the proposed regulation by explaining what prompted its creation, why it is necessary, and what it would do. Any relevant statutory requirements should also be provided here.

Background and Summary of Existing Laws and Regulations
(Gov. Code § 11346.5, subd. (a)(3)(A) and (B).)
This section provides a brief overview of the proposed regulation and its purpose in relationship to Program, and includes a summary of any relevant laws or regulations affected by the regulatory proposal. As with the ISOR, the Background section should state why regulations are needed to support the program's regulatory purpose.

Policy Statement Overview
(Gov. Code, § 11346.5, subd. (a)(3)(C).)
The Policy Statement Overview must explain the problem the Department hopes to address with the proposed regulation, and should help the reader understand the need for action. It consists of the "Problem Statement," followed by a summary of the broad objectives or goals of the proposal. (See Appendix C: OOR Templates, Informational Digest for an example of OOR's preferred formatting for this section.)

Benefits
(Gov. Code, §11346.2, subd. (b)(1).)
This section lists the anticipated benefits of the proposed regulation. These benefits may include monetary and nonmonetary benefits such as the protection of public health and safety, worker safety, or the environment, the prevention of discrimination, the promotion of fairness or social equity, or an increase in openness and transparency in business and government. (See Appendix C: OOR Templates, Informational Digest for an example of OOR's preferred formatting for this section.)

Evaluation as to Whether the Regulations are Inconsistent or Incompatible with Existing State Regulations
(Gov. Code, § 11346.5, subd. (a)(3)(D).)
Program must provide a determination here as to whether the proposed regulation is inconsistent or incompatible with any existing state regulations. If it is not, Program may state:

"The Department has made a determination that these regulations are neither inconsistent nor incompatible with other state regulations."

Substantial Difference from Federal Regulation or Statute

(Gov. Code, § 11346.5, subd. (a)(3)(B) and (D).)

If there is a substantial difference from federal regulation or statute that difference should be described in this section of the ID and should include full citations. Program is advised to consult with their OLS Attorney on this portion of the regulatory package.

Incorporation by Reference

(CCR, tit. 1, § 2, subd. (c)(3).)

This section of the ID should list any forms or documents incorporated by reference as part of the regulatory proposal. (See also: Incorporation by Reference.)

ECONOMIC AND FISCAL DOCUMENTS

Under Government Code section 11346.5, state agencies must determine and present documentation of any cost impacts associated with their regulatory proposal, and must provide evidence supporting their conclusions. OAL is seeking the state agency's best estimation, based on available evidence, of the economic and/or fiscal impact(s) anticipated should a proposed regulation go into effect.

Department of Finance (DOF) staff, internal Program Budgets Staff, the OLS Attorney, and the OOR Coordinator are all available to assist Program with their economic and fiscal determinations, however, because Program possesses the greatest subject matter expertise of their own program(s) or agency, it is ultimately Program's responsibility to provide the economic and fiscal components required by the APA. Even if no economic or fiscal impact is anticipated, Program must still demonstrate this in the regulatory package.

Additionally, Program must use the Cost Estimating Methodology (CEM) as described in the State Administrative Manual (SAM) to generate their economic and fiscal estimates.

The full range of requirements and methodologies for determining and presenting economic and fiscal information as part of a regulatory package are described below.

Standard Form 399

(Gov. Code, § 11346.5, subd. (a)(6).)
State agencies are required to complete an Economic and Fiscal Impact Statement – Standard Form (Std.) 399 when promulgating regulations. DOF's instructions for preparing this form are published in sections 6601 through 6616 of the State Administrative Manual (SAM). The Std. 399 is intended to provide the regulated population with an overview of how the proposal would affect a number of economic aspects such as business expansion, job growth, and individual persons.

It is Program staff's responsibility to download and fill out the Std. 399.

The Std. 399 may be downloaded at: http://www.documents.dgs.ca.gov/osp/pdf/ std399.pdf

Economic Impact Assessment (EIA)

Each program must assess the economic impact of their proposed regulations on the population(s) directly affected. These population(s) include the individuals who:

- Must comply with the regulation;
- Must enforce the regulation;
- Receive a benefit from the regulation; and/or
- Incur a detriment from the regulation. *(Gov. Code, §11346.3.)*

Depending on whether the proposed regulation is a major or non-major regulation, the EIA requires different information and is presented in slightly different ways.

Non-major vs. Major Regulations

A "major regulation" is defined as one that, within one fiscal year will have an economic impact on California business enterprises and individuals in an amount exceeding fifty million dollars ($50,000,000) as estimated by the agency or program *(Gov. Code, § 11342.548, and CCR, tit. 1, §*

2000 subd. (g).) All other regulations are considered non-major.

To help expedite long review times Program should determine whether the proposed regulation is a major or non-major regulation as early in the regulatory development process as possible.

For non-major regulations the EIA must address the following items:

1) The creation or elimination of jobs in the state.
2) The creation or elimination of businesses within the state.
3) The expansion of businesses currently doing business in the state.
4) The benefits of the regulation to the health and welfare of California's residents, worker safety, and the environment. *(Gov. Code, § 11346.3, subd. (b).)*

These items shall be addressed in the ISOR and summarized in the Notice of Proposed Action (NOPA). Additionally, Program must prepare the CEM document required by the APA and described in SAM section 6607 (see below). *(Gov. Code, § 11346.5, subd. (a)(6).)*

For major regulations the EIA must address:

1) The creation or elimination of jobs in the state.
2) The creation or elimination of businesses within the state.
3) The competitive advantages or disadvantages for businesses currently doing business in the state.
4) The incentives for innovation in products, materials, or processes.
5) The benefits of the regulations, including but not limited to, benefits to the health, safety, and wellbeing of California's residents, worker safety, and the state's environment and quality of life. *(Gov. Code, § 11346.3, subd. (c)(1).)*

In addition to presenting this information in the ISOR and NOPA, Program must prepare a Standardized Regulatory Impact Analysis (SRIA) describing how they arrived at their conclusions (see below).

Cost Estimating Methodology (CEM)

The Cost Estimating Methodology (CEM) is the state's standard methodology, which must be used for estimating the costs of a regulatory proposal. *(Gov. Code, § 11346.5, subd. (a)(6).)* A document demonstrating that Program has engaged in this methodology is required for non-major regulations imposing a local mandate and, in practice, is included with every non-major regulatory package regardless of its mandate or cost. This CEM document is intended to "show the work" of the Program so that OAL may see how Program came to their economic/fiscal conclusions.

SAM sections 6606 and 6607 contain an in-depth description of the elements that must be provided and addressed in the CEM. In brief, these are:

1) The statement of the mandate;
2) Background or introductory material;
3) Working data;
4) Assumptions;
5) Calculations; and
6) Conclusion.

More information may be found in the online SAM, section 6000.

Standardized Regulatory Impact Analysis (SRIA)

All major regulations require a standardized regulatory impact analysis (SRIA) as detailed in Government Code section 11346.3, subdivision (c)(1)(A) through (F), in a manner prescribed by the Department of Finance (DOF), and pursuant to Government Code section 11346.36 (including regulations under CCR, tit. 1, §§ 2000 through 2004). The SRIA is a separate document and must address the following items:

1) The creation or elimination of jobs in California.
2) The creation of new businesses or elimination of existing businesses in California.
3) The competitive advantages or disadvantages for businesses currently doing business in California.
4) The increase or decrease of investment in California.
5) The incentives for innovation in products, materials or processes.
6) The benefits of the regulations, including, benefits to the health, safety, and welfare of California residents, worker safety, and the state's environment and quality of life, among others identified by the agency.

The SRIA tends to be a lengthy and detailed document. In order to avoid excessive duplication, state agencies may refer readers to the SRIA (i.e. "Please see the SRIA") from the appropriate sections in the ISOR.

Local Mandate Determination

(Gov. Code §§ 11346.5, subd. (a)(5).)

If the proposed regulations impose a mandate on local agencies or school districts, a statement of determination to this effect shall be made in the Informative Digest, and shall include whether the mandate requires state reimbursement pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code; and Section 6 of Article XIII B of the California Constitution; or Section 36 of Article XIII of the California Constitution. This determination must match the information provided on the Std. 399, Section A: Fiscal Effect on Local Government.

If the mandate requires reimbursement, a statement to that effect shall be made and at least one of the following items must be included in the statement or otherwise be included in the rulemaking file:

- A citation of an item in the Budget Act for the fiscal year in which the regulation will go into effect as the source from which the State Controller may pay the claims of local agencies or school districts; or
- A citation of an accompanying bill appropriating the funds as the source from which the State Controller may pay the claims of local agencies or school districts; or
- A letter or other documentation from DOF stating that the DOF has approved a request by the Department that funds be included in the Budget Bill for the next following fiscal year to reimburse local agencies or school districts for the costs mandated by the regulation; or
- A letter or other documentation from DOF stating that DOF has authorized the augmentation of the amount available for expenditure under the Department's appropriation in the Budget Act which is for reimbursement pursuant to Part 7

(commencing with § 17500) of Division 4 to local agencies or school districts from the unencumbered balances of other appropriations in the Budget Act, and that this augmentation is sufficient to reimburse local agencies or school districts for their costs mandated by the regulation. *(Gov. Code, § 11349.1, subd. (d)(3).)*

If a mandate exists but the Department finds that reimbursement is not warranted, the Department shall state the reasons for such a finding *(Gov. Code, § 11346.9, subd. (a)(2))*.

If the regulation does not impose such a mandate, and there are no costs for which reimbursement is required, the statement below shall be included in the ID:

"The Department has determined that the proposed regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code."

NOTICE OF PROPOSED ACTION (NOTICE)

The Notice of Proposed Action (notice) document is compiled by OOR staff based on information provided by Program in the ID template. (See also: RPT Phase I, Part 1: Drafting the Regulatory Package, Beginning the RPT Process, Step 4: Developing the Regulatory Documents.) Once the final draft of the regulatory package has been approved by the Department, DOF, and Agency, OOR submits the notice the OAL along with the initial rulemaking package. Once filed with the OAL, the notice initiates the 45-day public comment period and starts the one-year timeline for completion of the regulatory process.

In addition to the information provided by Program on the Informational Digest (ID) template, the notice must contain the following:

Public Hearing Information
(Gov. Code, § 11346.5, subd. (a)(1).)
The date, time, and place of any public hearing scheduled by Program or, if none is scheduled, information on how to request one.

Public Comment Period
(Gov. Code, §§ 11346.4, subd. (a), and 11346.5 subd. (a)(15).)
The specific date on which the written/public comment period closes (usually 45 days after the publication of the notice unless otherwise specified by statute).

Authority and Reference
(Gov. Code, § 11346.5, subd.(a)(2), and CCR, tit. 1, § 14.)
Program's authority and reference citations.

Mandated by Federal Law or Regulations
(Gov. Code, §§ 11346.2, subd. (c) and 11346.9.)
If adopting or amending regulations identical to previously adopted or amended federal regulations, the NOPA should provide a statement to that effect, together with a citation to where an explanation of the provisions of the proposed regulations can be found.

Other Statutory Requirements
(Gov. Code, § 11346.5, subd. (a)(4).)
Any Program-specific requirements or requirements specific to other related regulations or class of regulations.

Local Mandate
(Gov. Code §§ 11346.5, subd. (a)(5).)
The Local Mandate determination, if any. (See: Economic and Fiscal Documents, Local Mandate Determination.)

Fiscal Impact Statement
(Gov. Code, § 11346.5, subd. (a)(6).)
In accordance with DOF instructions *(SAM, §§ 6601-6616)*:

- The estimated cost to any local agency or school district requiring reimbursement.

- The estimated cost or savings to any state agency.
- An estimate of any other non-discretionary cost or savings imposed upon local agencies.
- An estimate of any cost or savings in federal funding to the state.

Housing Costs
(Gov. Code, § 11346.5, subd. (a)(12).)
Any significant effect(s) the regulation may have on housing costs.

Cost Impacts on Representative Person or Business
(Gov. Code, § 11346.5, subd. (a)(9).)
A brief description of any cost impacts known to the agency that a representative person or business would necessarily incur in reasonable compliance with the proposed action. If no such cost impacts are known then the following statement should be provided:

> "The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action."

Effect on Small Business
(CCR, tit. 1, § 4, subd. (a) and (b).)
A statement as to whether the regulations will affect small businesses. If no affect is anticipated, briefly explain how the program came to this determination.

Contact
(Gov. Code, § 11346.5, subd. (a)(14).)
The notice must include the names of an OOR and Program contact and their state telephone numbers and email addresses so that the regulated population may contact them for instructions or questions concerning the regulatory proposal.

Required Statements (OOR Coordinator)
In addition to compiling all the information submitted by Program, the OOR Coordinator is responsible for including the statements required by Government Code section 11346.5, subdivision (a), paragraphs (15) through (20) addressing the following (please refer to §11346.5 for more details):

- The date by which comments must be received.
- The availability of the rulemaking record.
- The ability of the public to request a public hearing.
- The availability of the changed regulation text prior to the final adoption, amendment, or repeal by the agency.
- The availability of the FSOR.
- The availability of regulatory materials on the agency's website (if applicable.)

REQUIREMENTS FOR EMERGENCY REGULATIONS

Government Code section 11342.545 defines an emergency as "a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, or general welfare."

There are two types of emergency regulations:

- Statutory
- Factual

In a statutory emergency, a statute expressly authorizes or requires a state agency to adopt certain regulations as an emergency, ***and*** the Legislature specifically determines that the situation is an emergency. In a factual emergency, an agency must provide proof, reasoning, and/or documentation that an emergency situation requiring immediate action exists. In this case, "immediate action" means that the time it would take to perform the regular rulemaking activities would be too long to avoid or prevent serious harm to the public.

Timelines and Notice

Emergency regulations have a shorter notice and comment period than regular rulemakings. The notice for an emergency regulation consists of the Finding of Emergency (FOE) document (see below) and the regulation text.

Typically:

- Five days before submission to OAL, the state agency must notice their regulatory mailing list, and post their FOE and regulation text on their website. *(Gov. Code, § 11346.1, subd. (a)(2).)*
- Public comments must be accepted for five days after the posting of the FOE. *(Gov. Code, § 11349.6, subd. (b).)*

However, if the emergency poses an immediate threat to the public, posting and public comment may not be required at all. *(see Gov. Code, § 11346.1, subd. (a)(3).)*

In addition, unless otherwise specified, the five-day notice period also applied to re-adoptions of the emergency regulation.

Finding of Emergency (FOE)

(Gov. Code, § 11346.1, subd. (b)(2).)

The FOE presents the facts supporting why immediate action is necessary to prevent harm to the public health and/or welfare. If an emergency situation existed and was known by the Department in sufficient time to have been addressed through non-emergency regulations, the FOE must explain the failure to address the situation through non-emergency regulations.

The contents of the FOE are listed in Government Code section 11346.1, subdivision (b)(2). They include:

1) A list of the facts demonstrating the existence of an emergency and the need for immediate action;
2) A list of any studies or reports the agency relied on in proposing the regulation;
3) The authority and reference citations to the statutes under which the agency is proposing the regulation;

4) An Informational Digest (ID);
5) Anything required by statute to be discussed specific to the state agency, regulation, or this type of regulation;
6) Local Mandate Determination;
7) An estimate of:
    a) The costs or savings to any state agency;
    b) The reimbursable cost to any local government agency;
    c) Any nondiscretionary costs or savings to state or local government agencies; or
    d) Any costs or savings in federal funding to the state.
8) The following statement as required by CCR, Title 1, section 48:

    "Government Code section 11346.1, subdivision (a)(2) requires that, at least five working days prior to the submission of the proposed emergency action to the OAL, the adopting agency provide a notice of proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the OAL, the OAL shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6."

9) If the agency knew of the emergency situation in time to address it through a regular rulemaking, facts explaining why this did not occur.

In addition to the FOE, the state agency must file the following with OAL:
1) The regulation text;
2) The Std. 399;
3) The Cost Estimating Methodology (CEM); and
4) A statement that the agency has complied with Government Code 11346.1, subdivisions (a)(2) or (3) (depending on what type of emergency the package represents, see item 8, above).

OAL Review for Emergency Regulations

Prior to submitting the emergency proposal to OAL, the state agency must provide a five-day public notice period during which notice of the proposal is mailed to everyone who has filed a request for notice.

Once this period has passed, OOR submits the emergency proposal to OAL. OAL then has 10 days to review the emergency regulations. During the 10 days, the state agency may change the regulatory text and add supporting documents to the file without providing additional notice to the public. However, agencies cannot change the regulatory subject matter into a different action without providing the five-day comment period specified in Gov. Code 11346.1, subdivision (a)(2).

Additionally, the five-day notice period also applies to the re-adoption process mentioned below.

Effective Period

After the five-day notice period and ten-day review by OAL, emergency regulations are filed with the Secretary of State and, absent any statutory restrictions, become effective for 180 days.

Alternately, if the state agency specified a different effective date in the regulatory proposal, the

regulations will become effective on the specified date.

Up to two emergency re-adoptions of 90 days each may be granted if the state agency needs more time to complete the necessary regular rulemaking. *(Gov. Code, § 11346.1, subd. (h).)* The five-day notice period will apply to each of these re-adoptions, as will OAL's ten-day review.

Notice and review periods should be factored into the re-adoption timeline. In other words, the 90-days allowed the state agency to complete their re-adoption ***includes***—and is not in addition to—the combined 15-day timeline for notice and review. If the state agency hopes to approve the emergency proposal within 90 days they need to submit it on the 80th day of the timeline.

Finally, a regular rulemaking must be filed with OAL before the emergency regulation expires in order to make the emergency regulation permanent.

See Appendix F: Emergency Regulations Flowchart and Government Code section 11346.1 for more on emergency regulations.

RPT PHASE I, PART 1 CONTINUED: APPROVING THE REGULATORY PACKAGE

Internal Approval
Once the regulatory documents are drafted and the Std. 399 is completed, the RPT review and approval process begins.

Note: Often, a draft Notice of Proposed Action (Notice) accompanies these documents. OAL often asks to see the notice along with the regulatory package even though the APA does not require this. Program is advised to work out any public hearing logistics, if applicable, early on in the regulations development process.

Step 5: RPT Concurrence
Once the regulatory proposal has been drafted, the RPT team reviews it for compliance with APA standards and legality. The full team then holds a meeting to finalize the documents prior to approval by Program's Center Deputy Director (see Center Approval, below). This meeting is called the "RPT meeting" or "RPT concurrence meeting."

Review
At least two weeks before the RPT meeting, Program staff distributes the draft documents to the team members for review. During the two weeks, the RPT members evaluate the drafts and make note of any issues and/or concerns for discussion.

RPT Concurrence Meeting
At the RPT concurrence meeting, the team:

1) Discusses any issues with the regulatory proposal that they have noticed during their review and revises the draft documents accordingly; and
2) Confirms the need for a public hearing.

Note: If a public hearing is needed, Program staff is responsible for scheduling the hearing (including court reporter and room). (See: The Rulemaking Project Team (RPT), Roles and Responsibilities.)

If possible, the regulatory documents should be finalized at this meeting. Once the team obtains concurrence, Program staff submits the draft documents to their Center Deputy Director for approval.

If documents are not finalized at this first meeting, team members use the feedback from the meeting to make any necessary revisions on their portion of the regulatory proposal, and then meet again until concurrence is achieved.

Step 6: Center Approval
The final draft of the regulatory proposal must be reviewed and approved by Program's Center Deputy Director in order to move to the next step in the review process. Each program/center has its own internal approval process. If the Center Deputy Director approves the package, the package moves to Step 8 (below). If not, the process moves to Step 7.

Step 7: Substantial Changes
If the Center Deputy Director requests substantial revisions to the regulatory proposal, the package is returned to the RPT team for changes and steps 4 and 5 of the approval process must be repeated

before the package can move forward.

OLS Concurrent Review

Once the Center Deputy Director has approved the regulatory proposal, the package returns to OOR and must be approved by OLS's Chief Counsel, Assistant Chief Counsel, the OLS attorney for the package, and OOR's Chief of Regulations. In order to expedite these approvals, OOR/OLS has recently instituted a process in which the above-named parties review the package in a single meeting.

Step 8: OLS Concurrent Review

Prior to the concurrent review, the reviewers receive an electronic copy of the regulation package The OOR Coordinator schedules the concurrent review meeting (typically two weeks out). Each reviewer uses this time to review the complete regulation package and then comes to the meeting prepared to provide their comments.

At the meeting, the reviewers discuss their respective substantive comments. Non-substantive comments (grammar/style) should also be provided but will not be the focus of the discussion. To the extent possible, the OOR Coordinator or other designated personnel uses a laptop to input any changes to the documents with the goal of finalizing the package at the meeting.

If the package is finalized at the meeting, the approval process continues as described below. If further review or changes are needed, another concurrent review must be scheduled and required approvals received before the process may continue.

Budget and Director's Office Approval

Once the package has been approved through the OLS concurrent review process, OOR becomes the "owner" of the official version of the regulatory package. It is now the OOR Coordinator's responsibility to keep track of the package as it is routed for further approval and through its final filing with OAL.

Step 9: Budget Approval

In order to obtain the required approval from the Department's Budget Office, the OOR Coordinator prepares a route slip to the Budget Office requesting approval of the Std. 399 and final CEM or SRIA.

The Budget Office:

1) Reviews and approves the Std. 399 and CEM or SRIA;
2) Develops and obtains the Budget Officer's signature on the Transmittal Memo to the California Health and Human Services Agency (Agency) and Department of Finance (DOF), as necessary; and
3) Routes the approved documents to OOR.

Step 10: Director's Office Approval

After receipt of Budget Office approval, the OOR Coordinator routes the package the Director's Office (DO). The OOR Coordinator includes a route slip and/or memo to the DO briefly explaining the contents of the package and specifies that review and approval is needed. (Please see Appendix C: OOR Templates for an example of this memo.)

Additionally, the OOR Coordinator includes a draft of the memos to DOF and Agency that are needed for Steps 11 and 12 (below), for the Director's approval. Typically, the Director will indicate their

approval by initialing each memo.

RPT PHASE II: EXTERNAL APPROVAL

Once the Budget Office and Director's Office have approved the package, Phase II of the RPT process begins.

Steps 11 and 12: Agency and DOF Approval

After receipt of the Director's sign-off, the OOR Coordinator hand delivers the package for the following sign-offs:

1) Agency
2) DOF

Agency and DOF are each allowed 60 days to review the package. Depending on the specific package and/or the anticipated workload at DOF (which is particularly high during state budget season) OOR may send a copy of the package to both Agency and DOF at the same time in order to expedite the review process. Otherwise, packages traditionally go to Agency first and are then picked up and delivered to DOF after Agency approval.

Note: A formal memo seeking approval from the appropriate executives at DOF and Agency must accompany the package. Examples of these memos can be found in Appendix C: OOR Templates. Additionally, an overview of Phases I and II of the RPT process are available in Appendix D: RPT Flowcharts and Process Breakdown.

RPT PHASE III: PUBLIC NOTICE THROUGH FINAL FILING

The third phase of the RPT process covers the steps from the regulatory package's initial filing with OAL, through the public comment/public hearing period, and on to the final filing with the Secretary of State.

Providing Notice and Initiating Public Comment

Step 13: Submission to OAL
Once the internal and external approvals have been completed, the OOR Coordinator transmits the rulemaking package to OAL for review and approval for publication in the California Regulatory Notice Register. OOR's includes the Std. 400 (required by CCR, tit. 1, § 6), and the notice (with public hearing and/or notice information as necessary) in this transmission.

The publication of the notice in the California Regulatory Notice Register begins the 45-day comment period and initiates the one-year notice period during which the regulatory proposal must either be finalized or re-noticed.

Step 14: Notice and Public Comment
The Department must give the public at least 45 days to submit written comments on the regulatory proposal.

To accomplish this, the OOR Coordinator submits the notice, proposed regulation text, and ISOR via email and the U.S. Postal Service to all parties who have requested notification of the Department's regulatory actions. Both OOR and Program keep their own lists of individuals who have requested notice, and both lists must receive notice during the public comment period. Additionally, OOR also provides a copy of the notice to the Director *(Gov. Code, § 11346.4, subd. (a)(2))* and posts it to the Department's website (*Gov. Code, § 11346.4, subd. (a)(6)).*

The comment period typically ends on the closure date set in the notice, however, the Department may extend the comment period pursuant to Government Code section 11346.8, subdivision (e), which provides that, if a new issue comes up at the public hearing and a member of the public requests additional time to respond, the Department must consider the request if it is practical and does not unduly delay action on the regulation.

Step 15: Comment Review (conditional)
Following the 45-day public comment period, Program must summarize and respond to any relevant received comments in an additional 15-day public availability period. Before any changes proposed during the 45-day public comment period are made available, however, the RPT Team, along with the OLS Chief Counsel, OLS Assistant Chief Counsel, and OOR Chief of Regulations review the regulatory package and assess the impact of any newly proposed language or provisions, including any fiscal/economic changes. Once approved, the package must again be approved by the DO.

Step 16: Re-Transmittal to DO (conditional)
If re-transmittal is warranted, the OOR Coordinator submits a new transmittal memo, containing the following items, to the DO:

1) A brief summary of what the changes to the regulations or the materials added to the

rulemaking file are intended to accomplish;
2) A clear description of the basis and consequences of any proposed changes that significantly alter Department policy from what was originally proposed. (Changes include responding to comments made in the initial 45-day comment period, changes the Department is initiating on its own, or both);
3) A brief discussion of any anticipated controversy;
4) A description of any anticipated fiscal impact and a revised EIA if needed;
5) A description of any pending legal action or legislation and its potential impact;
6) Revised regulation text;
7) Any changes to the documents relied on; and
8) Any other materials added to the rulemaking file during the comment period.

Step 17: 15-Day Public Availability Notice (conditional)

Once DO approval is granted, the OOR Coordinator develops the 15-day Public Availability Notice and, in collaboration with Program staff compiles the related rulemaking documents. The Department sends the 15-day public availability package via e-mail and U.S. Postal Service only to those individuals who commented on the original proposal, who testified at the public hearing, and/or who requested to receive changes.

Note: More than one 15-day Public Availability Notice may be sought if necessary and time permits. See also: Public Comment and Public Hearing, Opportunity to Comment on Further Changes.

PUBLIC COMMENT AND PUBLIC HEARING

The Department must consider all relevant material presented before adopting, amending, or repealing any regulation, and must demonstrate on the record that it considered the input received *(Gov. Code §§ 11346.8, subd. (a) and 11346.9, subd. (a)(3)).* This is done with a public comment period and, sometimes, a public hearing.

Note: No additional stakeholder engagement may be held by Program during the public comment and hearing period.

The Purpose of Public Participation in the Rulemaking Process

Public participation in the rulemaking process is designed to give the public a meaningful opportunity to participate in the adoption of state regulations, and to provide the public, OAL, and the judiciary with an adequate public record. Public participation also allows interested parties to present ideas and information that may improve the regulations.

All regulations with the exception of File and Print and Section 100 will typically include some form of public participation either through a 45-day public comment period (for non-emergency regulations), five-day comment period (for emergency regulations), or through a public hearing (if mandated by statute or requested by a member of the public).

Note: The APA does not require a public hearing unless one is required by statute or regulation. Additionally, agencies who choose, at their own discretion, to hold a public hearing must, "to the extent practicable," provide notice of the details for such a meeting by alerting the members of their agency's regulatory mailing list. *(Gov. Code, § 11346.8, subd. (a).)* (See also: RPT Phase III: Public Notice Through Final Filing, Providing Notice and Initiating Public Comment, Step 14: Notice and Public Comment.)

The 45-Day Public Comment Period

Once the notice is published in the California Regulatory Notice Register, it initiates a 45-day comment period. The Department must consider and respond to all comments submitted during the public comment period. (See: Responding to Public Comments, below.)

Public Hearing

A public hearing must be held if it is required by law or regulation, or if it is requested by a member of the public.

Required by Law or Regulation

If the state agency is required by law or other regulation to hold a public hearing they must provide the time, place, and nature of the hearing in the notice, and must provide notice to everyone on their regulatory mailing list at least 45-days prior to the hearing date.

Requested

(Gov. Code, § 11346.8, subd. (a).)

The state agency must hold a public hearing if one is requested no later than 15-days prior to the close of the public comment period. If a public hearing is requested after the mailing of the 45-day notice, the Department shall, to the extent practicable, provide notice of the time, date,

and place of the hearing by mailing the notice to everyone who has filed a request for notice.

Programs anticipating a request for public hearing should provide the required information on the initial 45-day public notice. This may be especially prudent if the regulatory proposal touched upon controversial or high profile subject matter.

Conducting the Public Hearing

(Gov. Code, § 11346.8.)

It is Program staff's responsibility to schedule, set-up, and conduct any public hearings. This includes scheduling the time, place, and court reporter for the hearing, and ensuring that any equipment (overhead screens, conference-call lines etc.) are functioning correctly before the proceedings begin. Based on past experience, it is recommended that Program staff arrive at least half-an-hour before the hearing begins in order to set up the room and ensure any technologies or equipment are functioning correctly.

If a public hearing is held, the state agency must accept both written and oral comments at the hearing. An agency is permitted to place reasonable restrictions on oral comments at hearings, including the length of time allotted to each speaker. Therefore, interested persons who wish to testify may also wish to bring a written testimonial to submit at the hearing. Limitations imposed by the agency will depend on the circumstances of the hearings.

The agency should consider how they intend to document the hearing (for example, by video recorder, by taking minutes, etc.)

Note: Public hearings are intended to provide the public with an opportunity to voice opinions on the rulemaking. They are not an arena for public debate. Agencies are not required to, and generally will not, provide a response to comments at the public hearing. Department personnel should never offer their own opinions or seek to either agree with or debate the ideas of any presenters.

Opportunity to Comment on Further Changes

The timeline for additional public comment depends on the changes (if any) made to the regulatory proposal after/as a result of the initial 45-day public comment period or public hearing.

Non-substantial Changes

(Gov. Code, § 11346.8, subd. (c)).

No further public comment period is needed for changes that do not materially alter the requirements, rights, responsibilities, conditions, or prescriptions contained in the originally proposed text *(CCR, tit. 1, § 40).* Examples of non-substantial changes include making grammatical or typographical changes. Such changes should be briefly identified and explained as non-substantial in the Final Statement of Reasons (FSOR) (see below).

15-Day Public Availability Period for Substantial, Sufficiently Related Changes and Additions to Documents Relied On

A 15-Day public availability period is required after the initial 45-day comment period in two instances:

1) When a substantial, sufficiently related change is made to the regulation text after the original

text was made available to the public *(Gov. Code, § 11346.8, subd. (c)).*

2) When the Department adds a document relied to the rulemaking file *(Gov. Code, § 11346.8, subd. (d)).*

A proposed change is sufficiently related to the original proposal if a reasonable member of the affected population could have determined from the Notice that the proposed change could have resulted *(CCR, tit. 1, § 42).* Such changes may be due to public comment or additional Department discussion.

Revisions to the regulation text must be clearly indicated, for example by using a double underline for newly added text and a ~~double strikeout~~ for newly deleted text *(CCR, tit. 1, § 46).*

The Department also must follow additional requirements per Government Code section 11346.8, subdivision (c) and 11347.1, CCR, title 1, section 44, and CCR, title 2, section 44 for responding to new comments in the FSOR, providing notice via mail to required persons, and making rulemaking record statements concerning departmental compliance.

45-Day Public Comment Period for Substantial, Not Sufficiently Related to the Regulatory Proposal
Modifications to the regulatory proposal as of result of the initial 45-day comment period that are not sufficiently related to the original proposal require a new 45-day public comment period.

Responding to Public Comments
All comments submitted and responses generated during the public comment period become part of the final rulemaking file.

What Requires a Response?
Government Code section 11346.5, subdivision (a)(15) states in part that the public notice shall include the date by which comments submitted in writing must be received. Comments received after this time period are considered late and do not require a response. However, if a decision is made to extend the comment period (for example, to accommodate anticipated comments from a stakeholder) all the comments received during the extended comment period must be responded to.

Late comments are still included in the rulemaking file *(Gov. Code, § 11347.3, subd. (b)(6)).*

Staff Responsibilities
For packages written by Program staff, it is Program staff's responsibility to respond to and compile public comments. The OOR Coordinator then ensures that all comments and responses are included with the FSOR for the final submission of the package to OAL.

For packages written by the Regulations Writing Attorney (RWA), the RWA will review comments in coordination with Program and assist with responses.

Program staff typically makes a copy of all written comments received to include in the final filing and annotates each comment with a number ("Comment # 1," "Comment # 2," etc.). They then create a response matrix summarizing the comments and responses along with an addendum listing the names

of the commenters (also annotated with a number: “Commenter #1,” “Commentor #2,” etc.). This allows Program to summarize groups of similar comments on the matrix. (See below for an example of the response matrix.)

Irrelevant or Repetitive Comments

Per Government Code section 11346.9, subdivision (a)(3)), the Department may:

- Aggregate and summarize repetitive or irrelevant comments as a group; and
- Respond to repetitive comments as a group or summarily dismiss irrelevant comments as a group.

A comment is irrelevant if it is not specifically directed at the proposed action or to the procedures followed by the Department in proposing or adopting the action (*Gov. Code, § 11346.9, subd. (a)(3))*. The Department’s response to such comments must include an explanation of why the comments are considered repetitive or irrelevant. For example:

> *“This regulation package addresses [regulatory subject matter]. The commenter references [unrelated subject matter], and the requirements of that program are not related to the contents of this rulemaking.”*

If more than a simple statement is made, all similar comments must be responded to equitably.

Comments of Support

General comments of support may also be summarized and responded to as a group. An example of such a response may be simple: “The Department appreciates these comments of support.”

Explanations and Summaries

The Department must explain its reasons for rejecting a comment. If accepting a comment, the Department must explain how the original proposal has been changed to accommodate the comment (*Gov. Code, § 11346.9, subd. (a)(3)).* If the commenter suggests specific regulatory language, this suggestion must be included in the summary of the comment.

Related Regulatory Packages

On occasion, the Department may find it helpful to reference a response to a prior/related regulation package. This can occur when there are sequential packages on the same/similar topic. In this case, the Department’s response should include the final OAL filing number of the previous regulation package. An attachment of the comment/response from the previous package may be attached to show that the issue was addressed.

Example of Comment/Response Matrix (Fig. 1)

Comment #	Subject	Commenter #	Comment	Response to Comment
1 **Key:** WT = written testimony. OT= oral testimony. E = exhibit	Section 51098.5 (Sign Language Interpreter Services – Definition)	27, 28 37, 48, 51	1.A. (WT) – 27: *The (1.A.) signifies that this is the 1st version (A) of comment #1 (for this subject) and it was provided by commenter 27.* 1.B. (WT) – 28: *The (1.B.) signifies that this is the 2nd version (B) of comment #1 (for this subject) and it was provided by commenter 28.* 1.C. (OT) – 37: *The (1.C.) signifies that this is the 3rd version (C) of comment #1 (for this subject) and it was provided by commenter 37.* 1.D. (OT) – 48: *The (1.D.) signifies that this is the 4th version (D) of comment #1 (for this subject) and it was provided by commenter 48.* 1.E. (WT) – 51: *The (1.E.) signifies that this is the 5th version (E) of comment #1 (for this subject) and it was provided by commenter 51.*	1.A. - C. *(the response provided here would be applicable to comments 1.A. 1.B. & 1.C.)* 1.B. *(the response provided here would be applicable only to 1.B.)* 1.D. - E. *(the response provided here would be applicable to 1.D. & 1.E)*

FINAL FILING

Below are the items and processes involved in Program's final filing of the regulatory package with OOR.

Preparing the Final Statement of Reasons (FSOR)

(Gov. Code, § 11346.9.)

The FSOR is an update to the ISOR prepared after the 45-day public comment period and the 15-Day public availability notice(s) (if applicable). The FSOR must meet the same APA standards as the ISOR and includes:

1) An update of any additional documents relied on. *(Gov. Code § 11346.9, subd. (a)(1).)*
2) A determination of local mandate. *(Gov. Code, § 11346.9, subd. (a)(2).)*
3) A summary of each objection and/or recommendation made to the proposal. (*Gov. Code, § 11346.9, subd. (a)(3).)*
4) A determination of less burdensome alternatives considered and any accompanying documentation. *(Gov. Code, § 11346.9, subd. (a)(4).)*
5) An explanation of the reasons for rejecting any proposed alternatives that would lessen an adverse economic impact on small business. *(Gov. Code, § 11346.9, subd. (a)(5).)*
6) An updated Informative Digest (ID).
7) If no public hearing was held/requested: a statement such as "The Department did not receive a request for a public hearing."
8) If no comments were received during the 45 and/or 15-day comment periods, a statement to this effect.

No new material, reasoning, or other substantive changes can be added to the FSOR that were not previously provided to the public through the 45 or 15-day notices. *(Gov. Code §§ 11346.8, subd. (d) and 11347.1).* However, non-substantive updates may be included for clarity purposes.

Preparing the Final Regulation Text

The final regulation text shall be updated from the original regulation text as provided through the 45 and/or 15-day comment period(s) to reflect all post-proceeding changes. This means all cumulative changes from all comment periods are shown in ~~single strikeout~~ and single underline. (*CCR, tit. 1, § 8.)*

Preparing the Updated ID

The ID must also be updated to reflect any changes affecting existing laws and regulations as a result of comments received. If nothing has substantially changed, a statement noting this should be included in the updated ID.

Final Rulemaking Submission to OOR

Once the final regulatory package has been updated, Program should submit the following to OOR:

1) A transmittal memo with:
    a) A brief summary of what the regulations do now that that they have been amended through the comment period(s) (if applicable);
    b) A brief discussion of any controversy generated by the regulations; and

   c) An identification of any pending legal or legislative action and its anticipated impact.
2) The revised Regulation Text and the final documents incorporated by reference and/or relied upon.
3) Updated ID.
4) FSOR.
5) The comment response matrix.
6) Annotated comment letters for 45-day, 15-day, and additional 15-day comment period (if applicable).
7) Annotated hearing transcript (if applicable).
8) Any materials added to the package (if applicable).

Transmittal of a Filing Order/Certificate of Compliance

Once the regulatory package is submitted to OOR, it is sent to the Director's Office for review and signature on the standard form (Std.) 400. For non-emergency regulations, this final filing instrument is called a "Filing Order." For emergency regulations, it is called a "Certificate of Compliance." Once the Director's Office has signed the Std. 400, OOR transmits the regulation package and Filing Order or Certificate of Compliance to OAL.

OAL Review, Approval, and Disapproval

Once the Department files the final package, OAL has 30 working days from the date of submission to review the package and either approve or disapprove it. *(Gov. Code §11349.3, subd. (a).)*

If disapproved, OAL will issue a notice of disapproval to the Department specifying their reasons. OAL then has seven (7) calendar days to provide a written opinion detailing the reasons for disapproval *(Gov. Code, § 11349.3, subd. (b)).*

Grounds for disapproval include:

1) Failure to comply with procedural requirements, such as:
   a) The required 45-day public notice was not given.
   b) The 45-day public notice or the 15-day public availability was not distributed to required persons.
   c) Language different from that originally noticed was not properly made available through a 15-Day public availability, or was not substantially related to what was originally noticed.
2) Submission of an incomplete rulemaking file. For example, if:
   a) The filing is missing documents.
   b) The recommendations, objections, or written comments were not adequately responded to.
   c) Additional information added to the rulemaking file was not previously noticed.
3) Failure to comply with any of the six APA standards: authority, reference, consistency, clarity, nonduplication, and necessity.

If OAL issues a notice of disapproval, the Department is normally given an additional 120 days to correct the problem and resubmit amended regulations *(Gov. Code § 11349.4)*. Unless substantial changes have been made to the package, resubmission may be done without additional notice and public hearing. However, addressing a disapproval typically involves changes to the regulation text, additions to the rulemaking file or materials relied upon, or changes or additions to responses to

comments. Thus, typically these changes must be made available for an additional 15 days for public comment prior to resubmitting the revised package to OAL.

In many instances the Program, OOR, and the OLS Attorney can provide additional oral or written information if OAL has questions about a package. In many cases OAL will allows minor edits or corrections to be made informally rather than issuing a disapproval.

Note: Once a rulemaking file is submitted to OOR, it is critical that Program staff be available in case OAL requires clarification or further information during the review period.

Effective Date of Regulations

A regulation typically becomes effective after it is approved by OAL and filed with the Secretary of State as follows:

- On January 1 if the regulation or order of repeal is filed on September 1 to November 30, inclusive.
- On April 1 if the regulation or order of repeal is filed on December 1 to February 29, inclusive.
- On July 1 if the regulation or order of repeal is filed on March 1 to May 31, inclusive.
- On October 1 if the regulation or order of repeal is filed on June 1 to August 31, inclusive. *(Gov. Code, § 11343.4, subd. (a).)*

However, effective dates are different if:

- Prescribed by statute *(Gov. Code, § 11343.4, subd. (b)(1)).*
- The Department prescribes a later effective date in the filed rulemaking *(Gov. Code, § 11343.4, subd. (b)(2)).*
- The Department submits a written request to OAL demonstrating good cause for an earlier effective date (*Gov. Code § 11343.4, subd. (b)(3)).* This request should include the specific effective date desired, the reasons for requesting an early effective date, and whether an earlier effective date will have an impact on affected persons' ability to comply with the regulations.
- The regulation was filed as an emergency.

Effective Date of Emergency Regulations

Emergency regulations receive a ten-day review, sometimes subject to public notice, and five calendar days to submit comments (*Gov. Code, § 11349.6, subd. (b)*).

If approved by OAL, emergency regulations are filed with the Secretary of State and become effective for 180 days. A regular rulemaking process, including the 45-day and/or 15-day comment periods, as applicable, must occur in order for the emergency regulations to become permanent. At the end of the rulemaking process, the Department must file a Certificate of Compliance for approval by OAL, which is then filed with the Secretary of State, making the emergency regulation permanent.

The Rulemaking File

Government Codes section 11347.3, subdivision (b) sets out the required contents of the rulemaking file to be sent for OAL approval. It includes, in brief:

- Copies of any applicable petitions and related decisions.
- All published notices.
- All fiscal documents.
- All comments and responses
- An updated ID
- The ISOR and FSOR.
- All documents relied on and/or how to access them online.
- Other public documents relevant to the regulation or the rulemaking process.
- Other information, statements, reports, or data the Department is required by law to consider or prepare in connection with the regulatory proposal.
- A Delegation Order (if the Director is unable to sign the required documents).
- An Index or Table of Contents with a Certification signed by the Chief of OOR.

The rulemaking file is accompanied by the Filing Order or Certificate of Compliance (for emergency regulations), which consists of the final regulation text along with the Std. 400 as signed by the Director (or designee) indicating adoption of the proposed changes (to adopt, amend, or repeal the regulations).

CDPH - Office of Regulations and Hearings
Regulation Timeline/Action Plan- Regular with Furlough

Please fill in the yellow highlighted areas.

Title of Proposed Regulation: | **Date of Action Plan:** | **DPH-**

Finish Date based Step 1: 1/0/00

Step	Action	Projected Days to Complete	Cumulative Days to Complete	Projected Date	Actual Date	Actual Number of Days	New Effective Date Based on Actual Date	Responsible Party	Notes/Comments
	Phase I - Regulation Development								
1	Start Date of Project is determined by the addition to the RTL	n/a	n/a			n/a		OOR Co-lead	
	Assemble initial Rulemaking Project Team (RPT) (Program, OOR, OLS, Budgets, at minimum) meeting	14	14					Program Co-lead	
1.1	Initial RPT meeting	1	15					Program Co-lead	
2	Develop regulation package (reg pkg: ISOR, ID, reg text, 399, CEM).	265	280					RPT (Program Co-lead)	
2.1	Distribute reg pkg and set up RPT meeting.	14	294					RPT (Program Co-lead)	
2.2	RPT final review meeting. (Reconciliation of remaining issues.)	1	295					Program & OOR Co-Leads	
2.3	Finalize documents and obtain concurrence of RPT to proceed.)	7	302					Program & OOR Co-Leads	
3	Obtain Center Deputy approval and route to OOR.	21	323					Program Co-lead	
3.1	OLS/OOR concurrence review and mtg. Memos to Agency and DOF are forwarded to OOR Chief and ACC for signature.	21	344					OOR Co-lead	
3.2	Budgets and DO concurrent approval of pkg and Std. 399/CEM and route back to OOR.	21	365					Budgets	
4	Route for oversight agency's approval.	1	366					OOR Co-lead	
5	Phase II - Control Agency Review/Approval								
5.1	Agency review of the reg pkg.	90	456					OOR Co-lead	
5.2	DOF review of the reg pkg. (If applicable)	90	546					OOR Co-lead	
	Draft web page, prepare emails and hardcopy mailings during approval routings.	0	546					OOR Co-lead	
	Draft and obtain OOR Chief approval of Public Notice (PN).	5	551					OOR Co-lead	
6	Phase III - Public Participation Process								
6.1	Prepare PN package (PN, ISOR, reg text, Std. 399/CEM) for submittal for OAL's review/approval.	7	558					OOR Co-lead	
6.3	**OAL's review of the PN.**	**3**	561					**OOR Co-lead**	
	Submit OAL approved reg docs to web coordinator for posting.	7	568					OOR Co-lead	
6.4	Duplication and Mailing.	21	589					OOR Co-lead	

6.5	A) Post PN on CDPH Website. B) Publication of PN in Notice Register and begin Public Comment Period. (30th day) [Starts one-year clock.]	1	590					OOR Co-lead	
6.6	Last day to request a Public Hearing. (15 days before end of 45-day comment period.)	30	620					OOR Co-lead	
6.7	End of 45-day Public Comment period/Public Hearing (45 days from Step 6.5.)	15	635					OOR Co-lead	
6.8	A) Review and evaluate public comments and determine if any revisions should be made to the regulations as noticed. B) If STD 399 revisions are needed, see OOR for next process steps.	30	665					Program Co-lead	
(R15-day) 6.9	Make any necessary changes to the regulations.	21	686					Program Co-lead	
(R15-day) 6.10	RPT concurrence to proceed.	14	700					RPT (Program Co-lead)	
(R15-day) 6.11	Obtain Center Deputy approval.	14	714					Program Co-lead	
(R15-day) 6.12	Prepare 15-day notice and route for the OOR Chief's approval.	7	721					OOR Co-lead	
(R-15-day) 6.13	Duplication and Mailing and begin 15-Day Availability.	14	735					OOR Co-lead	
(R15-day) 6.14	**Regulation text revisions are made available for public comment. (End 15-Day Availability)**	**15**	750					**OOR Co-lead**	
(R15-day) 6.15	Repeat Step 6.8 to determine if 2nd 15-Day Availability Period is required. If yes, repeat Steps 6.8 thru 6.14. If no, continue to Step 6.16.	30	780					RPT (Program Co-lead)	
6.16	Prepare Updated Informative Digest (UID), responses to all comments, regulation text, and FSOR.	30	810					Program Co-lead	
6.17	RPT review of Updated Informative Digest, All Responses to Comments, Regulation Text, and FSOR.	14	824					RPT (Program Co-lead)	
6.18	Finalize documents and obtain concurrence of RPT to proceed.	7	831					RPT (Program Co-lead)	
6.19	Obtain Center Deputy approval.	14	845					ProgramCo-lead	
7	Complete rulemaking file (STD 400, UID, updated reg text and FSOR).	21	866					OOR Co-lead	

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8	Obtain OOR Chief and ACC approvals. OOR Chief certifies rulemaking file. File submitted to OAL for review/approval.	21	887					OOR Co-lead	
9	**OAL review of package and if approved, filing with the SOS.**	**45**	932					**OOR Co-lead**	**Statute allows 30 working days.**
10	**Regulations become effective on a quarterly basis dependent on submittal date.**	**90**	1022					**OOR Co-lead**	**See OOR for info.**
Total Time to Complete This Regulation Package:			**Days**	**Months**	**Years**				
			0	0.0	0.00				

Actual review time frames will vary depending on the size and complexity of each regulation package.

Program Lead maintains the official version of regulation documents through Center Approval (Step 3). OOR Lead maintains the official version from Step 4 through the end of the process. Co-leaders will ensure that each Lead has copies of the most current version at all steps through the process.

CDPH-Office of Regulations and Hearings
Regulations Action Plan-Emergency with Furlough

Please fill in the yellow highlighted areas.

Title of Proposed Regulation:	**Date of Action Plan:**	**DPH-**
	Priority List Finish Date:	**Priority Number:**

Step	Action	Projected Calendar Days to Complete	Cumulative Days to Complete	Projected Date	Actual Date	New Projected Date based on Actual Date	Actual Number of Days	New Temporary Effective Date Based on Actual Date	Responsible Party	Notes/Comments
1	Start Date of Project is determined by the Departmental Priority List	n/a	n/a			n/a	n/a		OOR Co-lead	
	Assemble initial Rulemaking Project Team (RPT) (Program, OOR, OLS, Budgets, at minimum) meeting.	24	24						Program Co-lead	
1.1	Initial RPT meeting	2	26						Program Co-lead	
2	Develop regulation package (emerg pkg).	175	201						RPT (Program Co-lead)	
2.1	Distribute reg pkg and set-up RPT meeting.	16	217						RPT (Program Co-lead)	
2.2	Final Review RPT meeting and decide if Public Hearing is needed. (Reconciliation of remaining issues.)	6	223						Program & OOR Co-Leads	
2.3	Finalize documents and obtain concurrence of RPT to proceed.	15	238						Program Co-Lead	
3	Obtain Center Deputy approval.	15	253						Program Co-lead	
3.1	OOR signs off complete package and forwards to Budget Office.	12	265						OOR Co-lead	
3.2	Obtain approval of fiscal analysis w/399 and route back to OOR.	15	280						Budgets	
4	Director's Office review of the reg pkg.	21	301						OOR Co-lead	
5	Agency and DOF approval of reg pkg and STD 399 w/attachments.									
5.1	Agency review of the reg pkg.	102	403						OOR Co-lead	
5.2	DOF approval of the reg pkg. (If applicable)	102	505						OOR Co-lead	
6	Public Participation Process									
6.1	Prepare NPEA, Emerg Pkg, and PN for Director's signature.	5	510						OOR Co-lead	
6.2	Route NPEA, Emerg Pkg, and PN for the Director's signature, via OLS.	21	531						OOR Co-lead	
6.3	Duplicate and mail NPEA (OSP).	51	582						OOR Co-lead	
6.4	NPEA Period (5 working days)	14	596						OOR Co-lead	
6.5	Submit Emerg Pkg to OAL.	2	598						OOR Co-lead	

CDPH-Office of Regulations and Hearings
Regulations Action Plan-Emergency with Furlough

Step	Action	Projected Calendar Days to Complete	Cumulative Days to Complete	Projected Date	Actual Date	New Projected Date based on Actual Date	Actual Number of Days	New Temporary Effective Date Based on Actual Date	Responsible Party	Notes/Comments
6.6	**OAL reviews Emerg Pkg and files pkg with SOS. Regs become effective upon filing with SOS. Post on CDPH Website.**	**10**	**608**						**OOR Co-lead**	
	Temporary Effective Date							**New Effective Date Based on Actual**	n/a	
	180th day		**180**				**180**		n/a	
6.7	**OAL's review of the PN.**	**3**	**611**						**OOR Co-lead**	
6.8	Duplication and Mailing.	51	662						**OOR Co-lead**	
6.9	Post PN on CDPH Website.	2	664						**OOR Co-lead**	
	Publication of PN in Notice Register begins Public Comment Period. (30th day) [Starts one-year clock.]	0	664						OAL	
6.10	Last day to request a Public Hearing. (15 days before end of 45-day comment period.)	51	715						OOR Co-lead	
6.1	End of 45-day Public Comment period/Public Hearing (45 days from Step 6.9.)	25	740						OOR Co-lead	
6.1	Review and evaluate public comments and determine if any revisions should be made to the regulations as noticed. If no, continue to Step 6.20. If STD 399 revisions are needed, see OOR for next process steps.	47	787						Program Co-lead	
(15-day) 6.13	Make any necessary changes to the regulations.	25	812						Program Co-lead	
(15-day) 6.14	RPT Team concurrence to proceed.	15	827						RPT (Program Co-lead)	
(15-day) 6.15	Obtain Center Deputy approval.	15	842						Program Co-lead	
(15-day) 6.16	Prepare 15-day notice and route for the Director's signature, via OLS.	15	857						OOR Co-lead	

CDPH-Office of Regulations and Hearings
Regulations Action Plan-Emergency with Furlough

Step	Action	Projected Calendar Days to Complete	Cumulative Days to Complete	Projected Date	Actual Date	New Projected Date based on Actual Date	Actual Number of Days	New Temporary Effective Date Based on Actual Date	Responsible Party	Notes/Comments
(15-day) 6.17	Duplication and Mailing.	51	908						OOR Co-lead	
(15-day) 6.18	**Regulation text revisions are made available for public comment. (15-Day Availability)**	**15**	923						**OOR Co-lead**	
(15-day) 6.19	Repeat Step 6.12 to determine if 2nd 15-Day Availability Period is required. If yes, repeat Steps 6.13 thru 6.18. If no, continue to Step 6.20.	9	932						RPT (Program Co-lead)	
6.20	Prepare Updated Informative Digest, responses to all comments, regulation text, and FSOR.	25	957						Program Co-lead (RPT Assist)	
6.2	Review of Updated Informative Digest, responses to comments, regulation text, and FSOR.	15	972						RPT (Program Co-lead)	
6.2	Finalize documents and obtain concurrence of RPT to proceed.	25	997						RPT (Program Co-lead)	
6.2	Obtain Center Deputy approval.	15	1012						Program Co-lead	
7	Complete rulemaking file.	12	1024						OOR Co-lead	
8	Obtain Director's Approval. OOR Chief certifies rulemaking file. File submitted to OAL.	3	1027						OOR Co-lead	
9	**OAL review of package and if approved, filing with the SOS.**	**45**	**1072**						**OOR Co-lead**	
10	**Regulations become effective upon filing with SOS.**	**1**	**1073**						**OOR Co-lead**	
	Total Time to Promulgate This Regulation (based on number of Actual Days to date):						**Days**	**Months**	**Years**	
							0	0.0	0.00	

Rulemaking days expired (from Steps 6.9 to 8): 0
Rulemaking days left (from 360 days): 360

*Actual review timeframes will vary depending on the size and complexity of each regulation package.
Bold font indicates fixed days.

Guide to

Public Participation in the Regulatory Process

Office of Administrative Law

INTRODUCTION

In California, laws are enacted by the Legislature and are called "statutes". Often times, the Legislature enacts statutes that allow or require a state agency in the Executive Branch to adopt "regulations". A "regulation" is a policy or procedure affecting the public or any segment of the public that implements, interprets, or makes specific a statute the state agency enforces or administers. Unless expressly exempted, state agencies must follow the procedures and requirements set forth in the California Administrative Procedure Act (Government Code § 11340 *et seq.*) (APA) and rules adopted by the Office of Administrative Law (OAL). Once properly adopted, regulations have the force of law and therefore can directly affect the legal rights and duties of members of the public.

The APA is designed to provide the public with a meaningful opportunity to participate in the adoption of regulations by California state agencies and to ensure the creation of an adequate record for OAL and judicial review. Every California state agency must satisfy the basic minimum procedural requirements established by the APA for the adoption, amendment or repeal of an administrative regulation unless the agency is expressly exempted by statute. The following materials are intended to provide guidance on how members of the public can participate in the rulemaking process.[1] This includes a general overview APA and sources of relevant information, a discussion on what must be adopted pursuant to the APA, an overview of the regular rulemaking process and an overview of the emergency rulemaking process.

[1] / This document is for information purposes only. For specific legal requirements and procedures, please review the California Administrative Procedure Act (Government Code § 11340 et seq.) (APA) and rules adopted by the Office of Administrative Law (OAL).

WHAT IS A REGULATION THAT MUST BE ADOPTED PURSUANT TO THE APA?

Not every statute requires the adoption of an implementing regulation. In this regard, it is useful to think about three types of statutory provisions:

1) ***self-executing, 2) wholly-enabling and 3) susceptible to interpretation.***

A self-executing statutory provision is so specific that no implementing or interpreting regulation is necessary to give it effect. An example is a statutory provision that provides: "The annual licensing fee is $500."

In contrast, a wholly-enabling statutory provision is one that has no legal effect without the enactment of a regulation. An example is a statute that provides: "The department may set an annual licensing fee up to $500." This type of statute cannot be legally enforced without a regulation setting the fee.

A statutory provision that is susceptible to interpretation, may be enforced without a regulation, but may need a regulation for its efficient enforcement. An example is a statute that provides: "There shall be adequate space between hospital beds." Conceptually, this statute could be enforced on a case-by-case basis, but such enforcement would probably present significant difficulties. *(It does not violate the APA to enforce or administer a statute on a case-by-case basis so long as no rule or standard of general application is used that should have been adopted pursuant to the APA.)*

Every "regulation" is subject to the rulemaking procedures of the APA unless expressly exempted by statute.

IT'S MANDATORY Compliance with the rulemaking requirements of the Administrative Procedure Act is mandatory. (***Armistead v. State Personnel Board.***) All regulations are subject to the APA, unless expressly exempted by statute. (***Engelmann v. State Board of Education.)*** Any doubt as to the applicability of the APA should be resolved in favor of the APA. (***Grier v. Kizer***.) If a rule looks like a regulation, reads like a regulation, and acts like a regulation, it will be treated by the courts as a regulation whether or not the issuing agency so labeled it. (***SWRCB v. OAL***.)

"Regulation" means <u>every</u> rule, regulation, order, or standard of general application or the amendment, supplement, or revision of <u>any</u> rule, regulation, order or standard adopted by <u>any</u> state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure.

A GENERAL RULE ***A standard or procedure of general application (general rule) is a standard or procedure that applies to an open class. (***Roth v. Department of Veterans Affairs***.) An open class is one whose membership could change*****. This broad definition includes many classes of rules that are exempt from notice and comment under the federal Administrative Procedure Act.**

THE PROHIBITION The APA specifically prohibits any state agency from making any use of a state agency rule which is a "regulation" as defined in Government Code section 11342.600, that should have, but has not been adopted pursuant to the APA (unless expressly exempted by statute). Such a rule is called an “underground regulation” and its efficacy may be challenged to OAL or to a court.

No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a “regulation” under the APA unless it has been adopted as a regulation and filed with the Secretary of State pursuant to the APA. Government Code section 11340.5(a)

Armistead v. State Personnel Board

In 1978, the California Supreme Court made it clear that compliance with the rulemaking requirements of the Administrative Procedure Act is mandatory. (***Armistead v. State Personnel Board.***) In doing so, the court quoted a 1955 legislative report finding that noncompliance with APA rulemaking requirements was common.

> "The committee is compelled to report to the Legislature that it has found many agencies which avoid the mandatory requirements of the Administrative Procedure Act of public notice, opportunity to be heard by the public, filing with the Secretary of State, and publication in the Administrative Code.
>
> "The committee has found that some agencies did not follow the act's requirements because they were not aware of them;

some agencies do not follow the act's requirements because they believe they are exempt; at least one agency did not follow the act because it was too busy; some agencies feel the act's requirements prevent them from administering the laws required to be administered by them; and many agencies . . . believe the function being performed was not in the realm of quasi-legislative powers.

"The manner of avoidance takes many forms, depending on the size of the agency and the type of law being administered, but they can all be briefly described as 'house rules' of the agency.

"They consist of rules of the agency, denominated variedly as 'policies,' 'interpretations,' 'instructions,' 'guides,' 'standards,' or the like, and are contained in internal organs of the agency such as manuals, memoranda, bulletins, or are directed to the public in the form of circulars or bulletins." [First Report of the Senate Interim Committee on Administrative Regulations (1955) as cited in ***Armistead,*** p. 205.]

HOW TO DETERMINE WHETHER AGENCY'S POLICY OR PROCEDURE SHOULD BE ADOPTED PURSUANT TO THE APA

Preliminarily determine whether the particular policy or procedure is already set out in an applicable statute or duly adopted regulation. (Generally, duly adopted regulations are printed in the California Code of Regulations.) The adoption of a policy or procedure as a "regulation" pursuant to the APA is not required if you find the specific policy or procedure in an applicable statute or duly adopted regulation.

If you determine that the policy or procedure (i.e., rule) is not set out in an applicable statute or duly adopted regulation, use the following three-step analysis to determine whether the policy or procedure must be adopted as a regulation pursuant to the requirements and procedures of the APA:

First, is the policy or procedure either:

- a rule or standard of general application, *or*
- a modification or supplement to such a rule?

Second, has the policy or procedure been adopted by the agency to either:

- implement, interpret, or make specific the law enforced or administered by the agency, *or*
- govern the agency's procedure?

Third, has the policy or procedure been expressly exempted by statute from the requirement that it be adopted as a "regulation" pursuant to the APA?

If the policy or procedure satisfies steps one and two, then it is a "regulation" as defined in the APA and must be adopted pursuant to the APA unless it falls within an express statutory exemption from the requirements of the APA. Generally, all "regulations" issued by state agencies are required to be adopted pursuant to the APA, unless *expressly* exempted by statute. (Government Code section 11346.) If the policy or procedure does not fall within an express statutory exemption, then it is subject to the rulemaking requirements of the APA.

EXPRESS STATUTORY EXEMPTIONS ARE FOUND IN THE APA AND IN OTHER STATUTES. THE FOLLOWING ARE SOME OF THE EXPRESS EXEMPTIONS SET OUT IN THE APA.

- **INTERNAL MANAGEMENT:** "A regulation that relates only to the internal management of the state agency." (Government Code Section 11340.9(d).)

  The internal management exception to the APA is narrow. A regulation is exempt as internal management if it:

(1) directly affects only the employees of the issuing agency, and

(2) does not address a matter of serious consequence involving an important public interest. (***Armistead, Stoneham, Poschman,*** and ***Grier***.)

- **FORMS:** "A form prescribed by a state agency or any instructions relating to the use of the form, but this provision is not a limitation on any requirement that a regulation be adopted pursuant to this chapter when one is needed to implement the law under which the form is issued." (Government Code Section 11340.9(c).)

  This legislative language creates a limited statutory exemption relating to forms. A regulation is *not* needed if the form's contents consist only of existing, specific legal requirements.

  By contrast, if an agency *adds any language which satisfies the definition of "regulation" to the existing legal requirements*, then, under Government Code section 11340.9(c), a formal regulation is "needed to implement the law under which the form is issued." Section 11340.9(c) cannot be interpreted as permitting state agencies to avoid mandatory APA rulemaking requirements by simply typing regulatory language into a form because this interpretation would allow state agencies to ignore the APA at will.

- **AUDIT GUIDELINES:** "A regulation that establishes criteria or guidelines to be used by the staff of an agency in performing an audit, investigation, examination, or inspection, settling a commercial dispute, negotiating a commercial arrangement, or in the defense, prosecution, or settlement of a case, if disclosure of the criteria or guidelines would do any of the following:

  "(1) Enable a law violator to avoid detection.

  "(2) Facilitate disregard of requirements imposed by law.

"(3) Give clearly improper advantage to a person who is in an adverse position to the state." (Government Code Section 11340.9(e).)

- **ONLY LEGALLY TENABLE INTERPRETATION:** "A regulation that embodies the only legally tenable interpretation of a provision of law." (Government Code Section 11340.9(f).)

- **RATE, PRICE, TARIFF:** "A regulation that establishes or fixes rates, prices, or tariffs." (Government Code Section 11340.9(g).)

- **LEGAL RULING OF TAX COUNSEL:** "A legal ruling of counsel issued by the Franchise Tax Board or State Board of Equalization." (Government Code Section 11340.9(b).)

- **PRECEDENT DECISION:** A quasi-judicial decision by a state agency that is designated pursuant to Government Code Section 11425.60 as a precedent decision is expressly exempt from being adopted as a "regulation" pursuant to the APA.

THE RULEMAKING PROCESS

- **Delegation of Authority:**

How can a state agency in the executive branch adopt rules and regulations that have the force of law? The California Constitution separates the powers of the state government into the legislative, executive, and judicial branches. Branches charged with the exercise of one power may not exercise either of the others' except as permitted by the Constitution. The Constitution also vests the legislative power of the State in the Legislature, but reserves the powers of initiative and referendum to the people.

California courts have long recognized that under the Constitution, the Legislature may delegate quasi-legislative powers to a state agency in the executive branch by statute. Therefore, if the Legislature has enacted a statute delegating quasi-legislative power to an agency, that agency has authority to adopt regulations within the scope of that delegation.

- **What Prompts a Rulemaking?**

All regulations are prompted by the identification of a "problem" that needs to be addressed by the agency through the adoption, amendment, or repeal of regulations in order to enforce or administer a statute. For example, when the Legislature enacts a new program or amends statutes governing existing programs, the Legislature often leaves it up to the agency administering the program to implement the statutory changes. The agency must then adopt, amend, or repeal regulations to avoid the use of prohibited "underground regulations."

- **Preliminary Activities / Regulation Development & Analysis:**

Once an agency determines that the adoption, amendment or repeal of regulations is necessary, the agency performs legal and factual research needed to develop and support the documents required to conduct a formal APA rulemaking proceeding. While much of this research is done internally by the agency, some agencies involve the public during this stage through workshops or other informal proceedings where the agency may invite interested persons to provide input or information. The APA provides that an agency must engage in pre-notice public discussions regarding complex proposals or large proposals. However, a decision whether to engage in such discussions is not subject to review by OAL or the courts.

In conducting a rulemaking, the APA requires that an agency evaluate, analyze, and consider certain matters in addition to making specified determinations and findings with regard to the rulemaking action. These include, but are not necessarily limited to:

- A rulemaking agency must find that no alternative would be more effective in carrying out the purpose for which a regulation is proposed, or would be as effective as and less burdensome to affected private persons than the adopted regulation, or would be more cost effective and equally effective in effectuating the purpose of the statute.
- A rulemaking agency must determine whether the regulation "may have" or "will not have" a significant, statewide adverse economic impact directly affecting business. The agency must solicit alternatives if it determines that the proposed regulation "may have" a significant adverse economic impact on business.
- A rulemaking agency must describe the potential cost impact of a regulation on a representative private person or business, if known.
- A rulemaking agency must find that any business reporting requirement is necessary for the health, safety, or welfare of the people of California.
- A rulemaking agency must consider the substitution of performance standards for prescriptive standards.
- A rulemaking agency must state whether a regulation affects small business.

- A rulemaking agency must state whether a regulation differs from a federal statute or regulation and avoid unnecessary duplication or conflict.
- If a rulemaking agency makes a determination regarding significant effect on housing costs, it must include the determination in the Notice.
- A rulemaking agency must determine whether a mandate is imposed on a local agency or school district that requires reimbursement pursuant to Government Code, section 17500 et seq.
- A rulemaking agency must determine whether and to what extent the proposed regulations impact: 1) costs to any local agency or school district requiring reimbursement; 2) other non-discretionary cost or savings imposed on local agencies; 3) costs or savings to any state agency; and 4) costs or savings in federal funding to the state.
- A rulemaking agency must evaluate whether the proposed regulation is inconsistent or incompatible with existing state regulations.

- **Economic Analysis – Major Regulations v. Non-Major Regulations:**

In addition to the above determinations and findings, prior to preparation of the Notice of Proposed Action, the agency must determine whether the proposed regulation will be a "major" regulation. A "major regulation" is one in which the estimated costs or benefits exceed $50,000,000. All other regulations are considered "non-major" regulations.

For regulations that are not major regulations, the agency must prepare an Economic Impact Assessment (EIA). The EIA evaluates whether and to what extent the agency's proposed rulemaking will affect the creation or elimination of jobs, creation or elimination of businesses and expansion of existing businesses in California. The EIA also must explain the benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment. This assessment must be included as part of the ISOR.

Major regulations require the agency to perform additional pre-notice analysis, including preparation of a Standardized Regulatory Impact Assessment (SRIA) as prescribed by the Department of Finance (see Gov. Code, Sections 11346.3 and 11346.36; SAM 6600-6616). The SRIA

contains analysis for the EIA plus additional analyses, such as impacts on competitiveness, investment in California and incentives for innovation. Unlike the EIA, the SRIA must be provided to Department of Finance in advance of publication of the Notice of Proposed Action to allow the Department of Finance to provide comments to the agency. The SRIA must also be included as part of the ISOR.

During the preliminary activity stage, the agency will use the above information to develop a minimum of four documents necessary to initiate the formal rulemaking process. These include:

- **Express Terms**: The text of the proposed regulation will clearly identify any changes to the California Code of Regulations. Proposed additions to regulatory text will appear in underline and proposed deletions will be appear in ~~strike-through~~ format. The Authority and Reference citations that follow the text of each regulation section identify the statutes on which the section is based.

- **Notice of Proposed Action (NOPA):** The NOPA contains a variety of information about the nature of the proposed regulatory changes including various findings, determinations, statutory authority and the law(s) being implemented. The NOPA also contains procedural information, such as deadlines for submitting comments, scheduling of hearings (if any), and where copies of the Express Terms, ISOR, and any other supporting information can be obtained (see discussion below). For non-major regulations, the results of the EIA will be included in the NOPA. If the rulemaking is a major regulation, any comments provided by the Department of Finance, along with the agency's responses, will be included in the NOPA.

- **Initial Statement of Reasons (ISOR):** The ISOR is a document that explains the reasons why the agency is making the proposed regulatory changes. This includes an explanation of the problem being addressed, the purpose of and necessity for, and benefits of the proposed changes. The ISOR also identifies the factual material

upon which the agency relied in proposing the regulations. The ISOR also includes a number of the required determinations, findings and analyses discussed above including either the EIA or SRIA.

- **Economic and Fiscal Impact Statement (Form STD. 399):** The Form STD. 399 is a Department of Finance form that an agency is required to complete and have signed by the rulemaking agency's highest ranking official or that official's delegate. The Form STD. 399 includes information on the estimated economic (private) and fiscal (governmental) monetary impacts of the proposed regulation. Rules governing the Form STD. 399 can be found in the State Administrative Manual, sections 6600 through 6615.

- **PUBLICATION OF THE NOTICE OF PROPOSED ACTION (NOPA):**

Publication of the NOPA begins the formal rulemaking process. All NOPAs are published in the California Regulatory Notice Register (Notice Register), which is issued every Friday. Publication of the NOPA serves as a public announcement by the agency that it is proposing to adopt, amend or repeal regulations in the CCR. The rulemaking agency will also post the NOPA, ISOR, Express Terms, and any other rulemaking documents on its website. In addition, no later than the date of publication of the NOPA, an agency is required to send the NOPA to everyone that has requested to be on the agency's mailing list for receipt of notice of any regulatory actions. The NOPA will be sent to recipients by regular mail, or email if the recipient has consented to receive notices by electronic communication. Interested persons who wish to receive NOPAs from an agency should contact the agency and request to be added to the agency's mailing list. OAL also publishes the entire Notice Register on its website each Friday and makes prior Notice Registers available online.

The NOPA contains a wealth of information about the proposed rulemaking, including the subject matter, a summary of existing laws, and how the proposed regulation implements, interprets or makes those laws more specific. The NOPA also contains important information about where and when interested members of the public can submit written comments

regarding the proposed rulemaking as well as the time and date of any public hearing(s) that may be held. Public comments and public hearings are discussed below.

- **SUBMITTING COMMENTS TO AGENCY ON PROPOSED RULEMAKING:**

  - **Submission of Comments:**

During the formal rulemaking process, there are two principal opportunities for interested persons to provide input to the rulemaking agency. The first is the written comment period. The second is the public hearing. This notice and hearing process is for the benefit of the regulated public and this is the time for interested persons to exercise their right to participate in the regulatory process.

  - **Written Comment Period:**

Even if an agency chooses not to engage the public or interested parties in preliminary discussions during the development phase for a rulemaking, the APA requires an agency to provide for a minimum forty-five (45) day written comment period wherein interested persons can submit written comments directly to the agency. This is often referred to as the "forty-five day comment period," although agencies may choose to provide a longer comment period. This forty-five day comment period begins when the NOPA is published in the Notice Register and will end when specified in the NOPA. When submitting comments, interested parties should make sure that the comment is received by the agency by the last day of the notice period. The NOPA will contain the name and address of the person at the agency to whom comments must be addressed to. In order to ensure that a comment is properly directed, the comment should reference the specific rulemaking to which the comment is intended, as some agencies may conduct multiple rulemakings at the same time.

- **Making a Comment**:

Effective comments are based on an understanding of the statutes and factual material the agency relies on in proposing the regulation, on an understanding of what the proposed regulation is intended to do, and on an understanding of the standards the regulation must satisfy. Comments should be directed at the proposed regulation provisions and/or procedures followed by the agency in proposing the regulations. One of the primary purposes of providing the opportunity for public comment is to allow interested persons to present ways of improving the regulations.

- **Public Hearings:**

Under the APA, an agency has an option as to whether it wishes to hold a public hearing on a proposed rulemaking action. (An agency's enabling statutes may eliminate this option by requiring a public hearing.) If a public hearing is scheduled, it must take place no sooner than forty-five (45) days after the date the NOPA is published in the Notice Register. The time, place, date and nature of the hearing will be set forth in the NOPA. However, even if an agency does not schedule a public hearing, any interested person may request a hearing if such request is made in writing within 15 days of the close of the written comment period. If a timely request for hearing is made, the APA requires the agency to conduct a hearing and to provide reasonable notice of the hearing to the public.

If a public hearing is held, the agency must accept both written and oral comments at the hearing. An agency is permitted to place reasonable restrictions on oral comments at hearings, including the length of time allotted to each speaker. Therefore, interested persons who wish to testify may also wish to bring a written testimonial to submit at the hearing. Limitations imposed by the agency will depend on the circumstances of the hearings. Note that the public hearing for a rulemaking is intended to provide the public with an opportunity to voice opinions on the rulemaking. Agencies are not required to, and generally will not, provide a response to comments at the public hearing.

➢ Consideration of Comments:

The APA requires a rulemaking agency to consider all relevant and timely comments presented to it during a comment period before adopting, amending, or repealing any regulation. This includes written comments received during the forty-five day comment period as well as written and oral comments received at the public hearing. An agency is required to respond to comments in a document called a Final Statement of Reasons (FSOR), however, the agency is only required to respond to comments that are directed at the proposed regulations or procedures followed (i.e., relevant) and that are received during the applicable comment period (i.e., timely). Comments not directed at the proposed changes or procedures followed are considered irrelevant and do not need to be responded to by the agency.

An agency must either accept or reject timely and relevant comments. If an agency accepts a comment, the FSOR must include an explanation of how the agency modified the proposed regulations to accommodate the comment. If an agency rejects the comment, the FSOR must include an explanation of the reason for the rejection.

• CHANGES TO PROPOSED TEXT OR RECORD AFTER 45 DAY NOTICE:

➢ Changes to Text:

After the initial public comment period, a rulemaking agency will often decide to change its initial proposal either in response to public comments or on its own. The agency must then decide whether a change is: (1) nonsubstantial, (2) substantial and sufficiently related, or (3) substantial and not sufficiently related.

Nonsubstantial changes are usually technical in nature and do not alter the regulatory effect of the proposed provisions, therefore, no further notice is required.

Substantial changes alter the meaning of the regulatory provisions and require further notice to the public. Substantial changes that are sufficiently

related (i.e., reasonably foreseeable based on the NOPA) must be made available for public comment for at least 15 days before adopting such a change. Therefore, before a rulemaking agency adopts such a change, it must mail a notice of opportunity to comment on proposed changes along with a copy of the text of the proposed changes to each person who has submitted written comments on the proposal, testified at the public hearing, or asked to receive any notices of proposed modification. The agency must also post this notice on its website. No public hearing is required. The public may comment on the proposed modifications in writing. The agency must then consider any comments received during the comment period that are directed at the proposed changes. An agency may conduct more than one fifteen-day opportunity to comment before the final version of the text is adopted.

If a change is substantial, but not sufficiently related to the original proposal (i.e. not reasonably foreseeable based on the NOPA), the agency must then publish another forty-five day notice in the Notice Register similar to the original NOPA. These changes are uncommon.

- **Addition of Material to the Rulemaking Record:**

A rulemaking agency must specifically identify any material the agency is relying upon for the proposed rulemaking in the ISOR. If during a rulemaking proceeding an agency decides to rely on material that the agency did not identify in the ISOR, the agency must make the document available for comment for fifteen days. This notice and comment process is similar to a fifteen-day notice for substantial, sufficiently related changes to the regulation text.

- **COMPLETING THE RULEMAKING PROCESS:**

- **Transmission to OAL:**

A rulemaking agency must transmit a rulemaking action to OAL for review within one year from the date that the NOPA was published in the Notice Register. The rulemaking record contains the complete record of an

agency's rulemaking action and is a public record. The rulemaking record documents the agency's compliance with each requirement in the APA.

After an agency submits its rulemaking record to OAL, OAL then has thirty (30) working days to review the rulemaking record to determine whether the record demonstrates that the rulemaking agency satisfied the procedural requirements of the APA, and to review regulations for compliance with the six substantive APA standards: Authority, Reference, Consistency, Clarity, Nonduplication, and Necessity (discussed below). OAL may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulations. If the rulemaking record demonstrates that the agency complied with the APA, OAL will file the final regulation text with the Secretary of State.

- **Retention of Rulemaking Record:**

Once a regulation is approved by OAL and filed with the Secretary of State, the rulemaking record is returned to the rulemaking agency. The rulemaking agency is then required to maintain the rulemaking record indefinitely or transfer the rulemaking record to the State Archives.

- **EFFECTIVE DATES:**

Generally, regulations become effective on one of four quarterly dates based on when the final regulations are filed with the Secretary of State: January 1 if filed between September 1 and November 30; April 1 if filed between December 1 and February 29; July 1 if filed between March 1 and May 31; and October 1 if filed between June 1 and August 31. Effective dates may vary, however, if: a different effective date is provided for in statute or other law; the adopting agency requests a later effective date; or the agency demonstrates good cause for an earlier effective date.

EMERGENCY RULEMAKING ACTIONS

- **EMERGENCY:**

A state agency may adopt emergency regulations in response to a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, or general welfare, or if a statute deems a situation to be an emergency under the APA. Because emergency regulations are intended to avoid serious harm and require immediate action, the emergency rulemaking process is substantially abbreviated compared to the regular rulemaking process.

- **NOTICE:**

Unless the emergency situation clearly poses such an immediate, serious harm that delaying action to allow public comment would be inconsistent with the public interest, the agency is required to provide at least five working days advance notice to everyone on its regulatory actions notice list prior to submitting the emergency regulations to OAL. After the minimum five working-day pre-notice, the agency submits the emergency rulemaking record to OAL. The emergency rulemaking record includes, without limitation, the notice of emergency, a finding of emergency describing the specific facts creating the need for immediate action, the proposed emergency text, Form STD. 399 and any supporting information.

- **PUBLIC COMMENT:**

When an emergency action is submitted to OAL, OAL publishes the emergency action on OAL's website that same day. Publication on OAL's website begins a five calendar-day comment period. Unlike a regular rulemaking, for an emergency action, comments are submitted both to the agency and directly to OAL. Comments should be directed at either the proposed regulations or the emergency procedures followed. For an emergency rulemaking, an agency may, but is not required to, summarize and respond to comments received. The state agency may submit a rebuttal to any comments made on an emergency regulation up to eight days after the regulation is submitted to OAL.

- **OAL REVIEW:**

OAL has 10 calendar days to review an emergency rulemaking action. OAL reviews emergency regulations to determine whether an emergency has been demonstrated factually or deemed by statute. OAL also determines whether the agency has complied with the procedural requirements of the APA for the adoption of emergency regulations, and whether the regulation satisfies the Authority, Reference, Consistency, Clarity, Nonduplication, and Necessity standards of the APA.

- **EFFECTIVE DATE:**

Once approved and filed with the Secretary of State, an emergency regulation usually takes effect immediately. An emergency regulation generally remains in effect for 180 days. During the time the emergency is effective, the rulemaking agency must conduct a regular rulemaking called a “Certificate of Compliance” to permanently adopt the regulation. If, however, the agency is unable to complete the rulemaking process within that time, the agency may request permission from OAL to readopt the emergency regulation for an additional ninety (90) days. The agency may be granted not more than two 90-day readoptions. If the agency does not complete the Certificate of Compliance action before the end of the effective period of the emergency, the emergency regulations will expire by operation of law and the CCR will revert to the pre-emergency text.

THE SIX APA STANDARDS

- **Authority and Reference standards**

Each regulation must satisfy the Authority and Reference standards. Complying with the Authority and Reference standards involves a rulemaking agency in two activities: picking appropriate Authority and Reference citations for the note that follows each regulation section to be printed in the California Code of Regulations, and adopting a regulation that is within the scope of the rulemaking power conferred on the agency.

"Authority" means the provision of law which permits or obligates the agency to adopt, amend, or repeal a regulation. Government Code Section 11349(b).

"Reference" means the statute, court decision, or other provision of law which the agency implements, interprets, or makes specific by adopting, amending, or repealing a regulation. Government Code Section 11349(e).

Each regulation section printed in the California Code of Regulations must have a citation to the specific statutory authority under which it was enacted and a citation to the specific statute or other provision of law that the regulation is implementing, interpreting, or making specific. As an example the Authority and Reference Citations for Section 55 of Title 1 of the California Code of Regulations reads as follows: “Authority cited: Sections 11342.4 and 11349.1, Government Code. Reference: Sections 11346.1, 11349.1, 11349.3 and 11349.6, Government Code.”

The statutes and other provisions of law cited in Authority and Reference notes are the agency's interpretation of its power to adopt a particular regulation. A rulemaking agency initially selects Authority and Reference citations when it is drafting the proposed regulation text and may revise and refine the citations during the course of a rulemaking proceeding. The goal is to have accurate, precise, and complete Authority and Reference citations printed in the California Code of Regulations with each regulation.

EXPRESS AND IMPLIED RULEMAKING AUTHORITY A statutory delegation of rulemaking authority may be either express or implied. In an express delegation, the statute expressly states that the state agency may or shall "adopt rules and regulations necessary to carry out this chapter" or some variation on that phrase. Thus, an express delegation *expressly* specifies that regulations shall or may be adopted by the agency.

In contrast, in an implied delegation of rulemaking authority, the applicable statutes do not expressly state that the agency may or shall adopt rules or regulations. Instead, a statute expressly gives a duty or power to a specified state agency, but makes *no* express mention of the authority to adopt rules or regulations. In similar circumstances, courts tell us that agencies which have expressly been given a duty or power by statute have implicitly been delegated the authority to adopt those rules and regulations necessary for the due and efficient exercise of a duty or power expressly granted.

OAL REVIEW FOR AUTHORITY OAL reviews regulations to ensure that they are authorized under controlling statutes. The statutes (and other provisions of law) the agency cites as Authority and Reference identify the sources of the rulemaking power that the agency is drawing on in promulgating a particular regulation. A regulation that is not within the

Each regulation adopted, to be effective, shall be *within the scope of authority conferred* and in accordance with standards prescribed by other provisions of law.

scope of an agency's express or implied rulemaking authority is void and cannot become effective.

In determining whether a rulemaking agency is empowered to adopt a particular regulation, OAL applies the same analytical approach employed by the California Supreme Court and the California Court of Appeal, as evidenced in published opinions of those courts.

JUDICIAL REVIEW OF AUTHORITY TO ADOPT A PARTICULAR REGULATION When reviewing a quasi-legislative regulation, courts consider whether the regulation is within the scope of the authority conferred, essentially a question of the validity of an agency's statutory interpretation. The courts must determine whether the rulemaking agency has exercised its authority within the bounds established by statute.

Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute. Government Code Section 11342.2.

The courts apply the following principle to determine whether a rulemaking agency has exercised its authority within the bounds established by statute.

An administrative regulation may not alter or amend a statute or enlarge or impair its scope. Such a regulation is void and must be struck down by a court.

In deciding whether a regulation alters, amends, enlarges, or restricts a statute, or merely implements, interprets, makes specific, or otherwise gives effect to a statute often a court must interpret the meaning of the

statute. In so doing, courts apply principles of statutory interpretation developed primarily in case law. It examines the language of the statute, and may consider appropriate legislative history materials to ascertain the will of the Legislature so as to effectuate the purpose of the statute. In making this determination, a court may consider, but is not bound by the rulemaking agency's interpretation of the statute at issue. As the California Supreme Court explained in *Yamaha v State Board of Equalization*, "Whether judicial deference to an agency's interpretation is appropriate and, if so, its extent-the 'weight' it should be given is ... fundamentally situational." The court identified factors to be considered relating to (1) the possible interpretive advantage of the agency and (2) to the likelihood that the agency is correct and suggested the following. "The deference due an agency interpretation ... 'will depend *upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.*'"

- **THE CONSISTENCY STANDARD**

Each regulation must satisfy the Consistency standard. In reviewing for compliance with the Consistency standard, OAL uses the same analytical approach used in judicial review of a regulation. This approach includes the principles discussed above regarding deference to an agency's interpretation of a statute.

"Consistency" means being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law. Government Code,

Commenters on proposed regulations often comment that a proposed regulation is inconsistent with a statute because it requires certain tasks not

specifically set out in statute. This situation does not present a Consistency problem so long as the tasks specified in the regulation are reasonably designed to aid a statutory objective, do not conflict with or contradict (or alter, amend, enlarge or restrict) any statutory provision.

In other words, no conflict is presented if the statute says “Thou shall do A” and the regulation says “Thou shall do B,” if one can do both A and B, and B is reasonably necessary to effectuate the purpose of A, and does not alter, amend, enlarge, or restrict A. In contrast, a conflict is presented if the statute says “Thou shall do A” and the regulation says “Thou shall not do A.”

- **THE CLARITY STANDARD**

Each regulation must satisfy the Clarity standard. Regulations are frequently unclear and unnecessarily complex, even when the technical nature of the subject matter is taken into account. They are often confusing to persons who must comply with them. The performance goal for drafting a regulation is the following. A rulemaking agency must draft regulation text in plain, straightforward language avoiding technical terms as much as possible using coherent and easily readable language. The measure of compliance with the performance goal is the Clarity standard. OAL has a duty to ensure that each regulation can be easily understood.

Clarity means written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them. Government Code Sec. 11349(c).

Persons presumed to be "directly affected" by a regulation are those who: (a) must comply with the regulation; or (b) must enforce the regulation; or (c) derive a benefit from the enforcement of the regulation that is not common to the public in general; or (d) incur from the enforcement of the regulation a detriment that is not common to the public in general. California Code of Regulations, Title 1, Sec. 16(b).

Situations in which OAL may presume a regulation is unclear.

1. The regulation has more than one meaning.

2. The language of the regulation conflicts with the description of its effect.

3. The regulation uses an undefined term which does not have a meaning generally familiar to those who are "directly affected."

4. The regulation uses language incorrectly, including incorrect spelling, grammar, or punctuation.

5. The regulation presents information in a format not readily understandable.

6. The regulation does not use citations which clearly identify published material cited in the regulation.

The following regulation drafting tips are drawn from <u>Drafting Legislation and Rules in Plain English</u>, by Robert J. Martineau, (West, 1991) pp 65-105.

1. Use only necessary words.

2. Use common words.

3. Avoid “lawyerisms.”

4. Be consistent.

5. Use short sentences.

6. Arrange words properly.

7. Tabulate to simplify.

9. Look for omissions and ambiguities.

10. Think through common application situations.

- **THE NONDUPLICATION STANDARD**

Nonduplication means a regulation does not serve the same purpose as a state or federal statute or another regulation.

Each regulation must satisfy the Nonduplication standard. A regulation that repeats or rephrases a statute or regulation "serves the same purpose" as that statute or regulation. Any overlapped or duplicated statute or regulation must be identified and the overlap or duplication must be justified. Citing the overlapped or duplicated statute or regulation in the authority or reference note satisfies the identification requirement. Overlap or duplication is justified if information in the rulemaking record establishes that the overlap or duplication is necessary to satisfy the Clarity standard.

- **THE NECESSITY STANDARD**

An agency conducting a rulemaking action under the APA must compile a complete record of a rulemaking proceeding including all of the evidence and other material upon which a regulation is based.

In the record of the rulemaking proceeding (record), the agency must state the specific purpose of each regulatory provision and explain why the provision is reasonably necessary to accomplish that purpose. It must also identify and include in the record any materials relied upon in proposing the provision and any other information, statement, report, or data the agency is required by law to consider or prepare in connection with the rulemaking action. The agency does this first in the initial statement of reasons. During the rulemaking proceeding, the agency may add new material on which it relies by notifying the public and providing a 15 day opportunity to comment on the proposal in light of the new material relied upon. The agency then states in the final statement of reasons what material has been added during the proceeding.

In addition, during the rulemaking, the public may submit recommendations or objections to the proposed regulation and submit material, including studies, reports, data, etc. for consideration by the agency and inclusion in the record. In the final statement of reasons, the agency must respond to all relevant input and explain a reason for rejecting each recommendation or objection directed at the proposed action, or explain how the proposal has been amended to accommodate the input. All of these materials constitute the record.

At the end of a rulemaking proceeding, the rulemaking agency must certify under penalty of perjury that the rulemaking record is complete and closed. The rulemaking agency then submits the complete record to OAL for review. In reviewing for compliance with the Necessity standard, OAL is limited to applicable provisions of law and the record of the rulemaking proceeding. Once OAL review is complete and the record is returned to the rulemaking agency, the file is the agency's permanent record of the rulemaking proceeding. No item in the file may be removed, altered or destroyed. Any judicial review of the regulation is based only on the evidence included in the rulemaking record.

What must be addressed in the record? Each regulation must satisfy the Necessity standard. OAL reviews the rulemaking record to ensure that each provision of regulation text that is adopted, amended, or repealed satisfies the Necessity standard.

> **"Necessity" means the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to facts, studies, and expert opinion. Government Code Section 11349(a).**

What is "substantial evidence"? The "substantial evidence" standard used by OAL is the same as the "substantial evidence" standard used in judicial review of regulations. The following is a definition of "substantial evidence" drawn from the legislative history of the Necessity standard.

> **Such evidence as a reasonable person reasoning from the evidence would accept as adequate to support a conclusion**.

A number of principles and limitations are involved in the application of this standard. Clearly, "substantial evidence" is more than "any evidence," but is nowhere near "proof beyond a reasonable doubt." A key characteristic of the standard is its deferential nature. The "substantial evidence" test was added to the Necessity standard by Chapter 1573, Statutes of 1982 (AB 2820). The following letter from Assemblyman Leo McCarthy to Speaker Willie Brown summarized the "substantial evidence" test as used in the Necessity standard:

"The principal addition AB 2820 makes to what we approved in AB 1111 in 1979 is a specific level of evidence that an agency must meet to demonstrate the need for a particular regulation. The standard is substantial evidence taking the record as a whole into account.

"That standard is a familiar one in the law and has been given a definite interpretation by the courts in the past. Our intent is that an agency must include in the record facts, studies or testimony that are specific, relevant, reasonable, credible and of solid value, that together with those inferences that can rationally be drawn from such facts, studies or testimony, would lead a reasonable mind to accept as sufficient support for the conclusion that the particular regulation is necessary. Suspicion, surmises, speculation, feelings, or incredible evidence is not substantial.

"Such a standard permits necessity to be demonstrated even if another decision could also be reached. This standard does not mean that the particular regulation necessarily be 'right' or the best decision given the evidence in the record, but that it be a reasonable and rational choice. It does not mean that the only decision permitted is one that OAL or a court would make if they were making the initial decision. It does not negate the function of an agency to choose between two conflicting, supportable views.

"The proposed standard requires the assessment to determine necessity to be made taking into account the totality of the record. That means the standard is not satisfied simply by isolating those facts that support the conclusion of the agency. Whatever in the record that refutes the supporting evidence or that fairly detracts from the agency's conclusion must also be taken into account. In other words, the supporting evidence must still be substantial when viewed in light of the entire record." (California, Assembly Daily Journal, 208th Sess. 13, 663-34 (1982).)

- **FREQUENTLY ASKED QUESTIONS**

QUESTION:	***ANSWER:***
What are "regulatory agencies?"	*All state government entities authorized to adopt regulations, including agencies constitutional offices, departments, boards, commissions and bureaus are regulatory agencies.*
How can I find out about regulatory changes that state agencies are planning to undertake?	*The Rulemaking Calendar published by OAL annually, usually in March, provides a listing of rulemaking actions that agencies intend to undertake during the year. However, agencies are not precluded from undertaking rulemakings not included in the Rulemaking Calendar, therefore if a particular agency is of interest, interested persons should request to be added to that agency's regulatory mailing list.*
Is a state agency required to notify the public of regulations the agency plans to adopt?	*Yes. Each state agency must maintain a mailing list of all persons who want to be notified of proposed rulemaking actions. The agency is then obligated to send persons on the mailing list with the NOPA no later than the date the NOPA is published in the Notice Register.*
How can I determine if a regulatory action may affect me?	*The Informative Digest portion of the NOPA contains information about the rulemaking, including the subject matter and statutes being implemented.*
How can I find out why an agency is adopting regulations?	*The ISOR includes an explanation of necessity for why the agency is proposing to adopt the noticed regulations. This is available either on*

	the agency's website or from the contact person identified in the NOPA.
How can I review all of the information and documents an agency is relying on when it proposes a regulatory change?	*All information and documents relied upon by the agency for a rulemaking must be made available to the public during a public comment period. The NOPA will include instruction on where this information is available.*
How can I tell what regulatory actions have been submitted to OAL for final review and filing with the Secretary of State?	*OAL posts a listing of all rulemaking actions submitted for approval and filing with the Secretary of State on its website at www.oal.ca.gov.*
How can I tell whether a proposed regulation has been approved by OAL and its effective date?	*The Notice Register published every Friday contains a summary of recent regulatory actions approved by OAL and filed with the Secretary of State, including the date filed and the effective date of the regulations. OAL also posts a listing of all approved, disapproved or withdrawn actions each day on its website at www.oal.ca.gov.*
Where do I submit comments relating to a rulemaking?	*For a regular rulemaking, comments should be submitted to the rulemaking agency's contact person identified in the NOPA for that rulemaking.* *For emergency rulemakings only, comments should be submitted to both the rulemaking agency contact listed in the Notice of Emergency and to OAL.*
Where can I find the laws that describe how regulations must be adopted by agencies?	*The Administrative Procedure Act (APA) contained in Chapter 3.5 of the California Government Code,*

	commencing with section 11340, contains the statutes governing rulemaking. Regulations governing rulemaking are found in title 1, chapters 1 and 2, in the California Code of Regulations.
Where can I find existing state regulations?	*Regulations are printed in the California Code of Regulations (CCR). Hardcopy versions of the CCR available at several state and other libraries. The CCR is also available online through a link on OAL's website at www.oal.ca.gov.*

CITATIONS

Armistead v. State Personnel Board (1978) 22 Cal.3d 198, 149 Cal.Rptr.1

Engelmann v. State Bd. of Education (1991) 2 Cal.APP.4th 47, 3 Cal.Rptr.2d 264

Grier v. Kizer (1990) 219 Cal.App.3d 422, 268 Cal.Rptr. 244

Poshman v. Dumke (1973) 31 Cal.App.3d 932, 107 Cal.Rptr. 596

Roth v. Dept. of Veteran Affairs (1980) 110 Cal.App.3d 622, 167 Cal.Rptr. 552

State Water Resources Control Board v. OAL (1993) 12 Cal.App.4th 697, 16 Cal.Rptr.2d 25

Stoneham v. Rushen (*Stoneham I*) (1982) 137 Cal.App.3d 729, 188 Cal.Rptr. 130

Yamaha v. State Board of Equalization (1998) 19 Cal.4th 1, 78 Cal.Rptr.2d

Attachment Q29 (rev 10/9/19)

California sealed source and device (SS&D) evaluation program
SSD reviewer: all SSD reviewers.
Report period: 10/10/2015 to 9/27/2019.
Report information: all SSDs issued by CA program.

SS&D registry number	Manufacturer, distributor, or custom user	Product type and principal use	Date issued	Type of action	Reviewer/ concurrer
CA0321D805S	1288	Source Housing for a Level Sensor System. (D) Gamma Gauge.	03/15/2016	Inactivation	VK/RR
CA0598D125S	1777	Self-contained shielded panoramic irradiator/calibrator. (K) Gamma irradiator, Category II.	05/20/2016	Amendment	VK/RR
CA0533D013G	3755	Gamma Gauge. (D) Gamma Gauge.	05/25/2016	Amendment	MG/JF
CA1195D101S	6663	Materials Analyzer. (H) General neutron Source Application.	07/15/2016	Amendment	VK/RR
CA1418D101S	6875	Category I Self-Contained Gamma Irradiator	07/19/2016	New	MG/JF
CA0378S102S	1389	Level and Density Gauge Source Assembly. (D) Gamma Gauges.	07/21/2016	Correction	KD/RR
CA0305D114S	3775	Material Analyzer. (H) General Neutron Source Applications.	07/21/2016	Amendment	HA/JF
CA1218D102S	7873	Gamma gauge for non-intrusive inspection of vehicles and cargo. (D) Gamma Gauge.	07/25/2016	Amendment	KD/RR
CA0406D287S	1509	Ion Chamber Check Source (ICCS) Holder Assembly. (Y) Calibrators.	10/19/2016	New	VK/RR
CA1050D101S-CA8308D801S	7177	Stereotactic radiosurgery and radiotherapy. (AE) Gamma Stereotactic Radiosurgery.	02/08/2017	Inactivation	VK/RR

CA1050S102S-CA8308S802S	7177	Stereotactic radiosurgery and radiotherapy. (C) Medical teletherapy.	02/08/2017	Inactivation	VK/RR
CA0384S116S-CA0384S802S	1509	Radiography Source Assembly. (A) Industrial radiography.	05/12/2017	Inactivation	VK/RR
CA0406S223S-CA0406S877S	1509	Photon Disc Source. (U) X-Ray Fluorescence.	09/13/2017	Inactivation	RB/VK
CA0406S112S	1509	Gamma Gauging and X-Ray Fluorescence. (D) Gamma Gauges. (U) X-Ray Fluorescence.	09/13/2017	Amendment	KQ/VK
CA0406S110S-CA0406S878S	1509	Gamma Gauging and X-Ray Fluorescence. (U) X-Ray Fluorescence.	09/12/2017	Inactivation	KQ/VK
CA0406S128S-CA0406S879S	1509	Beta Sources for Thickness Gauges. (E) Beta Gauges.	09/13/2017	Inactivation	KQ/VK
CA0406S197S-CA0406S880S	1509	Strontium-90 Beat Source. (E) Beta Gauges.	09/13/2017	Inactivation	KQ/VK
CA0406S153S-CA0406S882S	1509	Gamma Source. (D) Gamma Gauges.	09/21/2017	Inactivation	KQ/VK
CA1218D101S	7873	Mobile gauge for vehicle inspection. (D) Gamma Gauge.	10/31/2017	Amendment	KD/RR
CA0309D103G-CA0309D801G	145	Radiological air monitoring station. (D) Gamma Gauge.	10/31/2017	Inactivation	KD/RR
CA0384S108S-CA0384S805S	2229	Radiography Source Pigtail Assembly. (A) Industrial Radiography.	10/25/2017	Inactivation	VK/RR
CA0384D105S-CA0384D803S	2229	Source Changer. (A) Industrial Radiography.	10/10/2017	Inactivation	VK/RR
CA0384S103U-CA0384S804S	2229	Radiography Source Assembly. (A) Industrial radiography.	10/11/2017	Inactivation	VK/RR
CA1195D101S	6663	Materials Analyzer. (H) General neutron Source Application.	10/11/2017	Amendment	MG/HA
CA0598D115S	1777	Gamma Irradiator/Calibrator. (K) Gamma Irradiator, Category II.	01/10/2018	Amendment	VK/RR

CA0305D106S	3775	Cross-Bely Elemental Analyzer. (D) Gamma Gauge.	01/29/2018	Amendment	VK/RR
CA1418D102S	6875	Category 1 Self Contained Gamma Irradiator. (J) Gamma Irradiator Category I	02/12/2018	New	MG/HA
CA0309D102S-CA8314D803S	145	Miniature Nuclear Battery. (Q) Thermal Generator.	02/13/2018	Inactivation	KD/RR
CA0309D101S-CA8314D802S	145	Miniature Nuclear Battery. (Q) Thermal Generator.	02/13/2018	Inactivation	KD/RR
CA0309D801G-CA8314D801G	145	Radiological air monitoring station. (D) Gamma Gauge.	03/22/2018	Inactivation	KD/RR
CA0124D101U-CA8317D801U	3925	Shipping/Storage Container and Nylon Ribbon Ir-192. (AA) Manual Brachytherapy.	06/28/2018	Inactivation	KD/RR
CA0406S116S	1509	Mossbauer Effect Source. (S) Foil Sources.	07/25/2018	Amendment	TM/VK
CA0406S240S	1509	Well Logging Source. (F) Well Logging.	07/27/2018	Amendment	VK/RR
CA0406S205S	1509	Beta Gas Source. (R) Gas Source.	07/30/2018	Amendment/ Transfer	KD/RR
CA0598D104S	1777	Irradiator. (J) Gamma Irradiator, Category I.	08/01/2018	Amendment	VK/RR
CA0598D103S	1777	Self-Contained Gamma Irradiator. (J) Gamma Irradiator, Category I.	08/03/2018	Amendment	VK/RR
CA0598D121S	1777	Gamma Source. (J) Gamma Irradiator, Category I.	08/08/2018	Amendment	VK/RR
CA0598S122S	1777	Gamma Source. Gamma Irradiator. (J) Category I or (K) Category II or (Y) Calibrators.	08/10/2018	Amendment	VK/RR
CA0406S290S	1509	Well Logging. (F) Well Logging.	08/20/2018	New	KD/HA
CA0305D113S	3775	Cross-Belt Elemental Analyzer. (H) General Neutron Source Applications.	08/15/2018	Amendment	VK/RR
CA0598D118S	1777	Irradiator. (J) Gamma Irradiator, Category I.	09/05/2018	Amendment	VK/RR

CA0406S215S	1509	Beta Ionization Ring Source. (N) Ionization Generator.	09/06/2018	Amendment	PF/VK
CA0406S229S	1509	Well Logging Source. (F) Well Logging.	09/12/2018	Amendment	PF/VK
CA0305D114S	3775	Material Analyzer. (H) General Neutron Source Applications.	09/03/2018	Amendment	KD/RR
CA1349D101G-CA8321D801G	7845	Industrial Chemical Monitor. (N) Ion Generators, Chromatography.	09/26/2018	Inactivation	PF/VK
CA0406S125S	1509	Brachytherapy Source. (AA) Manual Brachytherapy.	10/12/2018	Amendment	TM/VK
CA0406S171S	1509	Flexible Ruler Source. (X) Medical Reference Source.	10/18/2018	Amendment	PF/VK
CA0406S172S	1509	Calibration Source (Flexible Marker). (X) Medical Reference Source.	10/22/2018	Amendment	PF/VK
CA0406S220S-CA0406S883S	1509	Low Energy Photon Disc Source. (U) X-Ray Fluorescence.	10/23/2018	Inactivation	TM/VK
CA0406S136S	1509	X-Ray fluorescence Sources. (U) X-Ray Fluorescence.	10/26/2018	Amendment	TM/VK
CA0406D237S-CA0406D884S	1509	Non-Intrusive Gamma Radiation Inspection Device. (D) Gamma Gauges.	10/26/2018	Inactivation	TM/VK
CA0406S174S	1509	X-Ray Fluorescence Source. (U) X-Ray Fluorescence.	10/23/2018	Amendment	PF/VK
CA0406S149S	1509	Calibration Sources. (I) Calibration Sources.	10/12/2018	Amendment	PF/VK
CA0406S235S	1509	Point Source. (X) Medical Reference Sources.	10/24/2018	Amendment	PF/RR
CA0406S224S-CA0406S885S	1509	X-Ray Excitation Sources. (U) X-Ray fluorescence.	12/05/2018	Inactivation	PF/RR
CA0598D115S	1777	Gamma Irradiator/Calibrator. (K) Gamma Irradiator, Category II.	10/03/2018	Amendment	VK/RR
CA1489D101S	7947	Bulk Material Analyzer. (H) General Neutron Source Applications.	12/13/2018	New	KD/RR

CA0406S167S	1509	Am-Be Neutron Gauging Source. (H) General Neutron Source Applications.	12/18/2018	Amendment	PF/KD
CA0406S164S	1509	Gas Source. (R) Gas Sources.	12/20/2018	Amendment	PF/KD
CA1218D103S	7873	Gamma gauge for non-intrusive inspection of vehicles and cargo. (D)Gamma Gauge.	12/20/2018	Transfer	KD/RR
CA1080D103S	1025	Brachytherapy HDR Remote Afterloader. (AC) Photon-emitting remote afterloaders.	12/11/2018	Amendment	VK/RR
CA0661D103S	1025	High Dose rate (HDR) Remote Afterloader. (AC) Photon-emitting remote afterloaders.	12/11/2018	Amendment	VK/RR
CA0406S155S	1509	Gas Source. (R)Gas Sources.	11/29/2018	Amendment	PF/VK
CA0406S152S	1509	Radon Calibration Source. (I) Calibration Sources.	12/14/2018	Amendment	PF/VK
CA0406S227S	1509	Gamma Source. (D) Gamma gauges.	01/11/2019	Amendment	PF/VK
CA1218D104S	7873	gamma gauge for non-intrusive inspection of vehicles and cargo. (D) Gamma Gauge.	01/24/2019	Amendment	KD/RR
CA0661D103S-CA1080D105S	1025	High Dose Rate (HDR) Remote Afterloader. (AC) Photon-emitting remote afterloaders.	02/05/2019	Amendment	VK/RR
CA0406S231S	1509	Gamma Source. (D) Gamma Gauges.	01/28/2019	Amendment	PF/VK
CA0406S225S	1509	Rigid Line Source. (X) Medical Reference Sources.	02/25/2019	Amendment	PF/KD
CA0406S175S	1509	Gamma Source for Gauging and Calibration. (D) Gamma Gauges.	02/25/2019	Amendment	PF/KD
CA0406S156S	1509	Plated Foil. (S) Foil Sources.	03/20/2019	Amendment	PF/KD
CA0406S216S-CA0406S886S	1509	X-Ray Fluorescence Source. (U) X-Ray Fluorescence.	03/21/2019	Inactivation	PF/KD
CA0406S117S	1509	Calibration Source. (T) Other.	03/07/2019	Amendment	PF/VK
CA0406S222S-CA0406S887S	1509	Photon Calibration Source. (I) Calibration Source.	03/15/2019	Inactivation	VK/RR
CA0406S230S	1509	Gamma Source. (D) Gamma Gauges.	03/22/2019	Amendment	PF/VK

CA0384S107S-CA0384S806S	2229	Radiography Source Pigtail Assembly. (A) Industrial Radiography.	03/28/2019	Inactivation	PF/VK
CA0384S110U-CA0384S807U	2229	Radiography Source. (A) Industrial Radiography.	03/28/2019	Inactivation	PF/VK
CA0406S178S	1509	Line Source. (D) Gamma Gauges.	04/15/2019	Amendment	PF/RR
CA0406S176S	1509	Planar Calibration Source. (I) Calibration Source.	04/22/2019	Amendment	PF/KD
CA0406S194S	1509	Am-Be Neutron Source. (F) Well Logging.	05/14/2019	Amendment	PF/KD
CA0406S208S	1509	Gas Source. (R)Gas Sources.	05/14/2019	Amendment	PF/KD
CA0406S200S	1509	Ophthalmic Surface Applicators. (AA) Manual Brachytherapy.	05/29/2019	Amendment	TM/VK
CA0406S177S	1509	Gamma Gauging and Calibration. (D) Gamma Gauges. (I) Calibration Sources.	05/30/2019	Amendment	PF/KD
CA1327S101S-CA8322S801S	314	Disc Source. (T) Other.	06/20/2019	Inactivation	PF/KD
CA0384D106S-CA0384D813S	2229	Source Changer. (A) Industrial Radiography.	06/06/2019	Inactivation	PF/KD
CA0384S104U-CA0384S809S	2229	Radiography Source. (A) Industrial Radiography.	05/29/2019	Inactivation	PF/VK
CA0384D113S-CA0384D811S	2229	Source Changer. (A) Industrial Radiography.	05/28/2019	Inactivation	PF/VK
CA0384S111S-CA0384S808S	2229	Radiography Source Pigtail Assemblies. (A) Industrial Radiography.	05/30/2019	Inactivation	PF/TM
CA0384S117S-CA0384S810S	2229	Radiography Source Assembly. (A) Industrial Radiography.	05/29/2019	Inactivation	PF/TM
CA0406S291S	1509	Gamma Gauge, Well Logging. (D) Gamma Gauge, (F) Well Logging.	06/25/2019	New	TM/VK
CA0406S173S	1509	Pen Point Marker of Calibration Source. (X) Medical reference Source.	06/25/2019	Amendment	VK/TM
CA0403D102U-CA0403D802S	1673	Sealed Object Leak Testing Device. (T) Other.	06/25/2019	Inactivation	PF/VK

CA0384D112S-CA0384D812S	2229	Source Changer. (A) Industrial Radiography.	05/29/2019	Inactivation	PF/TM
CA0406S874S	1509	Medical Reference Sources (X)	08/14/2019	Correction	VK
CA0215S102B	2290	Gamma Gauge (D)	08/22/2019	Amendment	KD/VK
CA0626D101G	2290	Ion Generators Chromatography (N)	09/27/2019	Correction	VK
CA0384S114S	2229	Industrial Radiography (A)	09/18/2019	Amendment	VK/KD

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