

## **FINAL STATEMENT OF REASONS**

The information contained in the Initial Statement of Reasons (ISR) at the time of Public Notice remains unchanged, with the exception of the following modifications:

### **Section 30305.5(b)(2), (c)(4)(B), & (c)(4)(C):**

- All parenthetical phrases containing acronyms “e.g.” or “i.e.” are revised by adding a comma after the acronym for style consistency, resulting in no regulatory effect.

### **Section 30307:**

- Existing text not being amended was incorrectly shown in the initial proposal as subsections “(a) through (c)”, but is now revised to correctly indicate the section contained only subsections (a) and (b). This results in no regulatory effect.
- Initially proposed text shown as subsection (d) is revised to subsection (c), resulting in no regulatory effect.
- Subsection (c), initially subsection (d), was revised as follows:
  - The text is revised to clarify which value must be recorded. As proposed, the user was required to record two values (i.e., total fluoroscopic irradiation time and cumulative air kerma). However, the total fluoroscopic irradiation time is needed only when the equipment does not provide the cumulative air kerma value.
  - The first sentence is further revised for clarity and simplicity by splitting the sentence into two sentences.
  - The last (i.e., third) sentence is revised for clarity and simplicity.
- The section note is revised to address a recent change in the Note (Register 2020, No. 20), resulting in no regulatory effect.

### **Section 30418(d)(1):**

- As initially noticed, § 30418(d) was not proposed to be revised. However, due to the proposed revision of § 30423, to which section 30418(d)(1) cites, § 30418(d)(1) is revised to ensure the provision correctly cites to § 30423(b)(1) for clarity. By operation of § 30423(h), the revision results in no regulatory effect.

### **Section 30441:**

- Due to comments during the initial public participation period, initially proposed subsection (a)(9) was deleted for further evaluation and a 15-day public availability period was conducted. The received comments questioned whether the proposal, as it pertains to medications, was within the authority of the Radiologic Technology Act. A proposed regulation must be within the statutory authority granted by law. Authority, in addition to other standards, is a criterion for adopting regulations, and a review-basis under the rulemaking provisions of the Administrative Procedures Act (Gov. Code § 11340 et seq.) applied by the California Office of Administrative Law. If a proposed regulation fails to meet that standard, the proposal must be rejected. Based on that re-evaluation and received comments, subsection (a)(9), as initially proposed,

was re-inserted during a second 15-day public availability period with the following revisions:

- The initially proposed term and definition of “medications” is deleted and the proposed term and definition of “contrast media” is added. The proposed term and definition of “contrast media” (plural form) is based on the defined term “contrast medium” (noun form) found in Reference 13.
- The word “cardiac” as found in the phrase “peripherally inserted cardiac catheter” is changed to “central” so that the phrase would now read “peripherally inserted central catheter.”
- Due to re-inserting initially proposed subsection (a)(9) as revised, paragraphs (10) through (18) of subsection (a) are re-codified to maintain a coherent structure.

**SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD OF JULY 21, 2019 THROUGH AUGUST 5, 2019, THE PUBLIC HEARING HELD ON AUGUST 2, 2019, THE FIRST 15-DAY PUBLIC COMMENT PERIOD OF DECEMBER 3, 2019 THROUGH DECEMBER 18, 2019, AND THE SECOND 15-DAY PUBLIC COMMENT PERIOD OF JANUARY 10, 2020 THROUGH JANUARY 25, 2020.**

Following is the list of persons who commented on the initial proposed regulations (DPH-17-009) during the 45-day public comment period beginning on June 21, 2019 and ending at 5:00 p.m. on August 2, 2019. The Department received comments as identified below. A request to hold a public hearing was received so a public hearing was held on August 5, 2019. A 15-day public comment period was conducted beginning on December 3, 2019 and ending at 5:00 p.m. on December 18, 2019, resulting in received additional comments. A second 15-day public comment period was conducted beginning on January 10, 2020 through January 25, 2020, during which one comment letter was received.

**List of Commenters during Initial 45-day Proceeding held from June 21, 2019 through August 5, 2019.** (Written testimony)

1. Teri Braun-Hernandez, CRT(R), (CI)(M)(R), ARRT  
*(Item number(s) 1, 2, 3, 4)*
2. Marisa E Davis, Staff Radiologic Technologist, UCSF Medical Center  
*(Item number(s) 9, 10, 11, 12, 13, 14)*
3. Victor Castro  
*(Item number(s) 16)*
4. Lisette Alfonso, CRT, RT(R), ARRT, UCSF  
*(Item number(s) 9, 10, 11, 12, 13, 14, 17, 18, 19, 20)*
5. James A Vereecke, CRT  
*(Item number(s) 9, 10, 11, 12, 13, 14, 17, 18, 19, 20)*
6. Ricky Ng, CRT, RT(R), ARRT  
*(Item number(s) 9, 10, 11, 12, 13, 14, 17, 18, 19, 20)*

7. Simonette Sung, R.T., CRT  
*(Item number(s) 24)*
8. Monica Goranov  
*(Item number(s) 9, 10, 11, 12, 13)*
9. Michelle Zieglar  
*(Item number(s) 9, 10, 11, 12, 13)*
10. Christina Salani, CRT, Radiology, UCSF  
*(Item number(s) 9, 10, 11, 12, 13, 25)*
11. Linda Casavant  
*(Item number(s) 26)*
12. Barb Roth, Assistant to BJ Bartleson Vice President, Nursing & Clinical Services,  
California Hospital Association  
*(Item number(s) 27, 28)*
13. Allison Correia  
*(Item number(s) 9, 10, 11, 12, 13)*
14. Eric R Jines, RT(R)(CI) CRT, RCIS  
*(Item number(s) 28, 29, 30, 31,32)*
15. David Poon, CRT, RT(R), ARRT, Past President, California Society of Radiologic  
Technologist (CSRT)  
*(Item number(s) 17, 18, 19, 20)*
16. James Bell, RT (R)(CT)CRT  
*(Item number(s) 34, 35, 36, 37, 38, 39)*
17. Lois Richardson, Vice President & Legal Counsel, California Hospital Association  
*(Item number(s) 40)*
18. Shannon Chezick, Administrative Staff, CSRT  
*(Item number(s) 17, 41, 42, 43, 44, 45)*
19. Leah Pike, MD  
*(Item number(s) 46)*
20. Roy Anthony Brown, RT(R), (F), CRT, ARRT  
*(Item number(s) 47, 48)*
21. Tanya Zighera, RT(R)(CT)(ARRT)  
*(Item number(s) 49)*
22. Raymond Medina, RT, Clinical Coordinator, Keck Medicine of USC  
*(Item number(s) 50, 51, 52)*
23. Jessica Greif, RT(R)  
*(Item number(s) 17, 53, 54, 55)*
24. Shaun Mahon  
*(Item number(s) 17, 56, 57)*
25. Dyantha Burton, CRT  
*(Item number(s) 58, 59, 60, 61, 62)*
26. Lawrence Hong  
*(Item number(s) 64, 65)*
27. Mina Trevis  
*(Item number(s) 66, 67)*

28. Khyber Zaffarkhan, DO, FAAPMR, Medical Director, Board Certified, Physical Medicine & Rehabilitation, Life Care Planner  
*(Item number(s) 68)*
29. Daivd Laumann, CRT  
*(Item number(s) 69)*
30. Deborah Brueggman, CRT, ARRT, Kaiser Permanente  
*(Item number(s) 70)*
31. Michael Bojorquez, CRT, ARRT(R)  
*(Item number(s) 72, 73, 74, 75, 76, 77)*
32. Devin Galdi, RT  
*(Item number(s) 50, 51, 37)*
33. Earl Malan BS, RT(R)(CT)  
*(Item number(s) 78)*
34. Patricia Scira  
*(Item number(s) 79)*
35. Christina Ayon  
*(Item number(s) 80)*
36. Cristina Eftimiou, RT, VNC, Sutter Hospital, San Francisco  
*(Item number(s) 81)*
37. Misook Seong, RT(R)  
*(Item number(s) 9, 10, 11, 12, 13)*
38. Leslie Tresch, RT(R)CV, RCIS  
*(Item number(s) 82, 83)*
39. Kathleen E. Lawson, CRT(R,M,F), ARRT(R, CV, M)  
*(Item number(s) 84, 85)*
40. Mary K. Falkner, Manager, Imaging Services, Keck Medicine of USC  
*(Item number(s) 50, 42, 37)*
41. Suntara Poch, IR Tech  
*(Item number(s) 50, 42, 37)*
42. Ramon Ordonez, MRI Tech  
*(Item number(s) 50, 42, 37)*
43. Jimmy Ha, CT Tech  
*(Item number(s) 50, 42, 37)*
44. Anh Luong, Rad Tech  
*(Item number(s) 50, 42, 37)*
45. Vlad R. Ghenciu, Esq  
*(Item number(s) 17)*
46. Corey Hidalgo, BSRT, ARRT(R), CRT, Fluoro, Radiologic Technologist/Department Supervisor, Faculty-Health Sciences Department, California State University Northridge  
*(Item number(s) 86, 87)*
47. Colleen You, CRT  
*(Item number(s) 88)*

48. Ashlee Dematteo, Special Procedures Technologist, Dignity Health, Methodist Hospital of Sacramento  
*(Item number(s) 37)*
49. Fey Saephan  
*(Item number(s) 37)*
50. Janine McClure  
*(Item number(s) 89, 90)*
51. Stephanie Ryan-Redhair, Senior Special Procedures Technologist, Mercy Hospital Folsom  
*(Item number(s) 91)*
52. Cliff Marticorena, RT, C.T.  
*(Item number(s) 50, 42, 37)*
53. Leslie Kelly-Guerrero, RT, CRT  
*(Item number(s) 9, 10, 12)*
54. Dr. Carmen Saunders-Russell, EdD, CRA, RT(R)(M)  
*(Item number(s) 93)*
55. Peter J. Szpara  
*(Item number(s) 94)*
56. Lisa Chavers, Spinal Imaging Specialists  
*(Item number(s) 95, 96)*
57. William L. Faye, RHT  
*(Item number(s) 97, 98)*
58. Seth Dikun  
*(Item number(s) 99, 100, 101, 102)*
59. Mark Rigsby, RT(R)(CI), RCIS, RCSA, California Licensed Technologist  
*(Item number(s) 103, 104, 105, 106, 107)*
60. Manuel Gomez  
*(Item number(s) 108, 109)*
61. Annie Wiebel, TPMG Compliance, Kaiser  
*(Item number(s) 110)*
62. Diane R. Garcia, Former RTCC Member, Former Program Director, Diagnostic Medical Imaging Program  
*(Item number(s) 111)*
63. David Gliniewicz, CRT RT CT, Instructor at City College of San Francisco Diagnostic Medical Imaging Program  
*(Item number(s) 112)*
64. Cathy Robrahn, ARRT, ASRT  
*(Item number(s) 113)*
65. Bob Acherman, California Radiological Society  
*(Item number(s) 114)*
66. Christel Gho, RRT, RCP, RPSGT  
*(Item number(s) 115)*
67. Doris Abrishami, EdD, BSRT, (R)(M) ARRT, Associate Professor-Department of Health Sciences

- (Item number(s) 116, 117, 118, 119)*
68. Diane Przepiorski, Executive Director, California Orthopaedic Association  
*(Item number(s) 121, 122, 123, 124)*
69. Jeremy Ryan Miller, RT CRT(R) (CI) (VI) RCIS  
*(Item number(s) 126, 127, 128, 129, 130)*
70. Jason A. Everling, Rad Tech II, Kaiser Fontana OR Tech  
*(Item number(s) 131)*
71. Lorenza Clausen, CRT, RT(R) (CT) (MR), ARRT, MRSO  
*(Item number(s) 132)*
72. Kenneth Cortes, CRT, BA  
*(Item number(s) 136)*
73. Lilliana Bastianon  
*(Item number(s) 137)*
74. Michele Matassa Reams BSRT ARRT (R) (CT)  
*(Item number(s) 138)*
75. Michael Osborne, CRT RHF  
*(Item number(s) 135)*
76. Mary C. Hart, CRT-R, F, M, ARRT  
*(Item number(s) 140, 141, 142, 143)*
77. Norma A. Robles, BSRT, CRT ARRT (R) (M) (CT) CVT/Radiologic Technologist  
*(Item number(s) 144)*
78. Scott D. Smith, BSRS CRA RT(R VI) CRT  
*(Item number(s) 145)*
79. Saskia Kim, Regulatory Policy Specialist, California Nurses Association/National Nurses United  
*(Item number(s) 146, 147)*
80. Taylor Hensley  
*(Item number(s) 137)*
81. Thomas Litawa, CRT(F)  
*(Item number(s) 148, 149)*
82. Christopher H. Cagnon, PhD, DABR, FAAPM, RTCC Member  
*(Item number(s) 150)*
83. Sharon Buchanon  
*(Item number(s) 17)*
84. Tim Madden, American College of Cardiology – California Chapter  
*(Item number(s) 151)*
85. Anita M. Slechta MS, BSRT, RT(R)(M), FASRT, REHS Professor – Health Sciences Department Director-BS Radiologic Sciences California State University Northridge  
*(Item number(s) 152)*
86. Peggy McElgunn, Esq. Executive Director Alliance of Cardiovascular Professionals  
*(Item number(s) 157-172 )*
87. Terese C. Eddy  
*(Item number(s) 108)*
88. Chau Thai

- (Item number(s) 175)*
- 89. Thomas Oshiro, Ph.D., DABR, Associate Clinical Professor – Radiological Sciences, David Geffen School of Medicine at UCLA
- (Item number(s) 176)*
- 90. Rachelle Campbell, MSHA, CRT, RT(R), Program Director, Radiologic Technology, Foothill College
- (Item number(s) 177)*
- 91. Marcy Morigeau CRT, BS
- (Item number(s) 178)*
- 92. Holly Jensen
- (Item number(s) 178)*
- 93. Liana Watson, DM, RT(R)(M)(S)(BS)(ARRT), RDMS, RVT, FASRT, PMP, CAE
- (Item number(s) 179)*
- 94. Savina Castello, RT
- (Item number(s) 178)*

**List of Commenters during Public Hearing held on August 2, 2019.** (Verbal and Written testimony)

- 2a. Marisa E Davis, Staff Radiologic Technologist, UCSF Medical Center
- (Item number(s) 15)*
- 4a. Lisette Alfonso, CRT, RT(R), ARRT, UCSF
- (Item number(s) 21, 22, 23)*
- 10a. Christina Salani, CRT, Radiology, UCSF
- (Item number(s) 25)*
- 14a. Eric Jines, RT(R)(CI) CRT, RCIS
- (Item number(s) 32)*
- 15a. David Poon, CRT, RT(R), ARRT, Past President, CSRT
- (Item number(s) 33)*
- 25a. Dyantha Burton, CRT
- (Item number(s) 63)*
- 30a. Deborah Brueggman, CRT, ARRT, Kaiser Permanente
- (Item number(s) 71)*
- 53a. Leslie Kelly-Guerrero, RT, CRT
- (Item number(s) 92)*
- 67a. Doris Abrishami, EdD, BSRT, (R)(M) ARRT, Associate Professor-Department of Health Sciences
- (Item number(s) 120)*
- 68a. Diane Przepiorski, Executive Director, California Orthopaedic Association
- (Item number(s) 125)*
- 71a. Lorenza Clausen, CRT, RT(R) (CT) (MR), ARRT, MRSO
- (Item number(s) 56, 63)*
- 85a. Anita M. Slechta MS, BSRT, RT(R)(M), FASRT, REHS Professor – Health Sciences Department Director-BS Radiologic Sciences California State University

- (Item number(s) 153, 154, 155)*
- 95a. Erik Israel, RT, UCSF  
*(Item number(s) 180, 181)*
- 96a. Mira-Jee Granju, CRT, UCSF  
*(Item number(s) 182)*
- 97a. Jessica Grief, RT, UCSF  
*(Item number(s) 183)*
- 98a. Kristina Gorauov  
*(Item number(s) 184)*
- 99a. Micka Johnson, Kaiser  
*(Item number(s) 185)*
- 100a. Rene Davinder Utagar, Interventional Specialist, Kaiser  
*(Item number(s) 186)*

**List of Commenters during the first 15-day Proceeding held from December 3, 2019 through December 18, 2019.** (Written testimony)

- 1b. Teri Braun-Hernandez, CRT(R), (CI)(M)(R), ARRT  
*(Item number(s) 5, 6, 7, 8)*
- 71b. Lorenza Clausen, CRT, RT(R) (CT) (MR), ARRT, MRSO  
*(Item number(s) 134)*
- 86b. Peggy McElgunn, Esq. Executive Director Alliance of Cardiovascular Professionals  
*(Item number(s) 173, 174)*
- 101b. Lisa Schmidt, Ph.D., RT(R)(M)(ARRT), CRT, Program Director Radiologic Technology, Pima Medical Institute  
*(Item number(s) 187)*
- 102b. Carter Degnan  
*(Item number(s) 188)*

**List of Commenters during the second 15-day Proceeding held from January 10, 2019 through January 25, 2019.** (Written testimony)

- 71c. Lorenza Clausen, CRT, RT(R) (CT) (MR), ARRT, MRSO  
*(Item number(s) 135)*
- 85c. Anita M. Slechta MS, BSRT, RT(R)(M), FASRT, REHS Professor – Health Sciences Department Director-BS Radiologic Sciences California State University  
*(Item number(s) 156)*

**Summary of comments and responses**

Note: The numbering methodology is outlined below:

- Number only = 45-day comment period



- Number with “-“ and number (e.g., 1-1) = indicates the specific correspondence (electronic mail, fax, etc.) number from the commenter
- Number with “.” and number (e.g., 1-1.1) = indicates the specific comment number found within each correspondence
- Number with “a” = public hearing
- Number with “b” = 15-day
- Number with “c” = 2nd 15-day
- Number and letter with “-“ and number (e.g., 1a-1) = indicates the specific correspondence (electronic mail, fax, etc.) number from the commenter received during a specific comment period (e.g., a, b, or c).
- Number and letter “.” and number (e.g., 1a-1.1) = indicates the specific comment number found within each correspondence received during a specific comment period (e.g., a, b, or c).

Commenter #	Summary and Response to Comments	Item #
1-1	<p><b>Commenter states that the proposal is well written, detailed, and that patients will be safe during fluoroscopic imaging.</b></p> <p><b>CDPH Response:</b> The comment is appreciated.</p>	1
1-2	<p><b>Asks, after reviewing the linked video, if a physician without training on units from the manufacturer understands how to setup their cases. Will the unit be setup to result in a substantial dose or in ALARA (As Low As Reasonably Achievable).</b></p> <p><b>CDPH Response:</b> The commenter provides no specific comment on the proposal or connects the proffered comment to the proposal. Physicians using X-ray equipment must obtain the applicable authorization from the CDPH by passing a written examination (17 CCR 30466) that addresses radiation protection, radiation biology and ALARA concepts. No change to the proposal was made due to this comment.</p>	2
1-3	<p><b>In light of AB 407, the commenter is concerned that section 30305.5(b) does not require a CRT in the room, and if it passes, the physician will not need to show competency through testing or show they have any training on the unit. A CRT needs to be in the room to set the technical factors so the physician will operate the unit in ALARA. Because the non-permitted person has no clue if the unit is operated in ALARA, the CRT needs to be in the room even if X-ray is off, and require that physicians get some kind of training on the unit.</b></p>	3

	<p><b>CDPH Response:</b> The comments regarding proposed legislation are outside the scope of this proposal. The recommendation to require physicians to get some kind of training on the unit is outside the scope of this proposal. However, physicians using X-ray equipment must obtain the applicable authorization from the CDPH by passing a written examination (17 CCR 30466) that addresses radiation protection, radiation biology and ALARA concepts. Also, § 30305.5(b)(2) prohibits the non-permitted individual from performing certain actions, including selecting the technique factors or mode of operation. Thus, either the certified physician or CRT must perform the indicated actions.</p> <p>The recommendation to require the CRT in the room, even if X-ray is off, is rejected as it a central component of RTCC’s recommendation. The commenter’s concern was discussed at numerous public meetings. No change to the proposal was made due to this comment.</p>	
1-4	<p><b>Commenter reiterates her concern regarding AB 407 and continues to recommend that a CRT be present in the room managing the radiation exposure and X-ray equipment regardless of whether the beam is off or on. The physicians are pushing not to show competency by taking the fluoroscopy test through AB 407, as such, the units will not be operated in ALARA without a CRT(F) setting the technical factors. Commenter shares video on the technical factors to provide context. AEC does not pick the proper programs or frame rates.</b></p> <p><b>CDPH Response:</b> See the response in Item 3.</p>	4
1b-1	<p><b>It appears the RT does not need to be in the room when the fluoroscopy unit is not emitting X-ray. Is troubled that the provision mentioning medication administration is deleted.</b></p> <p><b>CDPH Response:</b> The comment is correct: proposed § 30305.5(b) addresses the scenario when X-ray is not emitted. Regarding administration of medication, see response in Item six.</p>	5
1b-2	<p><b>Finds the removal of section 30441(a)(9) problematic. Questions whether medications include contrast. If so, technologists working as the scrub in interventional procedures will not be able to utilize medical devices designed specifically for contrast injections and will not be able to perform their jobs during the procedure.</b></p> <p><b>CDPH Response:</b> Regarding removal of § 30441(a)(9), in response to commenter 79, that provision was removed for further evaluation and an</p>	6

	<p>additional 15-day comment period was conducted. After that evaluation and review of this and other public comments, the proposal was revised and a second 15-day comment period was conducted to clarify that the provision was limited to contrast media and saline-based solutions, which encompasses adding heparin to saline. Heparin-based solutions, as referenced by the commenter, is inaccurate since heparin is the solute and saline (a solution of sodium chloride in purified water) is the solvent resulting in a saline-based solution.</p>	
1b-3	<p><b>Shared the Alliance of Cardiovascular Professionals’ letter believing they failed to read the indicated provision (i.e., § 30305.5(c)(4)).</b></p> <p><b>CDPH Response:</b> The comment is acknowledged and no change to the provision is needed. The provided comment letter is identified as commenter 86b, and is addressed in Items 173 and 174.</p>	<b>7</b>
1b-4	<p><b>This comment letter is duplicative of 1b-2 but was received on a different date and through a different email address.</b></p> <p><b>CDPH Response:</b> See Items 173 and 174 for summary and response.</p>	<b>8</b>
2-1.1; 4-1.1; 5-1.1; 6-2.1; 8.1; 9.1; 10-1.1; 13.1; 37.1; 53.1	<p><b>Concerned that the majority of the new recommendations by the RTCC are fiscally-driven, with virtually no mention of actual patient safety and dose minimization. Questions why, if non-certified persons are qualified to administer radiation, would RTCC feel the need for CRTs to train these persons.</b></p> <p><b>CDPH Response:</b> The public meetings of the RTCC included discussions of patient safety, radiation exposures, and related consequences. (Reference 3, pp. 11-20.) It appears that the commenters support their concerns on how many words relate to fiscal effects, and therefore are making a number of assumptions of intent based on the fiscal and economic statements. However, fiscal and economic statements must be addressed, and are presented within the Notice of Proposed Action. Thus, the comments focus almost entirely on the notice and its fiscal and economic statements.</p> <p>Specific to the concern regarding a CRT training non-certified persons, the ISR, pages 5 through 12, fully discusses the proposal (section 30305.5), the limitations placed on the non-permitted individual, the training requirements for that individual, who may provide the instruction to that individual, etc. The Department feels the commenters failed to review those discussions and construe the Notice’s statements as the actual proposal. The proposal does not allow the non-permitted person to operate the fluoroscopy unit. Section 30305.5(b) and (c) place numerous conditions on the certified S&amp;O and the</p>	<b>9</b>

	<p>non-permitted person, and so limit that non-permitted person to very specific actions with specific prohibitions. The regulatory text does not support an interpretation that would allow non-permitted persons to operate the fluoroscopy unit.</p> <p>As it relates to the RTCC membership, the RT Act requires that two members be CRTs. (HSC 114860(b).) During RTCC’s public meetings, CRTs were present and supported the RTCC’s recommendation (Reference 3, pp. 11-20).</p> <p>No change to the proposal was made due to these comments.</p>	
<p>2-1.2;  4-1.2;  5-1.2;  6-2.2;  8.2;  9.2;  10-1.2;  13.2;  37.2;  53.2</p>	<p><b>Seeking clarification as to why the RTCC is suggesting that CRTs train non-certified individuals when those individuals are considered qualified to administer radiation to patients without risk of over-exposure and incorrect equipment usage.</b></p> <p><b>CDPH Response:</b> The comment appears to not reflect what the actual proposal allows and limits. Proposed § 30305.5(c)(3) would allow a non-permitted individual to take certain actions, under specific conditions and prohibitions, provided that the individual has met the training requirement in § 30305.5(d). That training must be provided by certain qualified individuals, a CRT being one of them. The non-permitted individual’s actions remain extremely limited by the specified conditions and prohibitions. No change to the proposal was made due to this comment.</p>	<p style="text-align: right;"><b>10</b></p>
<p>2-1.3;  4-1.3;  5-1.3;  6-2.3;  8.3;  9.3;  10-1.3;  13.3;  37.3</p>	<p><b>Concerned that CRTs stand to be detrimentally impacted by having their scope reduced in the name of outsourcing radiation safety to “lesser-paid persons”. Recommends further research on whether the proposed regulations affect the creation or elimination of jobs from a source without vested interest. The RTCC currently has no CRTs on the committee.</b></p> <p><b>CDPH Response:</b> The Department disagrees such an impact will occur, as based on RTCC’s public meetings. Further, the term “lesser-paid persons” is used for purposes of the objective determination as to fiscal and economic impacts, and only means a person who is paid less than some other person. It is not a pejorative statement. Lastly, when RTCC made the recommendations, two CRTs were on the committee and participated in the discussions and recommendations. See also the response in Item 4.</p> <p>No change to the proposal was made due to this comment.</p>	<p style="text-align: right;"><b>11</b></p>

<p>2-1.4;          4-1.4;          5-1.4;          6-2.4;          8.4;          9.4;          10-1.4;          13.4;          37.4;          53.3</p>	<p><b>Concerned that this proposal creates the opportunity for fluoroscopic equipment to be used by persons with no formal education on radiation safety or the effects of ionizing radiation.</b></p> <p><b>CDPH Response:</b> The Department believes that the proposal ensures continued protection of patient and provider health and safety, since it places numerous restrictions and prohibitions on what the non-permitted individual is allowed to do with the equipment. No change to the proposal was made due to this comment.</p>	<p style="text-align: center;"><b>12</b></p>
<p>2-1.5;          4-1.5;          5-1.5;          6-2.5;          8.5;          9.5;          10-1.5;          13.5;          37.5</p>	<p><b>Request public hearing to be held by the RTCC to further discuss these proposals with patient safety and public health at the forefront of the discussion, as opposed to speculative financial savings.</b></p> <p><b>CDPH Response:</b> The RTCC discussed and adopted the recommendations after numerous public meetings. The financial and economic statements in the public notice do not represent the RTCC's discussion and reasons for the recommendation. Those statements are the objective fiscal/economic evaluation of the recommendation only. As indicated in those statements, there could be a financial cost or financial savings, depending on how a facility implements the proposal. No change to the proposal was made due to this comment.</p>	<p style="text-align: center;"><b>13</b></p>
<p>2-2.1</p>	<p><b>The state of California must not let anyone who is not certified handle or manipulate equipment designed to dose [sic] ionizing radiation. This is a matter of patient, staff, and public safety. Non-certified means unqualified. Commenter requests that Title 17 be not watered down with unsafe, careless regulations and amendments.</b></p> <p><b>CDPH response:</b> The public meetings of the RTCC included discussions of patient safety, radiation exposures, and related consequences. (Reference 3, pp. 11-20.) The proposal does not allow the non-permitted person to operate the equipment. It would allow them, under very limiting conditions, only to move the equipment or patient for very specific purposes. The RTCC considered radiation protection and ALARA principles during its numerous public meetings. No change to the proposal was made due to this comment.</p>	<p style="text-align: center;"><b>14</b></p>
<p>2a</p>	<p><b>Commenter is opposed to the changes being put forth to Title 17. Believes that uncertified is unqualified and that the patient's safety should not be compromised.</b></p> <p><b>CDPH Response:</b> See the response in Item 14.</p>	<p style="text-align: center;"><b>15</b></p>

3	<p><b>Concerned about children getting exposed to scatter radiation when accompanying their parents who are patients. The children are behind mobile barriers but questions whether this safety measure is adequate. Commenter seeks to adhere to ALARA to protect the public from unnecessary radiation exposure.</b></p> <p><b>CDPH Response:</b> The Department appreciates and shares the concern. However, the comment appears to be outside the scope of the proposal. CRTs are trained and educated on how to practice ALARA and to protect others, such as indicated in the commenter’s scenario. No change to the proposal was made due to this comment.</p>	16
4-2.1; 5-2.1; 6-1.1; 15.1; 18-1.1; 23.1; 24.1; 45-1; 45-2; 83	<p><b>Requests a public hearing.</b></p> <p><b>CDPH Response:</b> A public hearing was held on August 2, 2019.</p>	17
4-2.2; 5-2.2; 6-1.2; 15.2; 21-1.1;	<p><b>Concerned that the use of non-certified, non-permitted individuals completely goes against ALARA. Commenter cites American College of Cardiology’s rule on what a physician must do to practice ALARA. The commenter continues by saying that allowing non-certified, non-permitted individuals to operate an ionizing producing machine is irresponsible and dangerous. It is the responsibility of the RT to perform this task, as this is part of the RT’s standard of Practice.</b></p> <p><b>CDPH Response:</b> See the response in Item 14.</p>	18
4-2.3; 5-2.3; 6-1.3; 15.3;	<p><b>Concerned that physicians who perform radiologic fluoroscopic procedures on a daily basis lack basic understanding of Radiation Biology and Radiation Protections. Shared information wherein physicians were found to be inadequately trained on the use and risks of fluoroscopy and preventing radiation damage. States that RTs have the necessary education to help minimize radiation dose to patients and to staff.</b></p> <p><b>CDPH Response:</b> Physicians holding the applicable CDPH-issued certificate or permit have passed an examination addressing radiation biology and radiation protection. A review of the referenced clinical competence</p>	19

	<p>statement supports the examination requirement currently used by the CDPH. A review of the referenced study showed the study was a survey questionnaire of Turkish orthopedic surgeons. The Department believes the study cannot be used to reasonably describe California physicians' understanding of radiation protection, due to its limited scope.</p> <p>The proposal does not allow the non-permitted person to operate the equipment. It would allow them, under very limiting conditions, only to move the equipment or patient for very specific purposes. The RTCC considered radiation protection and ALARA principles during its numerous public meetings.</p> <p>No change to the proposal is made due to this comment.</p>	
<p>4-2.4; 5-2.4; 6-1.4; 15.4</p>	<p><b>Believes the recommendation puts patients at risk in an effort to save a clinic or organization money.</b></p> <p><b>CDPH Response:</b> See response in Item three.</p>	<p><b>20</b></p>
<p>4a.1</p>	<p><b>Commenter believes that the proposed adoption of section 30305.5 has a great probability of causing harm to the public. Allowing non-permitted, non-certified individuals who do not hold fluoroscopy permits and who are not CRTs to operate fluoroscopic equipment puts all patients and staff at risk of getting unnecessary and/or excessive radiation.</b></p> <p><b>CDPH Response:</b> See the response in Item 14.</p>	<p><b>21</b></p>
<p>4a.2</p>	<p><b>Commenter believes that this proposal will do away with the certified technologist who has years of experience and training seemingly for the sake of saving money and saving the doctor some time. CRTs act as a patient advocate for radiation safety and are responsible for ensuring that the physicians and other staff are safe as well.</b></p> <p><b>CDPH Response:</b> See the responses in Items 11, 13, and 14.</p>	<p><b>22</b></p>
<p>4a.3</p>	<p><b>Commenter shares experiences wherein the surgeon is directing a nurse or vendor to move the equipment and take images, but the imaging results are low quality and the technical factors are incorrect because the surgeon does not have any real knowledge of how to properly operate the equipment. This results in several images being taken because the equipment is not being centered properly.</b></p>	<p><b>23</b></p>

	<p><b>CDPH Response:</b> Physicians using X-ray equipment must obtain the applicable authorization from the CDPH by passing a written examination (17 CCR 30466) that addresses radiation protection, radiation biology and ALARA concepts. The public meetings of the RTCC included discussions of patient safety, radiation exposures, and related consequences. (Reference 3, pp. 11-20.) The authorized physician exercises their medical judgement in all instances, even when a non-physician disagrees with an action.</p>	
7	<p><b>Commenter states that it is not safe for a nurse, non-radiologist MD, scrub tech, speech therapist, etc. to even touch the control console for the fluoroscopic equipment because they could inadvertently crush the patient with the flat panel by pushing the wrong function on the control console. Recommend limiting those permitted to move fluoroscopic equipment to only X-Ray Technologists.</b></p> <p><b>CDPH Response:</b> See responses in Items 14, 19, and 23.</p>	<b>24</b>
10-2; 10a	<p><b>Commenter has seen a lot of negligence due to lack of knowledge in radiation safety in her 12 years of being a technologist. She has helped educate doctors and save patients from receiving excessive dose during their procedure. Questions whether an unlicensed person will have the same confidence or insights to help a doctor that is focused on the procedure. Fears that without a licensed professional technologist in the room, there will be many missed opportunities for safety and limiting radiation exposure.</b></p> <p><b>CDPH Response:</b> See responses in Items 14, 19, and 23.</p>	<b>25</b>
11	<p><b>Requested a copy of the regulation texts for the proposed rulemaking.</b></p> <p><b>CDPH Response:</b> A copy of the text was provided.</p>	<b>26</b>
12-1	<p><b>Informed CDPH that the link for the Initial Statement of Reasons leads to an incorrect document. Requested the correct document.</b></p> <p><b>CDPH Response:</b> The website linkages were corrected and the commenter was provided the correct document.</p>	<b>27</b>
12-2	<p><b>Acknowledged receipt of requested documents.</b></p> <p><b>CDPH Response:</b> The Department appreciates the acknowledgment.</p>	<b>28</b>
14-1.1	<p><b>Believes that this is a negligent proposal that could impact the safety of patients and workers in the fluoroscopic suite.</b></p>	<b>29</b>



	<b>CDPH Response:</b> See the response in Item nine.	
14-1.2	<p><b>Witnessed physicians who hold X-ray supervisor and operator certificates focused on other aspects of the procedure while neglecting their SID [<i>source to image distance</i>]. The commenter, licensed and present in the room, specifically focused on the X-ray, was able to prevent unnecessary exposure to the patients and staff. Commenter shares various examples wherein issues were mitigated due to having a properly licensed individual in the operating units during all procedures and believes greater regulations rather than less safe regulations that are geared towards profit are needed.</b></p> <p><b>CDPH Response:</b> See responses in Items 9, 13, 14, 19, 23, and 35.</p>	<b>30</b>
14-1.3	<p><b>Concerned that the proposal is yet another attack on the struggling middle class in the state of California. The rich are getting richer while the American people are getting less quality health care.</b></p> <p><b>CDPH Response:</b> The comment provides no specific connection to any proposed provision. Thus, the comment is outside the scope of the proposal.</p>	<b>31</b>
14-2; 14a	<p><b>Because of the commenter’s education and understanding of the equipment, he was able to change certain practices and prevent unnecessary radiation exposure to both the patient and the staff. In the commenter’s experience, physicians can lose focus on the proper X-Ray positioning because they must focus on the patient. It is important that the RT is in the room paying close attention to the aspects of the X-Ray equipment during the procedure. The radiation can cause somatic and genetic damage squamous cell carcinomas, leukemia, thyroid cancers, stomach cancers, and birth defects, to cite a few examples of the damage that can occur to both patients and staff members. Believes that certified radiologic technologists should be the only ones to move the C-arm in real-time movement for the patient during fluoroscopy. It would be reckless and neglectful to lower the standard of care by anyone other than a person with the proper education.</b></p> <p><b>CDPH Response:</b> See the response in Items 9, 13, 14, 19, 23, and 35.</p> <p>Specific to limiting machine use to only CRTs, the comment is rejected as inconsistent with the RT Act because the RT Act authorizes physicians to use fluoroscopy for purposes of medical practice.</p>	<b>32</b>

15a	<p><b>Concerned as to who evaluates the instruction provided to non-permitted individuals and deems it to be appropriate. RTCC members have not defined the quality of instruction. Commenter shares different accreditation methods radiology programs undergo. Commenter also shares two studies wherein the surgeons lacked adequate training on radiation safety. Believes that this proposal waters down the RT Act.</b></p> <p><b>CDPH Response:</b> The ISR, pages 5 through 12, fully discusses the proposal (section 30305.5), the limitations placed on the non-permitted individual, training requirements for that individual, who may provide the instruction to that individual, etc. The specific training is not intended to result in a person becoming a certified radiologic technologist, whereas accredited radiologic technology programs are intended for that purpose. Thus, the two training programs cannot be compared. See also the responses in Items 12, and 14.</p> <p>Regarding the identified studies, see the response in item 19.</p>	<b>33</b>
16-1	<p><b>No comments on the proposal are provided.</b></p> <p><b>CDPH Response:</b> See responses to items 35 through 39.</p>	<b>34</b>
16-2.1	<p><b>Believes the proposed changes to 30305.5 is abuse waiting to happen. Licensed CRTs need to be present for all fluoroscopic exams to ensure patients are not overexposed. Although many doctors have Supervisor/Operator licenses, in his experience, they see these as an unnecessary burden on them placed by the state. Believes CRTs are the last line of defense for patient exposure and that the cost savings to providers cannot compare to the potential injury that abuse of fluoroscopic equipment would cause.</b></p> <p><b>CDPH Response:</b> The Department believes the RTCC’s recommendation as carried out in this proposal places appropriate restrictions to prevent abuse, balancing risks of procedures requiring continuous X-ray emission versus those procedures that do not. Regardless of the perception that doctors may have of the RT Act, the law applies and provides authority for taking disciplinary action on those who effectuate abuse. Doctors and CRTs are both critical to patient protection and radiation exposure reduction. Doctors exercise their medical judgement as to whether radiation should or should not be given at all, and the CRT carries out the doctor’s X-ray order by using the least amount of radiation to obtain an acceptable X-ray image so the doctor can accurately interpret the image and make a diagnosis. Also, as indicated in the Notice of Proposed Action, an organization may see an additional cost,</p>	<b>35</b>

	or may see a savings, depending on how, or whether, the organization implements the proposal.	
16-2.2	<p><b>Supports section 30307(b) [sic]; exposure must be documented to ensure that ALARA goals are maintained.</b></p> <p><b>CDPH Response:</b> It appears the commenter intended to cite to subsection (c). The support is appreciated. No change to the proposal was made due to this comment.</p>	<b>36</b>
16-2.3; 32.3; 40.3; 41.3; 42.3; 43.3; 44.3; 48; 49; 52.3	<p><b>Recommends that a licensed CRT needs to be present during all fluoroscopy procedures.</b></p> <p><b>CDPH Response:</b> The recommendation to require the CRT in the room, even if X-ray is off, is rejected as contrary to a central component of RTCC's recommendation. The commenter's concern was discussed at numerous public meetings. No change to the proposal was made due to this comment.</p>	<b>37</b>
16-2.4	<p><b>Supports section 30417 and having an experienced technologist mentor and train students under a radiologist's supervision in order to impart best practices to future technologists to improve care.</b></p> <p><b>CDPH Response:</b> The support is appreciated.</p>	<b>38</b>
16-2.5	<p><b>Seeking more clarification on section 30441. CT technologists are qualified to start IVs and introduce contrast media to patients under the supervision of a radiologist, however, introducing other medications without qualified people present creates a serious liability for the technologists introducing the medication.</b></p> <p><b>CDPH Response:</b> See the response in Item 147.</p>	<b>39</b>
17	<p><b>Requested a specific set of documents relied upon by the Department to create the proposed regulations.</b></p> <p><b>CDPH Response:</b> CDPH sent the requested documents.</p>	<b>40</b>
18-1.2	<p><b>The proposed regulations are incorrect and contradict the original RTCC recommendation on April 13<sup>th</sup>. According to the meeting minutes, a certified diagnostic radiologic technologist must be present in the room.</b></p>	<b>41</b>

	<p><b>CDPH Response:</b> It appears the comment is addressing the summary of the RTCC’s recommendation in the public notice, not the actual proposed regulatory text. As indicated in the April 2016 meeting (Reference 4, pp. 11-12) from which the commenter quotes, the quotation is addressing the 5<sup>th</sup> part of RTCC’s approved 5-part motion. (Reference 4b, p. 1.) This is specified in § 30305.5(c), and addresses when the CRT must be present in the room. Part 3 of the RTCC’s approved 5-part motion (Reference 4b, p. 1; proposed § 30305.5(b)) does not require the individual to be a CRT. Thus, the Department disagrees the proposal contradicts RTCC’s recommendation. No change to the proposal was made due to this comment.</p>	
18-1.3; 40.2; 41.2; 42.2; 43.2; 44.2; 52.2	<p><b>Section 30305.5(c) allows the physician to have a non-qualified person moving the equipment and patient during fluoroscopy procedures without a CRT in the room. Operators need to be well trained, and this proposal jeopardizes public health and safety.</b></p> <p><b>CDPH Response:</b> Section 30305.5(c)(2) requires the presence of a qualified person (i.e., CRT or PA) as recommended. Further, the proposal is consistent with RTCC’s recommendation as shown in the April 2016 meeting minutes. (Reference 4, p. 11.) The allowed actions are very limited, and numerous prohibitions are placed on the individual such that they are not operating the equipment. (§ 30305(c)(4).) No change to the proposal was made due to this comment.</p>	<b>42</b>
18-2	<p><b>Duplicate comments sent via email.</b></p> <p><b>CDPH Response:</b> See response in items 17, 41, 42, 43, 44, and 45.</p>	<b>43</b>
18-3	<p><b>Sent duplicate comments. Requested to be notified of when the hearing will occur.</b></p> <p><b>CDPH Response:</b> Notification was sent.</p>	<b>44</b>
18-4	<p><b>Duplicate comments sent via USPS.</b></p> <p><b>CDPH Response:</b> See responses in items 17, 41, 42, 43, 44, and 45.</p>	<b>45</b>
19	<p><b>Seeking clarification regarding section 30307(b) [sic]; if an X-Ray is obtained on a mini-fluoroscanner (Hologic Insight) in an office, does the air kerma need to be documented in the patient’s medical record?</b></p> <p><b>CDPH Response:</b> It appears the commenter intended to cite to § 30307(c). The indicated equipment has only one mode of operation: fluoroscopy.</p>	<b>46</b>

	<p>According to the manufacturer’s equipment specifications, it is not equipped with a “radiography” mode. Thus, the provision applies. No change to the proposal is made due to the comment.</p>	
<p>20.1</p>	<p><b>Recommend creating a distinction between auto or manual mode. This needs to be identified when moving equipment or a patient during fluoroscopic X-Ray procedures. Techniques change while in manual mode, which would comply with existing policy and allow non-licensed and non-certified personnel to participate in certain medical procedures that do not require equipment or patient movement.</b></p> <p><b>CDPH Response:</b> The recommendation is rejected because the proposal is not intended to allow a non-permitted individual to energize the equipment to emit radiation, to select any technique factors or, mode of operation, or to make any adjustments to the unit that would affect a patient’s radiation exposure. (§ 30305.5(c)(4).) Those actions are considered as performing radiologic technology, invoking the RT Act requirements.</p> <p>Fluoroscopy equipment, regardless of it being operated in automatic mode or manual mode, still displays either the cumulative air kerma, or uses the five-minute timer. This is discussed in the ISR for § 30307(c). The commenter’s reasoning is confusing as to how such a distinction would limit any perceived impacts.</p>	<p><b>47</b></p>
<p>20.2</p>	<p><b>Recommends that the focus should be placed on determining repeat rates when fluoroscopy is used for procedures using only single shots.</b></p> <p><b>CDPH Response:</b> The recommendation is rejected. Fluoroscopy equipment can have a radiographic mode that, when actuated, allows the unit to function as a general radiographic unit, and will not impact the fluoroscopy time or the determined air kerma. Single shots can be obtained by actuating the radiographic mode, or by leaving the unit in fluoroscopy mode and pressing, and quickly releasing, the exposure button. Manual mode is not the same as the radiographic mode. Thus, the recommendation, separately and when combined with the recommendation in Item 29, would require a burdensome and complex recording methodology to capture data for use of the equipment in different operating modes.</p> <p>Further, converting fluoroscopic times to actual patient exposure is not a simple conversion factor. Fluoroscopic time or the displayed air kerma, in part, is needed for the physics calculations and assumptions, but those factors are not directly equivalent to a determined patient exposure. Those factors can also be used to identify ways for fluoroscopists to reduce overall radiation exposures in furtherance of ALARA principles. The Department</p>	<p><b>48</b></p>

	disagrees with the comment that for fluoroscopy procedures the number of images taken is the measurement for X-ray technologists and technicians. For general radiography, yes, but for fluoroscopy the measurement is cumulative fluoroscopy time, or air kerma. Repeat rates are generally used in general radiography to identify the reasons for rejecting an image. Reasons for rejection are often that images are too light, too dark, are blurry, fail to show the intended body part, etc. A high repeat rate indicates increased radiation exposures, since each time an image must be repeated the patient must be exposed again.	
21	<b>The proposed changes would lead to significant patient safety issues; the commenter is opposed to the changes.</b>  <b>CDPH Response:</b> See the response in Item 12.	<b>49</b>
22.1; 32.1; 40.1; 41.1; 42.1; 43.1; 44.1; 52.1	<b>States the RTCC recommendation #3 is incorrect, and should include “provided a certified diagnostic radiologic technologist is present in the room and is managing the radiation exposure and X-Ray equipment.”</b>  <b>CDPH Response:</b> See the responses in items 41 and 42.	<b>50</b>
22.2; 32.2,	<b>Non-licensed individuals are not trained and knowledgeable about radiation protection techniques during fluoroscopy. The lack of knowledge may result in excessive radiation to our patients and will jeopardize the health and radiation safety of patients in California.</b>  <b>CDPH Response:</b> See the responses in items 41 and 42.	<b>51</b>
22.3	<b>Commenter requests that the CDPH reconsider the proposed regulations and revise to require the presence of a CRT during all fluoroscopy procedures.</b>  <b>CDPH Response:</b> See the responses in items 41 and 42.	<b>52</b>
23.2	<b>Allowing individuals without proper education in radiation safety, radiation biology, and radiation physics shows an egregious disregard for patient and public safety.</b>  <b>CDPH Response:</b> See the responses in items 9 through 14.	<b>53</b>
23.3	<b>Physicians simply do not have a background in radiation safety.</b>	<b>54</b>

	<p><b>CDPH Response:</b> Physicians holding the applicable CDPH-issued certificate or permit have passed an examination addressing radiation biology and radiation protection. No change to the proposal is made due to the comment.</p>	
23.4	<p><b>The savings is negligible compared to the potential damage that will be inflicted on patients and staff. ALARA must be preserved and radiation safety and patient care prioritized over revenue.</b></p> <p><b>CDPH Response:</b> See the responses in items 9, 11, 12, 13, and 14.</p>	<b>55</b>
24.2; 71a.1	<p><b>A CRT is the best person to assist the surgeon during fluoroscopic procedures. Training and experience allows a CRT to guide the surgeon in the use of radiation to produce quality images with minimum exposure to the patient following the ALARA principle.</b></p> <p><b>CDPH Response:</b> See the responses in item 35.</p>	<b>56</b>
24.3	<p><b>Concerned that if an unqualified individual performs the RT’s job, the patient could be exposed to dramatically higher doses of radiation due to lack of knowledge. Patients regularly ask about the risks of radiation. A non-certified individual may give confusing and incorrect information to the patient, leaving the patient worried, concerned, and perhaps even reluctant to go ahead with the procedure. DPH-17-009 does not appear to benefit patients.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>57</b>
25-1	<p><b>Opposed to section 30305.5 because of the change in patient care radiation protection standards that may result if this proposal passes.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>58</b>
25-2	<p><b>Inquired if not attending the hearing will decrease her argument against the Title 17 change.</b></p> <p><b>CDPH Response:</b> Not attending a regulatory public hearing has no effect on arguments for or against a regulatory change.</p>	<b>59</b>
25-3	<p><b>Opposed to section 30305.5 because of the change in patient care radiation protection standards that may result if this proposal passes. Commenter believes the proposed change takes away protection</b></p>	<b>60</b>

	<p><b>standards that are in place to prevent patients from excessive/unsafe radiation exposure.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	
25-4	<p><b>Inquiring if it would be possible to postpone the hearing because she is unable to attend.</b></p> <p><b>CDPH Response:</b> Due to scheduling public meetings, postponement was not possible. See also the responses in Items 59 and 62. No change to the proposal was made due to this comment.</p>	<b>61</b>
25-5	<p><b>Requesting CDPH disregard her prior email as she will be able to attend the public hearing.</b></p> <p><b>CDPH Response:</b> The commenter was able to attend the public hearing. No change to the proposal was made due to this comment.</p>	<b>62</b>
25a; 71a.2	<p><b>Concerned that the proposed changes to section 30305.5 puts patients at risk for excessive radiation exposure during fluoroscopy procedures. Believes that reducing radiation protection standards by allowing any non-professional to operate fluoroscopy equipment is a danger to public safety.</b></p> <p><b>CDPH Response:</b> The Department appreciates the concern but the proposal does not allow unlimited operation of the equipment. It states what tasks a non-permitted person can do, and places numerous limitations on those tasks. No change to the proposal is made due to the comment.</p>	<b>63</b>
26.1	<p><b>Allowing non-certified or non-permitted individuals to move the fluoroscopic equipment during use under certain conditions is concerning. The proposed recommendation does not specify what “certain conditions” would be allowed. It is also unclear if this means a janitor or secretary can move the fluoroscopy unit.</b></p> <p><b>CDPH Response:</b> It appears the commenter only read the public notice. The proposal does state the conditions, and defines the term “non-permitted individual.” No change to the proposal is made due to the comment.</p>	<b>64</b>
26.2	<p><b>The proposed RTCC recommendations should not be adopted. Title 17 was put in place to protect the public from unnecessary radiation exposure by having a diagnostic and fluoroscopic licensed radiologic</b></p>	<b>65</b>



	<p><b>technologist that has gone through a licensed and certified radiologic technology course of schooling. These changes would put a patient at risk.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	
27-1	<p><b>Request unknown.</b></p> <p><b>CDPH Response:</b> CDPH contacted the commenter to clarify.</p>	<b>66</b>
27-2	<p><b>Requested details of DPH-17-009.</b></p> <p><b>CDPH Response:</b> CDPH sent requested documents.</p>	<b>67</b>
28	<p><b>Strong support of the proposed changes to section 30305.5.</b></p> <p><b>CDPH Response:</b> The Department appreciates the support.</p>	<b>68</b>
29	<p><b>Opposed to section 30441. There are too many possibilities of things going wrong when allowing a facility to use a CRT in lieu of an RN in administering medications during radiologic procedures. Concerned that patients may receive an allergic reaction and it may take an RN too long to get there. Also concerned that a medical doctor may request a technologist to inject something that is not allowed under this rule change.</b></p> <p><b>CDPH Response:</b> See response to comment 79.2.</p>	<b>69</b>
30	<p><b>Opposes any relaxation of regulations regarding the movement of fluoroscopic equipment by non-CRT personnel. The application of ionizing radiation in both diagnostic and fluoroscopic procedures requires many hours of clinical and classroom instruction in order for the radiography student to gain an appropriate level of respect and caution. There may be a dozen or more factors to check and verify before the exam should commence. The commenter shares various incidents that have occurred that required CRT intervention.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>70</b>
30a	<p><b>Opposes rule 3 and compares it to allowing airline attendants under certain circumstances to fly the plane. The equipment is not designed for non-licensed personnel. Believes that relaxation of the regulations will result in relaxation of the actual standards which will result in more</b></p>	<b>71</b>

	<p><b>incidents of overexposure. Cost savings is the absolute worst reason to enact these changes.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	
31.1	<p><b>Commenter believes that recommendation #3 is in direct contrast to the policy statement objective of “limiting use of X-ray to qualified persons”. It does not ensure the use of qualified individuals because the individuals would be non-certified and non-permitted. It does not reduce unnecessary radiation exposure to patients because non-certified and non-permitted individuals lack formal education and training in radiation safety.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>72</b>
31.2	<p><b>Commenter is concerned that section 30305.5 and AB 407 would lead to fluoroscopy procedures being performed by unqualified, non-certified, non-permitted individuals, all without training and education regarding radiation safety.</b></p> <p><b>CDPH Response:</b> The comment regarding proposed legislation is outside the scope of this proposal. The proposal does not allow non-permitted individuals to perform fluoroscopy procedures or to operate the equipment. It places numerous restrictive conditions on what that individual is authorized to do. No change to the proposal is made due to this comment.</p>	<b>73</b>
31.3	<p><b>Commenter questions how the RTCC can accomplish their objective to limit use of X-ray to qualified persons and reduce unnecessary radiation exposure to patients by removing the very safety provisions that serve that purpose. Commenter believes recommendation #3 needs to be deleted.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>74</b>
31.4	<p><b>Recommends removing the comment about savings as it is misleading. The savings is not tangible for most facilities because the technologists have been administering contrast.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>75</b>
31.5	<p><b>The requirement to document Air Kerma is concerning as legacy fluoroscopic equipment may not have the physical capability of displaying or reporting Air Kerma. Equipment will have to be replaced. Commenter recommends revisions to mirror the Joint Commission</b></p>	<b>76</b>

	<p><b>Standard or suggests changing the wording to: “Radiation dose from fluoroscopy equipment is to be reported in a retrievable format in accordance with the regulatory agency requirements the service provider has achieved deemed status.”</b></p> <p><b>CDPH Response:</b> Section 30307(c) clearly addresses equipment that does not display Air Kerma, and does not require replacement of any equipment. Further, the recording of the number of images is noted in the patient record, but the fluoroscopic time is not affected when a radiographic (e.g., spot-film) image is taken. RTCC membership includes a radiological physicist and functions as the subject matter expert for these types of issues. The recommended language is rejected as it merely directs the user to report dose as required by the regulatory agency. Since the CDPH is the regulatory agency, the proposal states the requirement.</p> <p>No changes to the proposal are made due to the comment.</p>	
31.6	<p><b>Concerned with the practicability of having enough technologists with at least two years’ experience overseeing students. If the technologist has less than two years’ experience, the commenter recommends that the employer should have documentation from the department medical director and certified supervisor and operator that such technologist has been deemed competent to make that determination. However, AB 407 would render the certified supervisor and operator void. This would place the technologist in sole oversight. Recommends absolving AB407 and supports RTCC recommendation #4.</b></p> <p><b>CDPH Response:</b> The comment regarding proposed legislation is outside the scope of this proposal. Section 30417(c) specifies how student oversight occurs, who makes the competency determination, and what documentation is required. The person making the competency determination (e.g., technician or technologist) must have at least two-years’ experience. A technologist with less experience may provide oversight, but may not make the competency determination. Thus, the commenter’s concern is already addressed. The Department appreciates the support of changes to § 30417.</p>	77
33	<p><b>Recommends that ASRT Practice Standards be adopted in its entirety.</b></p> <p><b>CDPH Response:</b> Because ASRT is a private organization and this proposal must be consistent with existing statutory authority, the ASRT practice standards cannot be adopted verbatim. No changes to the proposal are made due to the comment.</p>	78

34	<p><b>Commenter has witnessed situations wherein physicians and scrub techs do not protect themselves and believes that RTCC recommendation #3 will increase negligence and promote irresponsible behaviors.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14, and 35.</p>	<b>79</b>
35	<p><b>Recommends that a licensed radiologic technologist should be the only person handling fluoroscopy equipment.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>80</b>
36	<p><b>Commenter has been a radiology technologist for 10 years and has seen people over expose, break equipment, and not know how to handle X-ray machines because they lack qualifications. Believes that RTCC recommendation section 30305.5 is dangerous. The equipment can potentially emit radiation without the person realizing it. Questions why technologists have to pay for their fluoroscopy license if this recommendation allows whoever to move the fluoroscopy equipment. Commenter believes that their scope of practice is being reduced and being given to those who lack proper education on radiation protection.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14, 35, 42, and 47.</p>	<b>81</b>
38.1	<p><b>Commenter indicated that the received Notice of Proposed Action regarding the RTCC recommendations was very hard to understand and would like clarification to see if her understanding is correct – i.e., that someone without a license (e.g., an RN, CVT, or CRT without a fluoroscopy permit, but with 120 hours of training) can re-center the patient to the area of interest, but cannot pan, collimate, use filters, use image magnification factors, set technique, change film rates, etc. even under the direct supervision of a S&amp;O, CRT with an RTF permit, or PAF.</b></p> <p><b>CDPH Response:</b> The commenter’s summary is not accurate to what is proposed. The proposal (§ 30305.5) clearly states what the non-permitted individual can and cannot do, and specifies other conditions under which that person may perform very specific and limited functions.</p>	<b>82</b>
38.2	<p><b>Opposed to non-licensed personnel being allowed to operate X-ray equipment even if it is only for the purpose of re-centering the equipment to the area of clinical interest. Concerned that facilities may no longer hire X-Ray techs that are properly trained to operate X-ray equipment and exposure factors. Patients and everyone involved could be exposed to increased radiation.</b></p>	<b>83</b>

	<p><b>CDPH Response:</b> The Department disagrees such an outcome will occur. The proposal (§ 30305.5) clearly states what the non-permitted individual can and cannot do, and specifies other conditions under which that person may perform very specific and limited functions. See also responses in items 9 through 14.</p>	
39.1	<p><b>Commenter has witnessed physicians use X-ray with little to no safety in mind for either their patients or their staff. Recommends eliminating the ability of non-radiologist physicians from using or supervising X-ray, revert back to X-ray techs being supervised by radiologists, and under no circumstances allow unlicensed personnel to perform X-rays on patients.</b></p> <p><b>CDPH Response:</b> The recommendation is rejected because the RT Act gives non-radiologist physicians the right to use X-ray or supervise its use, provided the physician has met the CDPH standards. Physicians holding the applicable CDPH-issued certificate or permit have passed an examination addressing radiation biology and radiation protection.</p> <p>Also, the proposal does not allow unlicensed personnel to perform X-rays on patients. The proposal (§ 30305.5) clearly states what the non-permitted individual can and cannot do, and specifies other conditions under which that person may perform very specific and limited functions.</p>	<b>84</b>
39.2	<p><b>X-ray techs are specialized in radiation positioning and protection. Questions the expertise of an unlicensed person taking X-rays. Commenter fears that the proposed regulation will further undermine patient safety and promote a further disregard for radiation safety and protection. Believes that the issue this regulation is addressing is money if it passes.</b></p> <p><b>CDPH Response:</b> See the response in item 84.</p>	<b>85</b>
46-1.1; 46-2.1	<p><b>This regulation is stating that anyone can move the exam table and/or patient during a fluoroscopic procedure. Excess radiation can lead to skin erythema, skin epilation, and even acute radiation syndrome. It is crucial to have a CRT present to ensure that safety precautions will be taken for every moment of a fluoroscopic exam (or any radiologic exam) to protect the patient, worker, and genetic pool.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>86</b>

<p>46-1.2; 46-2.2</p>	<p><b>These regulations have not met the recommendations of the RTCC. This does not ensure radiation safety for any patient in a fluoroscopic exam room, only increases the potential for hazards and catastrophic consequences.</b></p> <p><b>CDPH Response:</b> See the response in item 41.</p>	<p><b>87</b></p>
<p>47</p>	<p><b>Believes the proposed change would allow individuals without fluoroscopic permits or Radiologic Technologist licensure to move patients and C-arms during fluoroscopic procedures. Unqualified persons operating the C-arm in Automatic Exposure Control will not ensure radiologic exposure levels to be ALARA. Commenter is opposed.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<p><b>88</b></p>
<p>50-1</p>	<p><b>To let an untrained individual move the patient, under the guidance of the doctor who is licensed, is appalling. The licensee is usually busy doing whatever their scope of practice is. Commenter requests that the department consider the risk that will be taken if this proposal is passed and states that the proposal should not pass.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<p><b>89</b></p>
<p>50-2</p>	<p><b>Commenter believes the proposed changes should not even be considered. States that the movement of the patient or equipment during fluoroscopic X-Ray procedures should be done by a trained Radiologic Technologist. Radiation exposure needs to be documented and put into the patient's chart. The department needs to consider the amount of education technologists have to protect the patients from unnecessary radiation exposure.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. Further, § 30307 addresses the commenter's recommendation to document exposure.</p>	<p><b>90</b></p>
<p>51</p>	<p><b>Radiologic technologists are trained in radiation safety which includes minimizing radiation and potential damage when safe measures are not followed. Requests that the department reconsider the proposed changes because physicians and their assistants are not trained in the areas mentioned, which could be detrimental to patients.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<p><b>91</b></p>

53a	<p><b>Certified radiologic technologists are well equipped to keep radiation safety and patient safety, commenter cannot imagine how a 120-minute training annually could prepare a non-permitted individual to successfully perform some of these tasks. The only reason provided for this proposed modification is a potential financial savings for medical organizations. There appears to be no legitimate justification for implementation of this modification, and there's certainly no justification for the increase in radiation this modification may present to patients and medical staff.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>92</b>
54	<p><b>Concerned with recommendation number 3. Commenter believes that oversight by the physician is inadequate. The physician is responsible for the performance of the procedure in a safe manner, delivering the utmost of care to the patient and now must take on the added responsibility of leading and guiding an untrained person in patient positioning and equipment manipulation. Positioning of patients in relation to X-ray or fluoroscopic beam is under the direct purview of the radiologic technologist profession.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>93</b>
55	<p><b>It is unclear if the person without a fluoroscopy permit can pan the table. Seeking clarification on whether an X-Ray tech has to be present in each cardiovascular lab or can it be a licensed physician, CVT, and nurse.</b></p> <p><b>CDPH Response:</b> The proposal, §30305.5(c)(4)(C), clarifies that the non-permitted individual may not pan the table. Section 30305.5(b) and (c) address when a CRT need not be in the room, and when a CRT must be in the room, respectively. The proposal does not limit who may be in the cardiovascular lab. since the proposal is limited to the RT Act. No change to the proposal is made due to the comment.</p>	<b>94</b>
56.1	<p><b>A non-certified person will have little to no knowledge of how to properly protect patients from radiation exposure, even with training. It does not substitute for the extensive and specialized training and experience that certified technologists have.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>95</b>

56.2	<p><b>Certified radiologic technologists are essential for their understanding of evaluating radiologic projection produced by fluoroscopy, as well as their extensive knowledge of human anatomy and the applicable medical terminology. Moreover, if there is an emergency with the c-arm equipment, the licensed radiologic technologist will have the training and knowledge to rectify the situation. Using non-licensed personnel during fluoroscopy to save money raises the risk of being involved in high cost malpractice litigation, as well as costly attorney fees, which will outweigh any potential accrued savings.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14.</p>	<b>96</b>
57-1	<p><b>Requested a mailed copy of the regulation text and initial statement of reasons.</b></p> <p><b>CDPH Response:</b> CDPH sent the requested documents via electronic mail, with the option to have a hard copy physically mailed to the address the commenter provided as well.</p>	<b>97</b>
57-2	<p><b>Commenter confirmed that he would like a hard copy mailed to his P.O. Box.</b></p> <p><b>CDPH Response:</b> CDPH mailed a hard copy of the requested documents to the commenter.</p>	<b>98</b>
58.1	<p><b>Supports section 30441.</b></p> <p><b>CDPH Response:</b> The Department appreciates the support. See also response in Item 147. No changes to the proposal are made due to the comment.</p>	<b>99</b>
58.2	<p><b>Supports section 30307.</b></p> <p><b>CDPH Response:</b> The Department appreciates the support. No changes to the proposal are made due to the comment.</p>	<b>100</b>
58.3	<p><b>Recommends limiting the movement of Radiology equipment to doctors with a supervisory license and a registered technologist.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	<b>101</b>
58.4	<p><b>Recommends that students should only learn from staff techs that have at least two years of experience or more.</b></p>	<b>102</b>



	<p><b>CDPH Response:</b> The Department is unsure if the recommendation is consistent with the proposal or if the recommendation is to retain existing requirements. The Department assumes the recommendation is to retain existing requirements, so it is rejected. The proposal, § 30417, discusses why the RTCC made the recommendation. Students remain under the oversight of a qualified practitioner, and, for them to move from direct oversight to indirect oversight, if the qualified practitioner is a CRT or X-ray technician, that practitioner must have at least two years of experience. No changes to the proposal are made due to the comment.</p>	
59.1	<p><b>Commenter states that the proposed rulemaking is in direct conflict with 17 CCR 30450. Resents the proposal’s attempt to undermine the properly licensed technologists. The commenter believes this proposal undermines the properly licensed technologist. Radiologic Technology Fluoroscopy Permit Requirements should be rescinded and all licensed technologists should receive a refund.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. Regarding refunds, the comment is rejected as it is outside the scope of this proposal. No changes to the proposal are made due to the comment.</p>	103
59.2	<p><b>Foresees hospitals and physicians taking full advantage of the \$20/hr cost savings by employing non-licensed technologists under the guise of “under certain conditions”. Commenter sees no conditions listed and believes this entails whatever they choose the “conditions” to be.</b></p> <p><b>CDPH Response:</b> See the responses in items 9, 11, 13, and 41.</p>	104
59.3	<p><b>As stewards of radiation safety, commenter would like the profession to be elevated by the committee to be on the same level as the Registered Nurse and other professions.</b></p> <p><b>CDPH Response:</b> The comment is rejected since it is outside the scope of this proposal. The RT Act establishes the profession, requiring legislative action to accomplish the commenter’s recommendation.</p>	105
59.4	<p><b>Based on the commenter’s experience, physicians are very weak in their knowledge of radiation safety, exposure factors and using appropriate collimation of the X-Ray beam.</b></p> <p><b>CDPH Response:</b> Physicians using X-ray equipment must obtain the applicable authorization from the CDPH by passing a written examination (17 CCR 30466) that addresses radiation protection, radiation biology and</p>	106

	ALARA concepts. The authorized physician exercises their medical judgement in all instances, even when a non-physician assistant disagrees with an action. No changes to the proposal are made due to the comment.	
59.5	<b>Believes the proposed changes water down requirements and that eventually licensed technologists will lose their jobs or their credibility.</b>  <b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.	<b>107</b>
60.1; 87	<b>Allowing non licensed personnel to operate fluoroscopy equipment does not adhere to ALARA and puts patients at risk for exposure to radiation.</b>  <b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to these comments.	<b>108</b>
60.2	<b>This completely undermines radiologic technologists that have undergone training and schooling only to be replaced with uncertified personnel. Jobs for radiologic technologists will be eliminated because they will be replaced by less paid and less educated individuals. Commenter believes, as a licensing board, the department should have the best interest of the public, and the best interest of the technologist who pays the department to get licensed.</b>  <b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.	<b>109</b>
61	<b>The Initial Statement of Reasons posted is the same as the text document. Requested the correct copy.</b>  <b>CDPH Response:</b> The website linkages were corrected and the commenter was provided a correct copy.	<b>110</b>
62	<b>As a former RTCC member, allowing non-certified individuals to operate fluoroscopy and radiology equipment is irresponsible and dangerous. It will increase radiation dose to patients. Commenter indicates that there have been numerous peer reviewed scientific data which shows that this can have a negative consequence on patient care. Commenter continues to cite language from the American College of Cardiology regarding ALARA. The RTCC is in place to help protect patients in California, not help physicians save money for their practice by using non-certified personnel.</b>	<b>111</b>

	<b>CDPH Response:</b> See the responses in items 9 through 14.	
63	<p><b>Patients will no longer be safe because the non-certified individuals will not know the technical components to position the machine and properly penetrate the part of interest by using the lowest dose possible. This proposal is supported by two physician groups, who are looking to cut costs and increase the bottom line. Non-certified, is not qualified. Do not water down Title 17.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	112
64	<p><b>Recommends that only individuals who are certified and licensed, whether they are a doctor, nurse, or technologist, should handle X-Rays. As a licensed Radiologic Technologist, allowing non-licensed individuals to move patients and manipulate machines is a direct hit to all that I am held accountable for. Requests that the department uphold the rules that exist to make this profession an integral part of the health care field.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	113
65	<p><b>Supports RTCC recommendations, especially §§ 30441 &amp; 30305.5. Recommends that the RT or PA oversee the activities of the non-permitted individual while the fluoroscopy unit is energized.</b></p> <p><b>CDPH Response:</b> The Department appreciates the support. The proposal is consistent with the recommendation.</p>	114
66	<p><b>Concerned that section 30305.5 takes away protection standards that prevent patients from excessive/unsafe radiation exposure. Vehemently opposed to this provision and believes it should not pass.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	115
67.1	<p><b>Recommends eliminating § 30305.5(b) because even if the equipment is not emitting X-Rays, the assessment and reassessment of the exposure techniques and radiation safety need to be managed by a permitted radiologic technologist or a permitted PA who is knowledgeable in radiation protection.</b></p>	116

	<p><b>CDPH Response:</b> The recommendation is rejected because it is the physician (i.e., certified S&amp;O) who is making the assessment and reassessment. (§ 30305.5(b)(1)(C).) A CRT or PA may be in the room should the certified S&amp;O wish, but the task of assessment/reassessment is the physician's. No changes to the proposal are made due to the comment.</p>	
67.2	<p><b>By allowing a non-permitted individual to position a C-arm over a patient, the possibilities of performing multiple exposures by the surgeon to obtain the "correct" position greatly increases. It is a natural progression for a non-permitted individual to be told "just push the button" while the surgeon is occupied caring for the patient on the operating table. This has happened in many surgery departments in California.</b></p> <p><b>CDPH Response:</b> See the responses in Items 12, 14, 35, 47, 73.</p>	117
67.3	<p><b>When the non-permitted individual handles the movement of the fluoroscopy equipment, there is a great possibility in doing physical harm to the patient or the equipment, as well as contaminating the sterile field.</b></p> <p><b>CDPH Response:</b> The public meetings of the RTCC included discussions of patient safety, radiation exposures, and related consequences. (Reference 3, pp. 11-20.) Specific to sterile fields, it is very unlikely that the non-permitted individual would have no knowledge of maintaining sterility during procedures, since workers in such medical settings are educated in how to maintain sterility. No change to the proposal was made due to this comment.</p>	118
67.4	<p><b>The surgeon's role is to take care of the patient and complete the procedure successfully. These licentiates do not stop to reassess radiation protection parameters, record fluoroscopy time, or select other aspects of radiations safety. Nor should they have to. Recommends that a permitted Radiologic Technologist or a permitted PA needs to be present during all fluoroscopy procedures once the sterile field has been established, the beam has been turned on and the equipment has been energized.</b></p> <p><b>CDPH Response:</b> The public meetings of the RTCC included discussions of patient safety, radiation exposures, and related consequences. (Reference 3, pp. 11-20.) See the response in Item 116. Also, the physician is seldom the person who records fluoroscopy time and this proposal does not place that task on the physician. It is the user, as defined in 17 CCR 30100, who must ensure it is done; it would be done by whomever was designated under the policies and procedures of the facility where the procedure is performed. The</p>	119

	authorized physician exercises their medical judgement in all instances, including assessment and reassessment of radiation exposure consequences, even when a non-physician assistant disagrees with an action. No changes to the proposal are made due to the comment.	
67a	<p><b>Commenter recommends eliminating 30305.5(b) because even if the equipment is not emitting X-Rays, the assessment and reassessment of the exposure techniques and radiation safety need to be managed by a permitted radiologic technologist or permitted PA, who is knowledgeable in radiation protection. The possibilities of performing multiple exposures by the surgeon to obtain “the correct position” greatly increases. It is a natural progression for a non-permitted individual to be told just push the button, while the surgeon is occupied caring for the patient on the operating table. This has happened in many surgery departments in California.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	<b>120</b>
68.1	<p><b>Supports the RTCC recommendations allowing a non-permitted individual to move the fluoroscopy equipment or patient when the fluoroscopy machine is not emitting radiation. The proposed sets up different requirements for when the machine is and is not emitting radiation. There was testimony before the RTCC that allowing a surgeon to bring this individual into the operating room to assist them during the surgery was critical to a successful operation which may involve the movement of a body part during the surgery, particularly for pediatric patients.</b></p> <p><b>CDPH Response:</b> The Department appreciates the support. No changes to the proposal are made due to the comment.</p>	<b>121</b>
68.2	<p><b>Believes the RTCC recommendations put in place safety requirements, wherein the non-permitted individual must be under the direct supervision of an S&amp;O, a radiologic technologist must be present, and the individual must receive training.</b></p> <p><b>CDPH Response:</b> The Department appreciates the support. No changes to the proposal are made due to the comment.</p>	<b>122</b>
68.3	<p><b>Does not believe that these regulations, in any way, allows these non-permitted individuals to independently perform fluoroscopy as the opposition presented at the hearing.</b></p>	<b>123</b>

	<b>CDPH Response:</b> The Department appreciates the support. No changes to the proposal are made due to the comment.	
68.4	<p><b>Recommends requiring, in § 30305.5(b), another permitted individual in the room, not focused on the surgery, for accessing the change in spatial relationship as a result of the movement of the equipment. Recommends adding, in § 30305.5(d) regarding who can provide the educational training for the non-permitted individual, “the facility at which the service is being provided if the facility is meeting the Medicare Radiation Safety Accreditation Standards.” Facilities accredited by the Joint Commission are now also involved in providing radiation safety education to individuals working at their facility. We believe, that these facilities should be another way for non-permitted individuals to meet this educational requirement.</b></p> <p><b>CDPH Response:</b> Regarding § 30305.5(b), the recommendation is rejected for the reasons provided in the responses in Items 9 through 14. Regarding § 30305.5(d), the recommendation is rejected as unnecessary because the proposal provides the recommended flexibility to the facility in the same way those federal standards do.</p>	124
68a	<p><b>Believes that the proposed regulations are not intended to replace the RT that’s in the room, and clearly states that there would be an RT in the room and the unlicensed, unpermitted person would be under the direct supervision of the surgeon, who would have to have a fluoroscopy permit in order to even be in the room operating the fluoroscopy equipment.</b></p> <p><b>CDPH Response:</b> It appears the commenter accurately summarized the proposal. No changes to the proposal are made due to the comment.</p>	125
69.1	<p><b>Opposed to allowing non-permitted individuals to position patients or equipment during exposure of radiation. Commenter does not believe there should be two standards of education put in place for radiology departments during radiation exposure. This allows employers to hire non-permitted individuals, creating room for the rules to be challenged and abused. Commenter also believes that this will put the permitted individuals in a tough position of either reporting "out of compliance" activity and face retaliation from not only the employer but the co-worker that could be reported, or staying quiet while an employer abuses the new regulations for non-permitted staff to cut costs.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	126

69.2	<p><b>Changes to the non-permitted scope hurts permitted individuals by diluting the job description of the permitted individuals to a monitoring role vs a required hands-on role. There will be less need for permitted individuals, less jobs and decrease in pay. Allowing the use of non-permitted individuals to perform a function currently performed by a permitted individual will decrease jobs and decrease pay.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	127
69.3	<p><b>Believes that doctors with "licenses in the healing arts" will not actually supervise non-permitted individuals per the stipulations of the change. Also does not believe that non-permitted individuals would report physicians that encouraged them to go beyond their scope of practice.</b></p> <p><b>CDPH Response:</b> Regarding supervision, the certified S&amp;O is responsible for the health and safety of the patient, including their actions directing others in the room to carry out their direction. This includes directing the non-permitted individual performing tasks per the regulations. Further, this responsibility already exists within existing regulation and this proposal.</p> <p>Regarding reporting, this outcome inherently exists anytime a person's employment is dependent on others, is contingent on a person's willingness to report, occurs under existing regulations and will continue to exist even if the proposal is not adopted. No change to the proposal is made due to this comment.</p>	128
69.4	<p><b>Believes that the best way to ensure ALARA and proper patient handling is followed, as well as ensuring low occupational exposure, is to tasks performed by permitted individuals. Would be more amenable to non-permitted individuals positioning patients and moving equipment when the fluoroscopy and equipment are off. That way positioning and equipment can be corrected by permitted individuals prior to exposure.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	129
69.5	<p><b>Recommends that the ASRT standards be adopted. Believes that the ASRT does not support non-permitted or unlicensed individuals positioning patients or operating or adjusting X-ray equipment. Would like to see the ASRT practice standards for Cardiac Interventional and</b></p>	130

	<p><b>Vascular Interventional Technology added to the medical imaging and radiation therapy standards.</b></p> <p><b>CDPH Response:</b> As discussed in the ISR, pages 15 and 16, regarding § 30441, the practice standards were reviewed and determined to be useable by facilities to evaluate the performance of the individual. Those standards were beyond the scope of this proposal, so the recommendation is rejected. Lastly, the ASRT scope of practice cannot be adopted in an identical manner because any scope of practice must be consistent with state law, and some of ASRT's positions are inconsistent with the RT Act. Therefore, the recommendation is rejected.</p>	
70	<p><b>Radiologic Technologists have been trained to assist doctors in minimizing radiation exposure. Increasing the physician's fluoroscopy responsibilities may result in surgery cases where patients are overexposed accidentally. The doctor could hit the wrong pedal or the fluoroscopy may be active longer than necessary. It seems that this proposed change is due to financial reasons. Commenter does not believe things should change and is opposed to DPH-17-009.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	131
71	<p><b>Commenter shares examples wherein staff and patients failed to wear adequate protection during fluoroscopy, which necessitated intervention from a radiologic technologist to promote safety. In the commenter's experience, it is the technologist that has to remind the physician to turn fluoroscopy off. This is not to lessen the importance of the physician's or surgeon's skills in what they do best, but to remind one of the education and training necessary to protect them, their patient and their staff in the room. Concerned with proposed change #3, specifically "under certain conditions". Commenter cites to the motion that passed in the RTCC meeting minutes dated April 13<sup>th</sup>, 2016 which includes language requiring that a CRT be present. As such, commenter is opposed to the proposed regulations regarding movement of a patient or equipment by non-certified or non-permitted individuals without a CRT present because it would lower the standard of care that California currently provides and ignore the motion as it was passed.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	132



71a	<p><b>Opposed to the proposed regulations regarding movement of a patient or equipment by non-certified or non-permitted individuals “under certain conditions” without a California certified radiologic technologist present because it would be lowering the current standard of care. Commenter cites to the RTCC meeting minutes dated April 13<sup>th</sup>, 2016, and feels that Commenter has witnessed physicians with their foot on the pedal turn away from the monitor and continue without stopping fluoroscopy. The technologist has the requisite knowledge, training, and experience to reduce dose to the patient and scatter radiation to the workers in the room. Technologists can help problem solve issues that arise quickly without delays.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	133
71b	<p><b>Proposed 30441(a)(9) is being omitted. How does that affect CRTs who administer iodine and gadolinium contrast for exams? Also, does saline fall into that category? If this is omitted then will we not be able to perform that task of selecting, preparing and administering the medication through a peripheral IV?</b></p> <p><b>CDPH Response:</b> See response in Item 6. Also, both saline and iodine (a contrast medium) are encompassed by the revision. Pertaining to gadolinium, it is a contrast medium used for magnetic resonance imaging (MRI) procedures, which do not use ionizing radiation, so use of gadolinium is not addressed by this proposal.</p>	134
71c	<p><b>Commenter expresses confusion regarding § 30441(a)(9)’s statement identifying certain prohibited acts. Believes CRTs are currently authorized to establish IV lines for contrast injection needed to perform CT and MRI exams. Recommends revision to say CRT is allowed to establish an IV line.</b></p> <p><b>CDPH Response:</b> The recommendation is rejected because it is not consistent with the RT Act. CRTs, by virtue of only holding certification under the RT Act, are not currently authorized to establish an IV line for performing CT or MRI exams. If a CRT is establishing an IV line, then they would need to be doing so under some other law that grants that authority. HSC § 106985 authorizes a CRT, if specific requirements are met, to perform venipuncture to inject contrast, and saline-based solutions. However, HSC § 106985(f) prohibits establishment of an IV line. A regulation cannot authorize that which a law prohibits.</p>	135

72	<p><b>Based on the commenter’s experience, there is already a culture with a lack of concern and/or disregard for basic radiation safety principles by non-radiologist physicians and non-radiologic technologist healthcare personnel. Concerned that allowing unqualified and uneducated health care personnel to operate potentially dangerous ionizing radiation producing equipment is not in the best interest of the patients.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	136
73; 80	<p><b>No comments on the proposal are provided.</b></p> <p><b>CDPH Response:</b> Comments are very general with no specific comment on the proposal, or are unrelated to proposal. The Department agrees with the general comment that education and protection should be considered in decisions that involve radiation.</p>	137
74; 97-1; 98-3	<p><b>Opposed to allowing non-certified and non-licensed individuals to move patients or equipment during fluoroscopy procedures.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	138
75	<p><b>Objects to the proposed changes completely; training is crucial to patient and staff radiation protection. Any attempt to lessen these requirements is a lobbying effort from ASC’s [ambulatory surgery centers] to bypass the need to hire or outsource properly trained staff.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	139
76.1	<p><b>Commenter expresses how patients can be exposed to high doses of radiation depending of the procedure performed. Cites to a study wherein certain procedures may expose the patient to 300 to 1000 chest X-rays. Believes that it is unrealistic and dangerous for the supervisor and operator to constantly monitor patient-tube orientation and perform the procedure during fluoroscopy procedures. Recommends that only properly educated operators who have an extensive background in radiation protection, physics, and the biological ramifications of radiation should be allowed to operate radiography/fluoroscopy.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	140

76.2	<p><b>Believes that it is unrealistic and dangerous for the supervisor and operator to constantly monitor patient-tube orientation and perform the procedure during fluoroscopy procedures.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	<b>141</b>
76.3	<p><b>Disagrees with the fiscal impact statement indicating that costs will be reduced when using a non-CRT. In general, CRTs are the lowest paid employee in the operating room or cardiac cath lab. CRTs in California earn much less than registered nurses, physician assistants, or scrub techs.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	<b>142</b>
76.4	<p><b>Recommends that only professionals trained within the current scope of practice be allowed to perform fluoroscopy studies. Commenter cites to the existing regulation, CCR section 30450, which recognizes the important role of radiologic technologists to assure proper radiation protection principles are consistently applied during fluoroscopic procedures.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	<b>143</b>
77	<p><b>Oppose RTCC recommendation #3. If this goes into effect, recommends that the patient be informed that non-licensed personnel will be operating the c-arm so that the patient may be able to opt to reschedule when a qualified RT is available.</b></p> <p><b>CDPH Response:</b> See the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	<b>144</b>
78	<p><b>Commenter agrees that the CRT's scope of practice should be clarified but opposes sections 30305.5 and 30450 because the regulation changes may cause potential excess radiation exposure and greatly harm humans.</b></p> <p><b>CDPH Response:</b> The Department appreciates the support of § 30441. Regarding §§ 30305.5 &amp; 30450, see the responses in items 9 through 14. No changes to the proposal are made due to the comment.</p>	<b>145</b>

79.1	<p><b>PICC is not an acronym for peripherally inserted <i>cardiac</i> catheter. It stands for peripherally inserted <i>central</i> catheter.</b></p> <p><b>CDPH Response:</b> See response to comment 79.2.</p>	146
79.2	<p><b>The commenter believes that the creation of a scope of practice for CRTs and the authorization to administer intravenous medication, other than contrast materials, exceeds the Department’s statutory authority and is an unauthorized expansion of the role of CRTs.</b></p> <p><b>CDPH Response:</b> Based on the commenter’s discussion, it appears their belief is that exceedance of authority is limited to administration of medication, not to other provisions specified in § 30441. Thus, the comment was accepted for further evaluation. Two additional 15-day public comment periods were conducted during which the proposal was revised to specifically address contrast media and saline-based solutions, and to correct the meaning of PICC (item 146). No additional substantive comments on the revision were received.</p>	147
81.1	<p><b>Commenter is strongly opposed to RTCC’s recommendation #3 because it is in direct conflict with all patient care standards, believing the proposal puts the insurance company and doctor first. Commenter interprets “certain conditions” by listing five possibilities. Believes the proposal allows the non-permitted person to operate the fluoroscopy unit.</b></p> <p><b>CDPH Response:</b> The commenter provides a number of reasons why they strongly oppose RTCC’s recommendation as summarized in the Notice of Proposed Action’s (NOPA) informative digest, and the ISR’s background information. The summary is to give individuals enough information so they can decide whether to review the proposed regulation text and ISR for discussion of that proposal. Had the NOPA given all detail to the recommendation, the NOPA would essentially duplicate the ISR. Further, the tendered reasons were addressed during RTCC’s public meetings of October of 2013 (Reference 9a), April and October of 2014 (References 10 &amp; 1, respectively), April and October of 2015 (References 2 &amp; 3, respectively), culminating at the April 2016 meeting (Reference 4). Reference 3, pp. 11-20, discusses each meeting’s recommendation. The “certain conditions” are fully specified in the regulation text (§ 30305.5) and discussed in the ISR. The proposal places numerous limitations, conditions, and prohibitions on the non-permitted person such that it cannot be concluded they may operate the fluoroscopy unit.</p> <p>No change to the proposal is made due the comment.</p>	148

<p>81.2</p>	<p><b>Recommends that only fluoroscopy trained and licensed personnel should be allowed to position the patient or the machine. Believes the proposal would result in poor patient care standards and unnecessary radiation exposures.</b></p> <p><b>CDPH Response:</b> The comment inaccurately summarizes the proposal and the recommendation is rejected. The Department believes the concerns were adequately addressed by the RTCC and attendees of numerous public meetings as indicated in the responses in Items 9 through 14, and 148.</p>	<p><b>149</b></p>
<p>82</p>	<p><b>Implied recommendation to have a CRT be present when fluoroscopy is used.</b></p> <p><b>CDPH Response:</b> Due to the nature of the letter, in lieu of a summary, the letter is fully addressed within this response. The commenter, as indicated in their submittal, presents a high level discussion. A review of the letter supports that statement, and a reader is left with the impression it is written for the community in general. No specific comment on the proposal is found, except for the inference (p. 2, 2<sup>nd</sup> full paragraph) that § 30305.5, for efficiency and patient safety, should ensure the CRT is in the room any time fluoroscopy equipment is used, regardless of whether the X-ray beam is on or off. This inferred recommendation is rejected for the reasons discussed in the ISR for that proposal. See also the responses in Items nine through 14.</p> <p>Regarding the commenter’s recommendation to review comment of another individual, see commenter 89.</p> <p>No changes to the proposal are made due to the comment.</p>	<p><b>150</b></p>
<p>84</p>	<p><b>Recommends § 30305.5(h), to read “An individual who has not otherwise been certified or permitted under this act, who holds a cardiovascular credential issued by Cardiovascular Credentialing International, may assist the cardiologist (an S&amp;O holder) in the catheter lab as directed and determined by the cardiologist. This includes moving the C-arm, manipulating the patient and fulfilling instructions as directed by the cardiologist.”</b></p> <p><b>CDPH Response:</b> The comment is rejected as unnecessary since the proposal is broad in nature, allowing for such individuals with those credentials, and is also rejected as inconsistent with the RT Act in that it could allow non-permitted persons to perform tasks that only certified/permitted individuals may do.</p>	<p><b>151</b></p>

85	<p><b>As an RTCC member, the commenter strongly opposes proposed regulatory changes to Title 17 section 30305.5. It does not meet the intent nor the radiation protection guidance requirement of the original motion passed by RTCC on April 13, 2016. The actual discussion and motion that passed unanimously required that a certified diagnostic radiologic technologist be present in the room and managing the radiation exposure and X-Ray equipment.</b></p> <p><b>CDPH Response:</b> The Department disagrees that the proposal is not consistent with RTCC’s recommendation. See responses in Items nine through 14, 41, and 148.</p> <p>No changes to the proposal are made due to the comment.</p>	152
85a.1	<p><b>Commenter is a member of the RTCC and is strongly opposed to the proposed regulatory changes, specifically 30305.5 little (b). The member was present during these RTCC discussions, and states that the motion that was passed did not include scenario (b), or (c), or (d), or (e). Commenter believes these are significant changes that did not come from a public forum. Scenario (b) puts the safety of the people in jeopardy.</b></p> <p><b>CDPH Response:</b> The Department disagrees with the comments. The RTCC finalized part 5 of its 5-part motion on October 28, 2015. (Reference 3, p. 19.) The other four parts of the 5-part motion were presented to RTCC at that meeting. (Reference 3, pp. 19-20.) Scenario (b) is part 3, and scenarios (c), (d) and (e) are part 5, all of which were presented, discussed, and unanimously approved by nine RTCC members in a public meeting. No change to the proposal is made due to this comment.</p>	153
85a.2	<p><b>Commenter does not believe the proposed adoption of section 30305.5 provides any benefits to the patient or operator. These recommendations represent a quantifiable danger to public health. A key component in patient safety is being overlooked by allowing a non-certified user to position the C-arm. A CRT’s education cannot be condensed into a 2-hour crash course once per year. Commenter does not believe that any clarification of scope is warranted unless that clarification cites a quantifiable maintenance or reduction of public exposure to radiation.</b></p> <p><b>CDPH Response:</b> Regarding § 30305.5, see the responses in items nine through 14. Regarding scope of practice, the Department disagrees the scope should be only focused on radiation exposure since the education and training of CRTs covers other aspects of patient care, pharmaceuticals and</p>	154

	venipuncture, computer technology, basic educational needs, and understanding of ethics and laws related to performing radiologic technology, as specified in CRT curricula identified in 17 CCR 30421 and 30422. No change to the proposal is made due to this comment.	
85a.3	<p><b>Recommends removing scenario (b) from the proposed regulations.</b></p> <p><b>CDPH Response:</b> The recommendation is rejected. See the responses in items nine through 14, 153 and 154.</p>	<b>155</b>
85c	<p><b>Wonders if it means no more venipuncture. Also, regarding section 30441(a)(9), asks if “This provision shall not be construed to authorize a CRT to establish an IV line” is a contradiction.</b></p> <p><b>CDPH Response:</b> As initially proposed and revised, § 30441(a)(9) does not address performing venipuncture, but addresses the administration of contrast or saline-based solutions through an existing access line or port, which does not require performing venipuncture. Section 30441(a)(8) addresses venipuncture through citation to the law that grants a CRT that authority, provided the individual complies with that law. Thus, the revision does not affect venipuncture authority.</p> <p>Regarding a possible contradiction, the Department believes the phrase does not conflict with the provision. The provision speaks to accessing an “existing” access line, such as an IV line, and the prohibition is on interpreting the provision to mean the CRT may establish an IV line. If the line does not exist, it cannot be accessed, and the CRT may not bring it into existence.</p> <p>No change to the proposal is made due to these comments.</p>	<b>156</b>
86.1	<p><b>Is disappointed &amp; surprised the initial recommendations did not comport with RTCC’s discussions and determinations of the last six years. Requested to be placed on the list for communications and updates.</b></p> <p><b>CDPH Response:</b> The commenter was included as requested. As indicated in the ISR, RTCC recommendations presented in the proposal were discussed and made at the indicated public meetings. The topics being addressed in this proposal were not limited to that recommendation in which the commenter is most interested. See items 158 through 174 for further discussion.</p>	<b>157</b>
86.2	<p><b>States concern that clarifying the CRT scope of practice or when the RT Act was invoked was never discussed as the motivation of the</b></p>	<b>158</b>

	<p><b>proposal. Believes the revision’s motivation was to update the regulations to account for technological advances making equipment easier to operate, and to accept non-CRTs.</b></p> <p><b>CDPH Response:</b> The motivation of the CRT scope of practice was presented to RTCC at numerous public meetings. (Reference 9, pp. 7-17; Reference 1, pp. 13-17; Reference 4a, pp. 16-20.) See the response for Item 162.</p>	
86.3	<p><b>The commenter indicates the proposal is inconsistent with provisions in Title 22, CCR, specifically §§ 70435 and 70437.</b></p> <p><b>CDPH Response:</b> Those provisions, along with others found in 22 CCR, Division 5, Chapter 1 were reviewed in making the determination. However, we believe the commenter fails to recognize the legal hierarchy of laws and regulations, and misconstrues and ignores Title 22 provisions, which are also Department regulations.</p> <p>First, a regulation cannot override a law unless the law provides an exception. The RT Act is a law, and title 22 is regulation, but the RT Act does not provide an applicable exception. Second, 22 CCR 70433(i) recognizes the RT Act’s applicability to the cardiovascular surgery service, and to the cardiac catheterization laboratory service. Section 70435(a)(3) of Title 22 does indicate that, in part, a CVT shall assist during the performance of all procedures, and shall be trained in the use of all equipment identified in § 70437. However, § 70433(i) places a condition on all persons who operate X-ray equipment, requiring such persons to be compliant with the RT Act regulations. Thus, 22 CCR provisions recognize the requirements of the RT Act, and do not, and cannot, override the RT Act. Further, recognition to other ionizing radiation laws and implementing regulations are found in other 22 CCR, Division 5, Chapter 1 provisions: §§70253(d) (RCL: HSC § 114960 et seq.); 70253(e) (RT Act); 70438.1(c) (RCL &amp; RT Act); 70507 (RCL); 70513 (RCL); 70587 (RCL &amp; RT Act); 70591 (RCL &amp; RT Act); and 70593 (RCL). Therefore, the Department believes its initial determination that the proposal is not inconsistent with existing state regulations is correct.</p> <p>No change to the proposal is made due to this comment.</p>	159
86.4	<p><b>Regarding discussion of comments addressed in the ISR without being presented in a meeting, the discussion is new and removes the RT from the team, allowing them to do nothing for the entire case. It will be cost prohibitive.</b></p>	160



	<p><b>CDPH Response:</b> The Department believes the comment misconstrues the discussion. That discussion clearly states the event: comments with recommendations were received after RTCC discussion, and before publication of the proposal. Though it was not presented at an RTCC meeting, the Department considered it, and presented its reasons for rejection for public review and consideration. No comments from the public regarding the discussion were received, including no additional comment from the original commenter. Existing regulations, and this proposal, do not establish roles as the commenter recommended, so the Department is confused as to why the discussion would remove the RT from the team. The proposal makes no reference to specific roles or teams. See also the response in Item 161.</p> <p>No change to the proposal is made due to this comment.</p>	
86.5	<p><b>Believes the commenter, referenced in the ISR page 8, is influencing the writing of the regulation, restricting CVTs from panning, which has never been the case previously.</b></p> <p><b>CDPH Response:</b> The Department believes that the nature of public comment, in general, is an influencing process. As it relates to the referenced commenter, the panning issue was fully discussed at RTCC's October 2013 public meeting. (Reference 9a, pp. 62, &amp; 70 – 76.) As stated in the ISR, p. 8, the comment was received during the time period after the public meeting and before this proposal was published for public comment. The ISR informed the public of the comment, discussed the Department's consideration of it, and presented the Department's reasons for rejecting it or demonstrated that it was considered. No comments from the public regarding the discussion were received, including no additional comment from the original commenter.</p> <p>No change to the proposal is made due to this comment.</p>	161
86.6	<p><b>States that the purpose of the revision was not to establish the CRT scope of practice.</b></p> <p><b>CDPH Response:</b> The proposal addresses a number of RTCC recommendations, each of which were discussed and made at numerous public meetings held over a number of years. (ISR, pp. 3-4.) The proposal presented discussion and proposed regulatory text for the public's review and comment specific to RTCC's recommendation to establish the CRT scope of practice. See also the response for Item 158. The proposal was not limited only to the topic the commenter is most interested.</p>	162

	No change to the proposal is made due to this comment.	
86.7	<p><b>Believes that the certified S&amp;O should be able to supervise anyone.</b></p> <p><b>CDPH Response:</b> The proposal does not restrict who a certified S&amp;O may supervise for purposes of § 30305.5. Based on the commenter’s additional comment letter (#86b), it appears the commenter was unfamiliar with how the RCL, its regulations, and the RT Act and regulations work together.</p> <p>No change to the proposal is made due to this comment.</p>	163
86.8	<p><b>Believes the ISR fails to fully provide the historical events driving the revision. Presents a summary of the regulatory changes from initial adoption to current events, concluding the reason for the proposal is to reflect the use of fluoroscopy equipment in other settings besides imaging/radiology, and to allow other its use by others. The ISR misstates this history, and the fiscal impacts are inaccurate since they only consider imaging/radiology labs, and not other practice arenas. Commenter presents a chronology of events leading to the proposed revisions, concluding the proposal is not consistent with RTCC’s direction based on public meetings and meeting minutes.</b></p> <p><b>CDPH Response:</b> The Department disagrees with the commenter’s belief that the ISR fails to fully present the reasons for the proposal. The commenter believes the existing regulations were written when fluoroscopy was not used in other healthcare settings, other than imaging/radiology. The regulations were never intended nor written to be limited to imaging/radiology but to any use, regardless of setting, of X-ray equipment, and fluoroscopy X-ray equipment in particular to ensure compliance with the RT Act. This intent is also reflected in the response to item 159, regarding consistency with the Department’s Title 22 regulations. The commenter’s chronology of events may be the precipitating events for the commenter, but mischaracterize many of the events leading to RTCC’s recommendations, as found within the meeting minutes.</p> <p>No change to the proposal is made due to this comment.</p>	164
86.9	<p><b>Objects to § 30400(a)(37): Previously it was anyone acting within the scope of their certificate or permit. It now eliminates the work of a CVT because § 30305.5 limits use to someone as defined in § 30400(a)(37).</b></p> <p><b>CDPH Response:</b> Sections 30305.5 and 30400 are not related. The term “qualified practitioner” relates only to supervision of X-ray students under § 30417. It addresses RTCC’s recommendation regarding student training, not</p>	165

	the recommendation regarding movement of the patient or equipment during fluoroscopy procedures. Thus, the comment is rejected since the two provisions are not related.	
86.10	<p><b>Objects to § 30305.5(b) because CDPH does not have authority over who moves the equipment when no X-ray are being emitted. It would prevent a CVT (or RN) from moving the table so as to move a patient to or from a gurney to the table. It may greatly harm the patient.</b></p> <p><b>CDPH Response:</b> The comment is rejected. It appears the comment fails to recognize § 30305.5(b) is speaking to “during use of fluoroscopy equipment on a patient.” The proposal is not speaking to transferring the patient from a gurney onto the table, and vice versa. It speaks to the interim time when the patient is on the table for purposes of the medical procedure that is using a fluoroscope. The Department has authority, via enforcement of the RT Act, when the fluoroscope is being used.</p>	166
86.11	<p><b>For § 30305.5(c), presence of the certified S&amp;O should be enough. Having the CRT or PA also present is costly.</b></p> <p><b>CDPH Response:</b> The recommendation to revise the provision is rejected. The RTCC considered this during its numerous public meetings and believes the CRT or PA should be present when the patient or equipment is moved while X-ray is on. The Department agrees with RTCC, and presented the estimated fiscal impacts in the Notice, determining such costs, or savings, are variable depending on how a facility carries out staffing functions.</p>	167
86.12	<p><b>Believes that § 30305.5(a) fails to consider the shortages that will result because CVTs are not licensed but are essential for patient safety. It is costly.</b></p> <p><b>CDPH Response:</b> The Department disagrees with the comment because that provision is merely a method, via regulation, of reminding, and informing the uninformed, of the existence of the RT Act, in effect since 1971. Even if that provision was not adopted, the RT Act still applies and individuals remain subject to it. Thus, no workforce shortages or increased costs occur since that law is an effective law.</p>	168
86.13	<p><b>States that § 30441 is new and that the fiscal impact is wrong. Believes that only CRTs, if adopted, will be considered for roles and applications that are performed by RNs and CVTs.</b></p> <p><b>CDPH Response:</b> See the responses in Items 158 and 162. The Department believes the estimated fiscal impact is reasonable and remains</p>	169

	so, even though that provision was revised. See also responses in Items 6, 134, 135, 137, and 147. An additional 15-day public comment period was conducted and no substantive comments on the revision were received.	
86.14	<p><b>States that Cath Lab standards do not demand an RT to be present in the cath lab.</b></p> <p><b>CDPH Response:</b> The comment is rejected. See the response in item 167. Also, regardless of cath lab standards, or the type of medical facility housing a cath lab, the RT Act applies when diagnostic or therapeutic X-ray is used on or administered to human beings. (HSC § 106965(a).) The ISR, pages 5-12, discuss why an RT should be present.</p>	170
86.15	<p><b>Believes the proposals would harm patients, decrease manpower even more so, compromise quality, displace other educated and trained professionals, and greatly increase costs.</b></p> <p><b>CDPH Response:</b> The Department believes the outcome of the proposal is as stated in the Notice and the ISR. The indicated concerns were discussed and evaluated by the RTCC and the CDPH agrees that the proposal would not result in harm, decrease manpower, compromise quality, displace professionals, or increase costs. These determinations and impacts were presented to the public. See also items 173 and 174.</p>	171
86.16	<p><b>Recommends adding new language in § 30305.5 that reads: An individual who has not been certified or permitted under this act, [but] however holds a cardiovascular credential issued by Cardiovascular Credentialing International, may assist the cardiologist (an S&amp;O holder) in the cath lab as directed and determined by the cardiologist. This includes moving the C-arm, manipulating the patient and fulfilling instructions as directed by the cardiologist. Provides summarized support statements.</b></p> <p><b>CDPH Response:</b> The recommendation is rejected because a CVT falls within the definition of non-permitted individual. Proposed § 30305.5 would allow the CVT, or anyone meeting the defined term, to do what the commenter recommends. Thus, the proposed language is redundant and unnecessary. See also item 174.</p>	172
86b.1	<p><b>Expresses appreciation for opportunities to support the Department to ensure high quality care for patients.</b></p> <p><b>CDPH Response:</b> The Department appreciates the comment.</p>	173

86b.2	<p><b>Appreciates staff time spent in clarifying the definition of “non-permitted individual” and “user” and that they do allow a registered cardiovascular invasive specialist (RCIS) to practice under section 30305.5. Remains concerned that hospitals will interpret the provision to require the non-permitted individual to hold a specific permit. Requests a memo of guidance that an RCIS can assist the cardiologist if the hospital’s requirements are met.</b></p> <p><b>CDPH Response:</b> The Department thanks the commenter for the expression of appreciation.</p> <p>As discussed in the ISR (pp. 2 &amp; 3), this proposal is made under two different laws, each with their own terminology and implementing regulations. Thus, the proposal comingles these laws, and is placed within the RCL regulations using RCL terminology because the responsible party over the X-ray machine and its use is the user, as defined in § 30100. As indicated in the ISR, page 3, the RCL is a broad law, and the RT Act narrowly applies to medical use of X-rays. Thus, § 30305.5(a) was added to provide a connection. (ISR, p. 6.)</p> <p>As in all rulemakings, the Department conducts outreach to the community to ensure it is aware of the adoption, and to provide any needed guidance, such as requested. We believe the community will have little difficulty in understanding the proposal, since hospitals, where cardiac catheterization laboratories are housed, are aware of the RCL and its regulations. No changes to the proposal are made due to the comment.</p>	174
88; 98.4	<p><b>Proper education is necessary in order to provide optimal imaging and dosing for the patient; commenter believes that the training listed in the proposal is inadequate.</b></p> <p><b>CDPH Response:</b> See response in Item 180.</p>	175
89	<p><b>Commenter provided specific language recommendations to 30305.5.</b></p> <p><b>CDPH Response:</b> Due to the extensive discussion and language recommendations, the commenter’s letter is addressed fully within this response.</p> <p>Commenter believes the proposal’s parsing of who does what should be based on intent, not whether X-ray is on or off. This is rejected because it is a subjective standard, whereas the proposal is based on an objective standard. The proposal clearly states the specific action being allowed, and those actions that may not be performed by the non-permitted individual.</p>	176

	<p>The proposal’s language was carefully crafted by the RTCC, consisting of physicians and surgeons, CRTs, a medical physicist, and other licentiates of the healing arts. The provided table of who can do what is consistent with the proposal, and no revision to the proposal is needed.</p> <p>The commenter states that the proposal would prohibit a CRT from using fluoroscopy equipment under standing orders, such as a barium swallow exam performed with a speech therapist. The proposal would not prohibit this practice. When that procedure is performed, the CRT is operating, and administering X-ray, only and in accordance with the physician’s orders, but the speech therapist is not performing those tasks. The CRT, when performing under standing orders, cannot practice medicine (HSC § 106980(d)) or make diagnoses based on image interpretation (HSC § 106980(b)).</p> <p>The recommended revision to § 30305.5 is rejected as unnecessary because the physician determines the purpose, and whether the actions maintain patient safety, based on their medical judgement and personally directs the non-permitted individual. Some of the revisions go beyond the scope of RTCC’s recommendation and would encroach on regulatory arenas that the RT Act and the RCL do not encompass. The Department believes the proposal is reasonable, as recommended by RTCC, provides flexibility, retains patient safety, and is not overly burdensome should a facility wish to implement it.</p>	
90	<p><b>Commenter opposes the proposed regulation changes. States that RTCC’s third recommendation (Notice, p. 4) is incorrect from what RTCC recommended. It should have included “provided a certified diagnostic radiologic technologist is present in the room and is managing the radiation exposure and X-ray equipment...”</b></p> <p><b>CDPH Response:</b> The commenter focuses on the informative digest found in the Notice that summarizes the RTCC’s recommendation. See Item 148 for additional response.</p>	177
91; 92; 94	<p><b>Disagrees with the proposed rulemaking. Commenter is concerned that the proposed change will remove protection standards that are in place to prevent patients from excessive/unsafe radiation exposure.</b></p> <p><b>CDPH Response:</b> The Department believes the proposal will not result in excessive exposures or unsafe use. The RTCC conducted numerous public meetings during which it considered expressed concerns by members and the public. No changes to the proposal are made due to these comments.</p>	178

93	<p><b>ARRT opposes 30305.5 because it would lower the certification and education standards for personnel who perform medical imaging procedures, including fluoroscopy.</b></p> <p><b>CDPH Response:</b> The proposal would allow a non-permitted individual, under very limiting conditions, only to move, not operate, the equipment or patient for very specific purposes. The Department believes that due to those limiting conditions, it does not affect educational standards for those performing medical imaging. It also places numerous prohibitions on that individual, and the physician who is personally directing that individual. The required training was deemed adequate by the RTCC for the very limiting and specific actions that would be allowed. The RTCC considered radiation protection and ALARA principles during its numerous public meetings. No change to the proposal is made due to this comment.</p>	179
95a.1	<p><b>Observed critical positioning or exposure mistakes due to a lack of formal training in lesser regulated states. The amount of education a CRT undergoes to ensure a properly exposed image while minimizing patient dose cannot be condensed into 220 or 200 [sic] hours of training.</b></p> <p><b>CDPH Response:</b> The comment regarding other states regulatory oversight is outside the scope of this proposal. Proposed § 30305.5 does not allow the non-permitted individual to perform any imaging function, and very limiting conditions and prohibitions are placed on that individual. The ISR, for § 30305.5, provides the reasons for the specific training requirements.</p>	180
95a.2	<p><b>Commenter does not believe that clarification of scope is warranted, unless the clarification cites a quantifiable maintenance or reduction of public exposure to radiation.</b></p> <p><b>CDPH Response:</b> The Department disagrees that establishing the scope of practice is only warranted if reduction of radiation exposure is established. The ISR discusses the reasons for proposed § 30441.</p>	181
96a	<p><b>Amending Title 17 will negatively impact patient safety. To allow non-certified individuals to operate fluoroscopy equipment would be a disservice to the public, as radiologic technologists have the education and clinical experience in understanding radiation biology, radiation physics, and ALARA. Commenter does not believe non-certified individuals will be able to set the correct exposure factors and maintain ALARA.</b></p> <p><b>CDPH Response:</b> See the response in Item 10.</p>	182

97a	<p><b>Believes that 30305.5 contradicts the proposal’s goal to prevent patients and staff from receiving excessive radiation exposure due to facility’s use of unqualified individuals during fluoroscopy.</b></p> <p><b>CDPH Response:</b> The department believes that the proposal maintains an appropriate level of protection with flexibility.</p>	183
98a	<p><b>Section 30305.5 contradicts the goals outlined in this proposal to prevent patients and staff from receiving excessive radiation exposure.</b></p> <p><b>CDPH Response:</b> The department believes that the proposal maintains an appropriate level of protection with flexibility.</p>	184
99a	<p><b>Opposed to anyone other than a licensed X-ray technologist touching the C-arm and moving the equipment. Based on the commenter’s experience, there have been a lot of errors, mistakes and incidents that happen.</b></p> <p><b>CDPH Response:</b> See the responses in Items nine through 14, 19, 23, and 35.</p>	185
100a	<p><b>Representing everyone in the X-ray department at Kaiser Sacramento and probably all of Kaiser in the Northern California area, commenter expresses that only the licensed techs – X-ray radiology techs - should touch their machines.</b></p> <p><b>CDPH Response:</b> See the responses in Items nine through 14, 19, 23, and 35.</p>	186
101b	<p><b>Questions whether § 30441(a)(9) is relocated or deleted. If deleted, it alters the CRT scope of practice. Provides the ASRT scope of practice.</b></p> <p><b>CDPH Response:</b> See response in Item 71b. Also, as discussed in the ISR (pp. 15-20) for § 30441, the ASRT’s scope of practice is the basis for both the RTCC’s recommendation and this proposal, but the proposal cannot exceed statutory authority. Thus, the proposal is not identical to ASRT’s statements.</p>	187
102b	<p><b>Recommends that non-CRTs not be allowed to operate fluoroscopy equipment since they do not understand the effects of radiation and do not practice ALARA principles.</b></p> <p><b>CDPH Response:</b> The proposal, § 30305.5, does not allow the non-CRT to operate fluoroscopy equipment. It would allow them, under very limiting</p>	188



	<p>conditions, only to move the equipment or patient for very specific purposes. The RTCC considered radiation protection and ALARA principles during its numerous public meetings. No change to the proposal is made due to this comment.</p>	
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**ALTERNATIVES DETERMINATION:** In accordance with Government Code Section 11346.9(a)(4), the Department has determined that no alternative would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

This determination is based on the following:

- The RTCC is a statutorily required advisory committee to the CDPH for purposes of establishing standards of education, training, and experience for persons who use X-rays on human beings and to prescribe means for assuring that these standards are met. (HSC §§ 114840; 114870(a).)
- This proposal would adopt RTCC’s recommendations made after eight public meetings over a 3-year period during which members of the public, physicians and surgeons, chiropractors, radiologic technologists, podiatrists, medical physicists, X-ray technicians, X-ray school program directors, teaching staff and students, cardiovascular technologists, lobbyists, and other interested persons attended. All meetings complied with the Bagley-Keene Open Meetings Act (Gov. Code §§ 11120-11132).
- All public meetings included presentations of noticed topics, discussion by RTCC members, comment opportunity for all attendees, consideration of numerous presented alternatives, and voting of members.
- No received alternative substantively differed from those that were presented and considered by RTCC at those public meetings.

**IMPOSITION OF LOCAL MANDATE**

The Department has determined that the regulation 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, nor are there any other nondiscretionary costs imposed.

**IMPACT ON BUSINESS**

The Department has made a determination that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.