

**RADIOLOGIC TECHNOLOGY CERTIFICATION COMMITTEE (RTCC)
MEETING MINUTES**

October 29, 2014

California Department of Public Health
Auditorium
1500 Capitol Avenue
East End Complex
Building 172 Auditorium
Sacramento, California 95814

Frieda Y. Taylor, M.S., Chairperson

COMMITTEE MEMBERS PRESENT

Dale R. Butler, M.D.	Todd D. Moldawer, M.D.
Christopher H. Cagnon, Ph.D., FAAPM	Neil Mansdorf, DPM
Diane R. Garcia, MS, CRT, ARRT (R)(CT)	Michael L. Puckett, M.D., FACR
John L. Go, M.D.	Bonna Rogers-Neufeld, M.D., FACR
Johnson B. Lightfoote, M.D., FACR	Cliff Tao, DC

COMMITTEE MEMBER ABSENT

Linda L. Ortega, MS, CRT, ARRT(R)(CV)

STAFF

Ricardo Arriola, RTCC Coordinator	Phillip Scott, Senior Health Physicist
Lisa Russell, Supervising Health Physicist	

ALSO PRESENT

Ms. Doris Abrishami, California State University, Northridge	Ms. Nance Cavallin, ARRT
Mr. Bob Achermann, California Radiological Society	Ms. Dawn Charman, El Camino College
Ms. Becky Apodaca, American Society of Radiologic Technologists	Ms. Lorenza Clausen, CSRT
Ms. Teri Braun-Hernandez, CRT	Mr. Sean Jones, University of California, Davis
	Ms. Elizabeth Ortega, AFSCME Local 3299

Ms. Nancy Perkins, Bakersfield College
Ms. Stephanie Roberson, California
Nurses Association
Dr. Lisa Schmidt, Pima Medical Institute

Dr. Thomas Smith, University of
California, Davis
Dr. Mark Warford, California Podiatric
Medical Association
Dr. Jennifer Yates, Merritt College

MEETING SUMMARY

I. WELCOME / OPENING REMARKS

Chairperson Taylor called the meeting to order at 9:00 a.m.

Chairperson Taylor welcomed all meeting attendees and introduced the RTCC members and California Department of Public Health-Radiologic Health Branch (CDPH-RHB) staff. She then explained the meeting's timing process, evacuation procedure and RTCC's adherence to the newly adopted AB 2720. This requires that "A State body publicly report any action taken and the vote or abstention on that action of each member present for the action".

II. APPROVAL OF APRIL 2, 2014 RTCC MEETING MINUTES

MOTION I

The committee members approved the April 2, 2014 RTCC meeting minutes as written.

Motion: Committee Member Mansdorf

Second: Committee Member Butler

Vote:

10 Yes: Dr. Moldawer, Dr. Cagnon, Dr. Puckett, Ms. Garcia, Dr. Lightfoote, Dr. Butler, Dr. Mansdorf, Dr. Tao, Dr. Go and Dr. Rogers-Neufeld

0 No

0 Abstain

MOTION PASSED

Chairperson Taylor stated that the approved minutes would be visible on the CDPH-RHB website no later than 30 days from the meeting's date. She then

introduced the first speaker, Mr. Phillip Scott of the California Department of Public Health, Radiologic Health Branch.

III. OCCUPATIONAL EXPOSURE LIMITS

Phillip L. Scott

Senior Health Physicist

Strategic Planning and Quality Assurance Section

Regulations Unit

Senior Health Physicist Phillip Scott informed the Committee and audience members that the U.S. Nuclear Regulatory Commission (NRC) has published an Advanced Notice of Proposed Rule-making that may impact occupational dose limits as specified in Title 10, Code of Federal Regulations Part 20 (§10 CFR 20), which the Department has incorporated.

The NRC is looking at lowering the following doses:

- Lens of the Eye: From 15 rems per year to 2 rems averaged over 5 consecutive years with no single year exceeding 5 rems.
- Embryo Fetus of a Declared Pregnant Worker: From 500 millirem/gestation period to 100 millirem/gestation period.
- Whole Body Dose to Occupational Workers: From 5 rems per year to a 5 year average of 2 rems per year with the dose in any given year not to exceed 5 rems.

The NRC is also looking at:

- Moving to the international system, or the SI system, of metrics for doses.
 - i.e., talking about Sieverts and Grays rather than rems and rads.
- Using age-specific dose calculation methodologies, so as to reduce the numeric values for public exposure to radioactive effluents.

Mr. Scott informed the audience that comments must be submitted directly to the NRC.

DISCUSSION

COMMITTEE MEMBER CAGNON asked if the state had any concerns.

SENIOR HEALTH PHYSICIST SCOTT responded that the dose to the lens may come into question if wearing the badge outside of the apron. The value would come from the badge if they couldn't prove that eye protection was being used.

SUPERVISING HEALTH PHYSICIST RUSSELL responded that if an individual was wearing eye protection, RHB would have to do an investigation to verify that the lens dose was not over 15 rems. Pending an attestation and inspection, RHB would allow work to continue.

At this point, Mr. Scott's presentation was concluded.

Chairperson Taylor recognized Mr. Gonzalo Perez, Chief of the Radiologic Health Branch before introducing Mr. Scott's second presentation.

IV. LEGISLATIVE AND REGULATORY UPDATE

Phillip L. Scott

Senior Health Physicist

Strategic Planning and Quality Assurance Section

Regulations Unit

Senior Health Physicist Phillip Scott updated the Committee and audience members of the following regulatory and/or legislative items:

1. Bagley-Keene Open Meetings Act
 - Member names and voting actions must now be recorded along with all motions and actions taken

2. Address the Nuclear Regulatory Commission (NRC) regulations
 - RHB is ready to submit to Office of Administrative Law

DISCUSSION

None

At this point, Mr. Scott's presentation was concluded.

V. **WHOLE BODY COMPOSITION (WBC) & SCOPE OF X-RAY BONE DENSITOMETRY (XBD)**

Phillip L. Scott

Senior Health Physicist

Strategic Planning and Quality Assurance Section

Regulations Unit

Senior health physicist Scott shared background and directed the members to the two options being proposed.

- **OPTION 1:** Option one is where we just change the definition of x-ray bone densitometry to say basically, "...means a radiological examination of all or part of the skeleton or body utilizing x-rays from an x-ray source, which is mechanically joined to a detector for scanning all or part of the skeleton or body under computer control".
 - Option 1 is a definition change only, and it has very minimal regulatory revision needed. There are no additional supervision issues that come up by changing that definition. There are no internal administrative impacts for us, for the Radiologic Health Branch, and it... maintains terminology and consistency with national and international bodies.
- **OPTION 2:** Option two is to account for making our regulations more consistent with the international and national communities by using DEXA or D-E-X-A.
 - Option two is the definition change and terminology change. And this still has minimal regulatory revisions for consistency. There are no supervision issues that I can identify, but it does achieve terminology consistency.

Mr. Scott shared that option 2 is recommended.

DISCUSSION

COMMITTEE MEMBER ROGERS-NEUFELD: I don't see ISCD, which is International Society of Clinical Densitometry listed here. And they are very firm in DXA, D-X-A. And I think we should be consistent with our technologists and our national organization which certifies the doctors that read this.

COMMITTEE MEMBER CAGNON: First, I think the term of bone is a little bit outdated. I think that dual energy x-ray is all you need to say, DEXA or DXA. Second, this technology is starting to become seen fairly consistently now as a substitute for CT for certain applications. Do you see any problem with how this might cross over, people might want to use the CT to do this, and have their limited people do it?

SENIOR HEALTH PHYSICIST SCOTT: It already exists. Section 30447 restricts a limited permit, any permit category from performing procedures utilizing computerized tomography.

MOTION II

The committee members approved the vote accepting option two, which is change terminology from XBD to dual energy x-ray absorptiometry and revise definition per option one, but clarify purpose of the exam.

Motion: Committee Member Moldawer

Second: Committee Member Puckett

Vote:

9 Yes: Dr. Moldawer, Dr. Cagnon, Dr. Puckett, Ms. Garcia, Dr. Lightfoote, Dr. Butler, Dr. Mansdorf, Dr. Tao, Dr. Go

1 No: Dr. Rogers-Neufeld

0 Abstain

MOTION PASSED

Chairperson Taylor then dismissed for the morning break.

9:44 AM – 10:15 AM

Chairperson Taylor then introduced the next speakers.

VI. RTCC SUBCOMMITTEE: FLUOROSCOPY CONTENT WITHIN THE CURRENT ARRT EXAM UPDATE

Lisa Schmidt, Ph.D., RT (R) (M), CRT

Jennifer Yates, Ed. D., RT (R) (M) (BD)

Director, Merritt College Radiologic Sciences Program

Dr. Schmidt shared that the presentation included the preliminary findings after the subcommittee review and comparison between the American Registry of Radiologic Technologists (ARRT) 2014 Radiography Examination content specifications and the ARRT 2011 Fluoroscopy Examination content specifications. She also shared that both exams were reviewed and compared to determine the amount of fluoroscopy content within the radiography examination itself. The end result of the review and the comparison was to determine if the amount of fluoroscopy content within the radiography exam is sufficient for radiographers.

Dr. Yates then spoke about the committee's process for doing this comparison. The committee members each did an independent analysis and then were provided with the ARRT analysis by Dr. Lauren Wood, one of the committee members.

- Radiography Exam - 200 Questions
- Fluoroscopy Exam - 90 Questions
- All categories identified and compared
- Findings:
 - The content within the radiography examination is comparable to that of the fluoroscopy examination in depth and scope.
 - The current radiography examination has a minimum of 84 items that have equivalency to the fluoroscopy content when compared to the items found on the fluoroscopy examination.
 - The fluoroscopy examination has a total of 90 items.
- In summary, there is an overlap of the minimum of 84 items addressing fluoroscopic concepts, so there is overlap between the two exams.

Dr. Schmidt then shared a side by side comparison of the examination content area and the number of items that have equivalent content to the items on the fluoroscopy examination. Dr. Schmidt then stated the recommendations formed by the subcommittee.

RECOMMENDATIONS:

- With continuing education requirements in place, in addition to the ARRT Continuing Qualification Requirements (CQR) mandate, these are mechanisms in place that require registered technologists to maintain the educational knowledge associated with the profession.
- As there is considerable overlap of both exams, it is recommended by the committee that the State no longer require the fluoroscopy examination for state certification for individuals who have passed the ARRT radiography examination.
- Graduates from accredited programs obtain the fluoroscopy education and training necessary to perform fluoroscopy procedures, as evidenced by the ARRT examination, coupled with the continuing education requirements, and the upcoming CQR for radiographers in 2021.

Dr. Schmidt and Dr. Yates thanked the Committee and opened the floor for questions.

DISCUSSION

COMMITTEE MEMBER GO: Why is there so much overlap, if they're actually two different examinations? Is there not enough material to actually separate these two components, where you just test radiography separate from the fluoroscopy portion? Someone from ARRT should explain why there's so much overlap.

MS. NANCE CAVALLIN:

- The fluoroscopy exam is not taken nationally by all radiographers.
- I think only California is the only State that requires the fluoroscopy exam.
- All the other states accept the ARRT radiography exam to qualify radiographers for both radiography and for fluoroscopy.
- The purpose is for people who are not radiographers and do not have the background in radiation protection, radiation biology, and those other things that we emphasized in the fluoro exam.

COMMITTEE MEMBER ROGERS-NEUFELD: Do the technologists have to pay the fee twice for the same permit, the same certificate?

SENIOR HEALTH PHYSICIST SCOTT: No. If you're going for the certificate, there's an application fee and the exam fee that's paid to ARRT. So we use that

application fee to cover the costs of our processing the application, and that is a certificate. The fluoroscopy permit is above and beyond the certificate.

DR. SCHMIDT: The process for a graduate from my program is:

- Pay the ARRT \$200 to sit for their examination
- Pay \$75 to California for their registered technologist permit.
- Pay \$100 to the ARRT for their fluoroscopy exam, and
- Pay \$75 for the fluoroscopy permit.

CHAIRPERSON TAYLOR: To clarify what Dr. Schmidt is saying, if you are a graduate that gets your national certificate from ARRT, and you want to use radiography in California, it's what's called a direct issue.

- If you submit the application with that copy of that ARRT card, you don't have to take the exam again.
- But if you want to be an RT in California and you don't have that national card from ARRT, then you're applying as a California applicant, and then you have to take the ARRT exam to become an RT in California.

COMMITTEE MEMBER GO: What is your statistic of people who pass their radiography examination but fail the fluoro exam? If this is a redundant examination, you'd expect the pass rate to be the same.

DR. SCHMIDT: Radiography pass rate is 100%. Fluoroscopy, I haven't looked at my statistics recently, but it has been above 85%, I believe.

COMMITTEE MEMBER GO: The question is why is there a discrepancy then in theory, if everything covered in the fluoro examination is covered in the radiography examination? You should see the pass/fail rates to be similar.

SENIOR HEALTH PHYSICIST SCOTT: The question sounds like there's an underlying assumption that when you graduate and take the radiography exam, you immediately, or within a few months or weeks, take the fluoro exam. That doesn't always happen.

COMMITTEE MEMBER GO: If what Mr. Scott is saying is that they take the fluoro examination maybe years later, and that's true maybe there is a need for the fluoro examination then.

COMMITTEE MEMBER LIGHTFOOTE: Thank you for all of that work. What you've done is confirm that the fluoroscopy test is, in essence, a subset of the radiography test. And that the fluoroscopy test would be needed if, and only if, a health care provider comes to need a fluoroscopy permit from some pathway other than a JRCERT CRT program.

COMMITTEE MEMBER GARCIA: I would like to point out [that] you were discussing to keep the fluoroscopy permit, because it's continuing education on fluoroscopy. But that is exactly what the ARRT is doing with the CQR every ten years.

MS. CAVALLIN: The CQR requirements went into effect for those persons who have become certified and registered after 2011.

- So its ten years out from there that everyone will be required to do some sort of reassessment, not necessarily examination.
- If you are registered and certified before 2011, the CQR requirements do not apply.
- However, all registered techs do need to do continuing education, 24 credits every two years.
- There is a four hour continuing education requirement for fluoroscopy-specific courses which is a California requirement [if you hold a fluoroscopy permit.]

COMMITTEE MEMBER GO: So a person who's coming to California and they're grandfathered in because they passed the ARRT examination 20 years ago, would you have to get licensure to practice radiography and fluoroscopy separately?

DR. SCHMIDT: It's going to depend on what do in a day-to-day practice as a technologist.

- If you are a technologist who has passed the ARRT and you're currently working, then you are most likely conducting fluoroscopy exams on a day-to-day or a weekly type of situation, depending on where you work.

COMMITTEE MEMBER GO: You wouldn't have to take an examination then?

DR. SCHMIDT: No. If you have passed the ARRT examination, you've done your continuing education credits each year and you're doing what you were trained to do in an educational setting, then you're recognized by the ARRT.

SENIOR HEALTH PHYSICIST SCOTT: Under Health and Safety Code 107010, "Department may accept in lieu of its own examination a certificate of another agency or organization that certifies radiologic technologists, provided the certificate was issued on the basis of qualifications and an examination deemed by the Department to be reasonably equivalent to the standards established by the department."

That allows us to accept the ARRT examination in lieu of our own exam that we created back in 1970 or '71 initially, and then revised it slightly.

COMMITTEE MEMBER GARCIA: I have a couple of things I want to point out:

- ARRT updates their examinations continually (every two years), which is something California cannot do.
- The fluoroscopy permit is only for those who have passed RT programs for PAs and non-radiologist physicians.
- It is not for any other allied health profession to take, because that was a little bit implied.
- The ARRT exam follows the ASRT Curriculum on a national level

MS. CAVALLIN: The ARRT exams are based on practice. We take into consideration the ASRT's curriculum, but when we develop exams, we do what's called a practice analysis, and we revisit that every three years.

COMMITTEE MEMBER GO: It appears that there is a lot of redundancy... under the fluoroscopy examination when you did the breakdown:

- 84 of the 90 questions were equivalent to the radiography examination, which meant that there were six questions on the fluoroscopy examination which were not covered in the radiography [exam].
- What I'm not really getting a good feel of is the number of questions in the radiography portion that deal with fluoroscopy.
- Maybe the Committee needs to do a little more work to say, okay, of these questions how many of these questions actually deal specifically with fluoroscopy?

- There's going to be a lot of overlap, but... this should be examined in both the radiography examination and the fluoroscopy examination.
- What is it about those six other questions in fluoroscopy that were specific to only fluoroscopy?

MS. CAVALLIN: If you compare the two documents, there's a lot of overlap in that. The other thing is with our examinations at ARRT:

- We don't just have one examination for radiography and one examination for fluoroscopy.
- We have several forms of the examinations, many forms for the radiography examination that are out there at the same time.
- We do that for security reasons.
- The six other questions could have been things that also did relate to fluoroscopy, but were at a different level, perhaps just a higher level of radiobiology or radiation protection

COMMITTEE MEMBER GO: It's a simple question, yes or no. "Yes, you can separate this out" or "No, you can't" if you were to do the breakdowns even farther.

MS. CAVALLIN: If I did, I would be pulling out content for radiography also, [and] for radiographers, it's not okay.

COMMITTEE MEMBER LIGHTFOOTE: What I hear you saying is that you can make up a fluoroscopy test by taking 84 questions out of the existing CRT test. So I'd like to make a three-part motion.

MOTION III

Part I:

The RTCC recommends to RHB that it grant to CRTs who have completed a JRCERT-certified training program and who pass the ARRT examination a fluoroscopy permit.

PART II:

That California retain the fluoroscopy examination and fluoroscopy permit, which may be granted to appropriate health care professionals, specifically including PAs and M.D.s for the purpose of permitting them to do fluoroscopy in their health care profession.

PART III:

RTCC thanks the subcommittee for its energetic, creative, and innovative work.

Vote:

9 Yes: Dr. Moldawer, Dr. Rogers-Neufeld, Dr. Cagnon, Dr. Puckett, Ms. Garcia, Dr. Lightfoote, Dr. Butler, Dr. Mansdorf, Dr. Tao

1 No: Dr. Go

0 Abstain

Motion Passed

Chairperson Taylor called for lunch at 11:28 a.m.

LUNCH

Chairperson Taylor called for order at 12:53 p.m. She noted a change in speakers for the next presentation due to an unforeseen emergency. She then introduced the next two speakers, Ms. Diane Garcia and Ms. Becky Apodaca.

VII. UPDATE: RTCC SUBCOMMITTEE: PRACTICE STANDARDS FOR CERTIFIED RADIOLOGIC TECHNOLOGISTS
Diane Garcia, M.S., R.T. (R) (CT), ARRT, CRT
Becky Apodaca, B.S., RT (R), CRA

Ms. Garcia introduced Ms. Becky Apodaca who would be presenting in place of Professor Anita Slechta. She then discussed the following items:

- Subcommittee directive from the RHB: Create a Scope of Practice for CRT's in California.
- Definition of Scope of Practice: The scope of practice delineates the parameters of the specific practice.
- Subcommittee agenda
 - Overview of Committee Directive
 - Overview of ASRT practice standards, page – by – page
 - 6 sections
 - 1. Introduction
 - 2. Scope of practice
 - 3. Clinical performance

- 4. Quality performance
 - 5. Professional performance
 - 6. Advisory opinion statements
 - Recent Committee Activities
 - Review of ASRT Radiation Therapy Practice Standards
 - Review of ASRT Position Statements
- Subcommittee agreed that the ASRT Standards were the best way to address Scope of Practice.
- Identified terms that need definitions:
 - “Licensed Independent Practitioner”
 - S&O, Certificate, Licentiate?
 - Determine the context
 - “Starting or Maintaining IV access”
 - RHB will verify/evaluate the law and regulations for authority to grant or maintain IV access and if they are the same
 - “Administer Medications”
 - RHB Will define the term “medication”
- Further Identifications Needed:
 - RHB will Clarify and assure that at any site where contrast injection occurs there are clear protocols set for the RT who determines the dose of contrast based upon the type of contrast and the patient’s age, weight and medical/physical status.
 - “Injects into PICC line” needs clarification of the term “medication”
 - The ASRT standards require a Radiation Safety Officer... But California does not require an officer; it requires a radiation safety program.
 - Will the person who oversees or creates the required radiation safety program carry this title?

- Subcommittee Consensus:
 - When the RHB approves the terminology well enough to satisfy the laws and regulations and we complete the fine-tuning necessary for the ASRT practice standards to suit CA, the subcommittee will be able to move forward to adopt the ASRT document.

- Next Steps:
 - Phillip Scott of RHB and his staff are investigating and clarifying these potential conflicts.
 - The goal is to accept the Standards of Practice in California and to have imaging clinics and hospitals use them to develop their own scope with appropriate standards.

- The subcommittee also met to review the Radiation Therapy Practice Standards in the same page – by - page manner

- Identified terms that need definitions:
 - Page 6: Performing venipuncture as prescribed by a licensed independent practitioner.
 - Page 7: Participating in brachytherapy procedures.
 - Phillip Scott of RHB to define
 - Page 10: Determines the course of action for an emergency or problem situation.
 - Phillip Scott of RHB to define / investigate wording.
 - Licensed Independent Practitioner

- Advisory Position Statements:
 - Injecting Medication in Peripherally Inserted Central Catheter Lines or Ports with a Power Injector.

- Subcommittee recommendation: Suggestion for the definition- Medication: “A contrast material and also any adjunct material that is approved by the State of CA, which is required to support the safe administration of the contrast”
 - Placement of Personal Radiation Monitoring Devices
 - Subcommittee recommendations: Be aware that there are some facilities that do not require monitoring, i.e.: bone densitometry.
 - Medication Injection Through Existing Vascular Access
 - Definitions suggested by the committee:
 - Existing vascular access: Peripheral or central vascular access catheters or cannulas that include, but are not limited to, peripherally inserted central catheters, intravenous catheters, central vascular access catheters or cannulas, injection ports.
 - Medication: As defined previously.
 - Medication Injections by Radiologic Technologists
 - Subcommittee Recommendations: Definition of Medications: As defined previously.
- Next Steps:
 - RHB to:
 - Clarify legal authority on a number of statements within ASRT’s documents.
 - Clarify how the scopes of references are being evaluated.
 - Have discussions with legal counsel on possible enforcement issues.
- The Scope of Practice Subcommittee recommends:
 - RTCC moves to approve that RHB move forward on these clarifications and definitions so that the ASRT RT(R) and RT (T) Practice Standards can be used in California.

DISCUSSION

COMMITTEE MEMBER CAGNON: Phillip, your name is used in broad, bold print. What are your challenges to accomplish this? Any challenges you see off the bat?

SENIOR HEALTH PHYSICIST SCOTT: We will take the document, the items that are identified, and:

- Evaluate those through our legal counsel,
- Do the research necessary to address
 - Enforcement
 - Implementation
 - How the document should be used

It's all a challenge because a radiologic technologist is functioning in a medical capacity, and our authorization is specifically under the Radiologic Technology Act. Some of these questions, such as injection of medication, fall within a different set of laws in a different department structure, or a completely different State agency.

We have to look at the legal boundaries within the Department of our own laws, and maintain consistency between all State laws and regulations when we adopt regulations. That's the first question we ask. Can we even regulate it? Do we have that authority?

MOTION IV

The Scope of Practice Subcommittee recommends for the RTCC to move to approve that the RHB move forward on these clarifications and definitions, so that the ASRT RT(R) and the ASRT RT(T) practice standards can be used in California.

Motion: Committee Member Garcia

Second: Committee Member Lightfoote

Vote:

10 Yes: Dr. Moldawer, Dr. Rogers-Neufeld, Dr. Cagnon, Dr. Puckett, Ms. Garcia, Dr. Lightfoote, Dr. Butler, Dr. Mansdorf, Dr. Tao and Dr. Go

0 No

0 Abstain

MOTION PASSED

Chairperson Taylor introduced the next speakers, Mr. Phillip Scott and Ms. Lisa Russell.

VIII. CLARIFICATION OF FLUOROSCOPY PERMIT REQUIREMENTS

Phillip L. Scott

Senior Health Physicist

Strategic Planning and Quality Assurance Section

Regulations Unit

Lisa Russell

Supervising Health Physicist

X-Ray, Inspection, Compliance, and Enforcement Section

Supervising Health Physicist Lisa Russell provided an overview of the presentation to the audience and Committee.

- RHB Authority to grant Exemptions
 - California Code of Regulations, Title 17, section 30104
 - Although allowed to, RHB does not do it lightly without asking:
 - Is this necessary?
 - Will this result in undue hazard to health, life, or property?
 - Do the doses to individuals in the controlled areas or the uncontrolled areas exceed the limits?
- Text of the Regulation
 - What we're actually making the exemption for is for positioning the patient, and positioning the fluoroscopy equipment. We're not exempting anybody from needing a fluoro permit to select exposure factors, or for making exposures themselves.
 - That seems to be a misunderstanding that's out there based on some of the responses that we've had.
- Timing
 - This was prompted by a couple of facility inspections in June. We had findings that, based on our previous interpretation of

fluoroscopy and the old definition that that interpretation was based on, that there were citations for people performing fluoroscopy, and it was actually in the operating room.

- In discussion and investigation with this facility from June through August, and into early September, we determined that in order for them to provide the best medical care to their patients, they actually needed an exemption. The particular surgery that they were most concerned with was a pediatric hip dislocation.
- We looked at the issues that came before the RTCC last year:
 - Some questions we were specifically asked by the Committee about enforcement of the other guidance that we had, and that guidance was very black and white.
 - And it was based on the definition of fluoroscopy as being an exam. And once that exam started, fluoroscopy was engaged, and how you would define stopping and starting fluoroscopy as an exam when the surgery was a single exam and billed as such.
- We did put out an information notice in mid-September. And based on our feedback, that generated a free-for-all atmosphere, where people thought that now just anybody could go in and do anything associated with the fluoro machine, and that was never our intention.
- Basic Premise
 - The physician performing fluoroscopy and/or supervising the use of fluoroscopy does have valid permits. They're the actual responsible party by law (HSC 106965): for radiation safety in that room. They must hold:
 - A current and valid Radiology certificate or
 - A current and valid Fluoroscopy permit.
 - So with that being assumed and is law, we put that responsibility where it's deserved to be. We put it with the physician who wants somebody who is not a CRT to come in and perform any tasks for

them, and then we limited the tasks that they could provide.

- Why the CRT still needs a permit:
 - A CRT (with a fluoroscopy permit) may perform tasks under general supervision. Unilateral decision-maker in the room with the patient who will:
 - Ensure that the requested anatomy is correctly demonstrated for the interpreting physician to provide a diagnosis
 - Select the appropriate technical factors
 - Take appropriate steps to protect the patient and obtain high quality images, i.e. gonadal shielding, collimation
 - Examples:
 - Assisting a physician who does not have the expertise or desire to do these tasks in addition to their own
 - Performing these tasks for a physician not in the room
- Allowance and responsibilities under the exemption
 - Allowance:
 - Facility may elect to allow a physician or physicians to have assistance from a non-permitted person in either moving the patient or moving the equipment.
 - Yes:
 - Pan the table or the equipment during fluoro, to include cine
 - Move the patient
 - Reset the fluoroscopy timer
 - Rotate or flip the image (left to right / top to bottom)
 - Adjust contrast settings
 - No:
 - Change or select technical factors
 - Engage / disengage mag
 - Change or select frame rate
 - Change or set collimation

- Change or select filtration
- Actuate, energize, or push the button to initiate radiation exposure
- Responsibilities:
 - Supervising / directing physician must be physically present and personally directing the actions of the non-permitted person
 - Supervising / directing physician must identify and document all specific actions the non-permitted individuals will perform
 - Supervising / directing physician must document identified training
 - Equipment operating in AEC / AERC mode only
 - Before exposing or continuing to expose the patient, the supervising / directing physician must review and approve changes to the spatial relationship and technical factors that resulted from moving the patient or the equipment
 - Supervising / directing physician must demonstrate his / her own ability to perform all tasks for which he / she is responsible.
- Compliance
 - Documentation
 - Specific actions allowed by the facility
 - Training of the non-permitted person
 - Physician training and/or demonstration
 - Interviews
 - RT's
 - Non-permitted individuals
 - Doctors
 - Checklist

DISCUSSION

COMMITTEE MEMBER MOLDAWER: "I'm in complete agreement with the concept of the exemption to allow the medical practice... But I think that you are trying to over-engineer a process that has gone seamlessly for decades by imposing restrictions, regulations, and obligations that are unobtainable.

There's just no way that all of these players moving in various directions can meet the standard that you're trying to propose, given the vague training requirements that you're expressing.”

SENIOR HEALTH PHYSICIST SCOTT: What the exemption notice does include is the basic education, or the training the individual needs. The individual, who is going to do this if it's allowed, would have to receive training in:

- Equipment set up and operation
- Fundamentals of radiation safety
- Significance of radiation dose to include hazard of excessive exposure to radiation
- Biological effects of radiation dose, radiation protection standards, and then also expected levels of radiation from fluoroscopy equipment.
- Methods of controlling radiation dose, such as time, distance, shielding, and the characteristics and use of personal monitoring equipment.

COMMITTEE MEMBER MOLDAWER: Then my comment is that you're changing the practice of medicine and surgery that has existed in California for decades in a way that is unobtainable under current practice standards.

SUPERVISING HEALTH PHYSICIST RUSSELL: The alternative is to not follow the exemption and have a CRT perform those tasks. Although it has been the standard we have been citing the last couple years, we've had almost 150 citations for people who have been cited for performing fluoroscopy without a permit.

COMMITTEE MEMBER BUTLER: I think it's an overreach to require the surgical specialist in the operating room to meet these educational requirements that really have nothing to do with their job description as a surgical technician.

COMMITTEE MEMBER LIGHTFOOTE: I concur with Dr. Butler and Dr. Moldawer's concern that the way the exemption is written, it places the wrong burden on the wrong people. And the goal of RHB should not be to eliminate or obviate the necessity of CRT, but rather to exploit their expertise in the care of patients in lowering a radiation dose.

SUPERVISING HEALTH PHYSICIST RUSSELL: Actually, we would prefer to have a CRT in every fluoro room as well, because they do have the expertise.

But the way our initial black and white interpretation was did not allow that. And the way the law is written, a doctor with a fluoro permit is allowed to do everything.

COMMITTEE MEMBER GARCIA: That's sound great on paper, but it doesn't work in reality. Physicians cannot possibly, in any way, shape, or form, oversee all aspects of radiology in the surgical suite or any other suite, as well as focusing on the patient. Maybe they need to hire a few more CRT's, which might be the solution.

COMMITTEE MEMBER CAGNON: "It seems... that an issue we've been so far avoiding in this conversation is that there's a compensation issue too."

- I personally would love to have a CRT in every procedure absolutely. But I suspect the challenge at my institution and many institutions is I'm going to pay to have five different people in the room.
- You're talking about an entirely different direction than has been going in the State of California.
- You're talking about reversing that legislation, unless this committee is going to make the bold move of having a CRT always in the room.

COMMITTEE MEMBER Rogers-Neufeld: This committee is only advisory, but we do give a lot of our personal time and expertise to come here. I was personally surprised by this exemption, because I didn't see direction coming from this body of able experts that we should go in this direction. How did it get created?

SUPERVISING HEALTH PHYSICIST RUSSELL: We did have a specific request for an exemption. And it was based on patient medical need. So it's not something that we would traditionally go to RTCC for advice on or wait to grant the exemption, because the patients actually need to have surgery at the time.

COMMITTEE MEMBER GARCIA: I agree to a certain extent that some people should be able to manipulate - physicians, residents. For the most part, they're trained by the technologist in the x-ray department.

SUPERVISING HEALTH PHYSICIST RUSSELL: And that's why we left it to the facility to determine the scope of the training and who's providing it. The doctor has to sign off on it. That is appropriate.

COMMITTEE MEMBER GARCIA: Correct, but therein lies your problem, because the interpretation of what this exemption has stated it's going to be interpreted very differently by every facility, and/or by the physician. And as you're seeing all these citations now, and we have all these rules, you lessen the rules; it's going to be like the wild, wild West.

COMMITTEE MEMBER PUCKETT: You can delegate authority, but you can't delegate responsibility. And in the case of a CRT in the room, we have delegated the authority to run that machine, though we remain responsible for anything that happens thereof. So some of the question is how it's going to be enforced. And I think that's where some of the discomfort is because it's not defined.

SUPERVISING HEALTH PHYSICIST RUSSELL: That would be whatever specific surgery or particular case you've determined you need a non-permitted person to participate.

- We would have you define that for your facility or your practice in particular, and then we would look to see if you have trained the non-permitted person on what they need to do safely to do it.
- We're trying to put the responsibility for radiation safety in that room back with the surgeon who said I need a non-permitted person to do something.

COMMITTEE MEMBER LIGHTFOOTE: A non-permitted person, a surgical tech, should be able to position a patient for surgical purposes, but not for fluoroscopic purposes, in my opinion.

COMMITTEE MEMBER GO: I do see a couple problems with this:

- With regards to your proposal concerning the guidelines for training, it needs to come from the RHB and say that these are the requirements in terms of the guidelines that need to be followed by everyone.
- With regards to citations that are happening, do you actually suspend people's licenses? Exactly what do you do?

SUPERVISING HEALTH PHYSICIST RUSSELL: We can revoke certificates and permits. We can refer actions to the Medical Boards, the Dental Board, the Chiropractic Board, Podiatric Board, and we can also take cases to court and they can impose fines, but we don't have straight penalty authority.

Chairperson Taylor then noted that the meeting was ahead of schedule and would allow questions from the RTCC members and members of the audience.

MR. SEAN JONES: I'm Sean Jones, medical health physicist for UC Davis Medical Center.

- This new exemption draws a striking similarity to the C-arm spacer cone exemption law, where anyone can bring a C-arm into the room and plug it in and turn it on, and position the patient
- As far as the training goes for this exemption, I really like the second announcement, because it really defined the training and the radiation safety that they'd receive.
- And I'd just like to comment that it would be very useful for some of our practitioners, in some cases where CRT is not necessarily desired or useful.

MS. NANCY PERKINS:

- I consider radiation a hazard to life, and as a result any time you pan the fluoroscopy unit, you are changing dose, even in the AEC or AERC mode.
- I understand that the State is looking at putting some regulation into training to these non-permitted individuals, but I find it exceedingly vague. I cannot develop a curriculum for that.
- When we look at who is ensuring safe exposure, many of the fine doctors indicated their primary focus is the exam and the procedure. It's the pain management clinic. It's the hospitals. It's the surgeons. Their primary focus is to make sure the best outcome for the patient.

COMMITTEE MEMBER MANSDORF: At the last RTCC meeting we had a motion which was passed to have RHB return to us with some interpretation or definition of what we considered the fluoroscopic exam. One of the issues was when does the exam start, when does it end? We still haven't heard a definition yet.

MOTION V

Part I:

The RTCC recommends that the RHB rescind the letters of September 15th and September 30th.

PART II:

The RHB also develop a definition of fluoroscopy, which it will report and recommend back to RTCC, including elements such as when does fluoroscopy begin, when does it end, and the difference between moving a patient for clinical or surgical purposes, as opposed to fluoroscopic purposes, and to what extent is a CRT required during fluoroscopy. And, I'll also include in that, moving patients for the purpose of fluoroscopy for clinical purposes and for operative purposes.

PART III:

The RTCC thanks Ms. Lisa Russell for her very strong work.

Motion: Committee Member Lightfoote

Second: Committee Member Rogers-Neufeld

Vote:

5 Yes: Dr. Rogers-Neufeld, Ms. Garcia, Dr. Lightfoote, Dr. Tao and Dr. Go

5 No: Dr. Moldawer, Dr. Cagnon, Dr. Puckett, Dr. Mansdorf and Dr. Butler

0 Abstain

MOTION DID NOT PASS

COMMITTEE MEMBER BUTLER: I would make the motion that the RTCC reject the September 30th exemption to the California Code of Regulations, Title 17, and adopt and support the September the 15th, 2014 fluoroscopy permit requirements as outlined on these documents.

It's not everything that I would want to have. It is close enough, and it's an appropriate compromise that I think we could live with for now and then maybe we can work on some of the other issues in the longer term and get some better definitions.

COMMITTEE MEMBER GARCIA: I would agree for now, except for the fourth bullet point, if that would be removed. The fourth bullet point says:

- "During fluoroscopy operated in the automatic exposure control or automatic exposure rate control mode, a non-permitted individual may move the patient or the equipment at the request of, and under the direct oversight and personal supervision of a qualified person. The qualified person must review and approve of any changes to the spatial relationship and technical factors that resulted from the actions taken by the non-

permitted individual before the qualified person exposes or continues to expose the patient to x-rays".

COMMITTEE MEMBER PUCKETT: I would suggest that we go back to the 15th of September, and specifically delete the ability to continue to expose while moving the equipment or patient. That's just deleting those last few words.

COMMITTEE MEMBER LIGHTFOOTE: I'd speak in favor of deleting the fourth bullet altogether. I'm okay with moving the patient while the exposure is off, but the whole principle of radiation training, education, certification is that anybody who's moving the equipment while the fluoro is on or the patient while the fluoro is on should be trained and educated in radiation exposure, such as an S&O who is certified or a CRT.

CHAIRPERSON TAYLOR: Dr. Butler, would you like to restate your motion as originally [stated] or with deletion of the fourth bullet or a partial deletion of that fourth bullet? Would you like to keep your original motion?

COMMITTEE MEMBER BUTLER: I think I want to keep the motion as it is.

MOTION VI

That the RTCC reject the September 30th exemption to the California Code of Regulations, Title 17, and adopt and support the September 15th, 2014 Information Notice, fluoroscopy permit requirements as outlined on these documents.

Motion: Committee Member Butler

Second: Committee Member Moldawer

Vote:

5 Yes: Dr. Moldawer, Dr. Puckett, Dr. Butler, Dr. Mansdorf and Dr. Tao

5 No: Dr. Rogers-Neufeld, Dr. Cagnon, Ms. Garcia, Dr. Lightfoote and Dr. Go

0 Abstain

MOTION DID NOT PASS

Chairperson Taylor called for a break at 2:57 p.m.

BREAK

Chairperson Taylor called for order at 3:12 p.m. She then introduced the next speaker, Dr. Thomas Smith.

IX. REGISTERED CARDIOVASCULAR INVASIVE SPECIALISTS (RCIS) Thomas Smith, M.D., F. A. C. C., RCIS

Dr. Smith shared that his presentation was primarily to discuss the RCIS in relation to the most recent exemption released by the RHB, but in light of the discussion during the two previous motions, he would move quickly through his presentation and perhaps help foster some additional discussion in the cardiac catheterization lab.

DISCUSSION

COMMITTEE MEMBER PUCKETT: Dr. Smith, I would appreciate your comments or how you feel about taking the responsibility for ensuring the training and prior documentation of what actions that person would do when you need them to do that during the procedure, just how are you approaching that and do you feel that's appropriate?

DR. SMITH: From being an S&O, I accept that I am responsible for all of the exposure in the room... But as it's written, it's challenging from a physician standpoint to make sure that you are not missing anything that you're not -- that you have the knowledge and the ability to make sure that it's safe.

COMMITTEE MEMBER GO: You readily adopted the September 15th notice, but did you adopt the September 30th, where you actually have to document exactly what did that non-permitted person do in your suite?

DR. SMITH: We have not implemented, from the standpoint of actually affecting how we're doing fluoroscopy at our hospital. We have brought in those exemptions and are working through the committee to come up with a framework that would allow us to comply with those exemptions.

Chairperson Taylor then introduced the next speakers, Ms. Lorenza Clausen, Ms. Becky Apodaca, Ms. Nancy Perkins and Mr. Bob Achermann.

X. QUALIFICATIONS FOR PERFORMING FLUOROSCOPY IN CALIFORNIA

Anita Slechta, MS, BSRT, CRT, FASRT (ABSENT)

Lorenza Clausen, RT (R) (CT) (MR), ARRT, CRT

Becky Apodaca, B.S. RT (R), CRA

Nancy Perkins, M.A., Ed.

Ms. Clausen began by sharing the history of fluoroscopy including the early legislation and the adoption of The California Radiologic Technology Act (The RT Act). Ms. Clausen provided background on the enactment of the fluoroscopy permit in 1985 and noted the sporadic enforcement and policy revisions throughout the decades of the 1990's and the 2000's.

Ms. Clausen noted that in 2013 the definition of fluoroscopy was revised. This was due to the redefinition by the FDA, noting that this was more of a technique and not actually an examination. She also noted that the educational requirements actually were also revised in 2013. The ARRT examination is now used for the fluoroscopy exam as of January 1, 2013.

Ms. Apodaca then shared the comparison between four different settings in California. She shared the various educational elements of the primary pathway, ASRT radiography curriculum which includes image analysis, imaging equipment, principles of imaging, radiation biology, radiation production, radiation protection etc. as well as an example of the amount of time that it takes to become educationally prepared.

Mr. Bob Achermann referred to both the exemption and the information notices and shared the contents of a letter that was presented to the RTCC members.

Mr. Achermann shared the technical definition of fluoroscopy from the FDA regulation and the FDA website as both a type of medical imaging and a technique.

Ms. Nancy Perkins shared the last part of the presentation which focused on the licensure laws and regulations for fluoroscopy. She noted that fluoroscopy use:

- Is radiography personnel's number one exposure risk,
- Caused desquamation in the 1990's but NOT in California
 - Why? Because qualified, licensed & permitted individuals were operating fluoroscopy machines.

She also noted that in 1981, there was a need for a fluoroscopy permit and the rationale at the time was going back to the genetically significant dose calculations had radically increased for California citizens. She posed that the exemption and information notice released by the RHB usurped the authority of the RTCC. Ms. Perkins then shared multiple sections of the California Health and Safety Code that deal with Committee approval of regulations.

Ms. Perkins requested that the Committee consider rescinding the general exemption to the California Code of Regulations, Title 17 until the RTCC has had a chance to fully assess the net effect.

DISCUSSION

COMMITTEE MEMBER CAGNON: I think a big topic today has been this really thorny issue. I think most of us agree that ionizing radiation exposure is a big concern, how do we adequately monitor it and control it. I would add that we of course do see skin injuries in California, mainly from interventional cases.

COMMITTEE MEMBER GO: I think one of the points of contention with regards to the September 15th point was the fourth bullet with regards to the unpermitted individual and basically what role or training that person would actually have.

COMMITTEE MEMBER PUCKETT: As we address fluoroscopy, I'm in favor of the motion. I think it would be helpful to know some of the nature. Maybe Lisa could provide next time, categorize the 150 violations that she mentioned. It would be nice to know what the situation was, and then that way anything we do to try and address it would take that into account. So I would request that the enforcement side of the RHB give us the information.

MOTION VII

To form a subcommittee to make recommendations to the RTCC to amend the current regulatory definition of fluoroscopy and who can use fluoroscopy under what conditions. Also to make recommendations with regard to the exemptions that are currently in place.

Motion: Committee Member Cagnon
Second: Committee Member Lightfoote

Vote:

10 Yes: Dr. Moldawer, Dr. Puckett, Dr. Butler, Dr. Mansdorf, Dr. Tao, Dr. Rogers-Neufeld, Dr. Cagnon, Ms. Garcia, Dr. Lightfoote and Dr. Go

0 No

0 Abstain

MOTION PASSED

MOTION VIII

That the RTCC recommend that the following regulatory language be adopted:

"An individual under the direct and immediate supervision of the S&O may move the patient or fluoroscopy equipment, as instructed by the S&O, when the fluoroscopy equipment is not actuated or energized. Movement of the patient or equipment may change the spatial relationship between the patient and the fluoroscopic equipment. When there is a change in the spatial relationship between the patient and the equipment, an individual with a fluoroscopy permit must reassess the exposure technique and radiation safety consequences prior to any subsequent patient radiation exposure."

Motion: Committee Member Butler

Second: Committee Member Lightfoote

Vote:

8 Yes: Dr. Moldawer, Dr. Butler, Dr. Mansdorf, Dr. Tao, Dr. Cagnon, Ms. Garcia, Dr. Lightfoote and Dr. Go

0 No

0 Abstain

2 Absent: Dr. Puckett and Dr. Rogers-Neufeld

MOTION PASSED

Chairperson Taylor then invited the public to share comments.

XI. PUBLIC COMMENT

MS. DORIS ABRISHAMI: I have concerns about the exemption of the September 30th.

- You all, I think, agreed that the training parameters are vague.
- You're actually allowing or letting a non-permitted person reset the timer on the fluoro. That's one of the permissions that you're giving to a non-permitted person to do.
- If you look at the list on this presentation, you just voted on something that -- don't know if you noticed or not, but it says reset the fluoroscopy timer.

MS. ELIZABETH ORTEGA: I'm the Political Director for AFSCME, Local 3299. I'm here on behalf of 13,000 patients.

- Weakening the standards by expanding who can operate potentially dangerous equipment puts both patients and medical personnel at risk.
- This specialized nature of procedures that call for use of fluoroscopy demand a high degree of attention and expertise.
- We urge you not to cut corners and continue to require that only medical personnel certified in fluoroscopy be allowed to position and operate fluoroscopic equipment.

MS. STEPHANIE ROBERSON: I'm Stephanie Roberson, legislative advocate for the California Nurses Association.

- The California Nurses Association represents registered nurses who provide specialized care to patients in surgical suites, interventional radiology, and cardiac catheterization laboratories throughout California.
- We are very concerned that when we hear that any procedure involving the use of fluoroscopy would be performed without personnel specifically certified to operate this equipment.
- The growing use of increasing complexity of interventional fluoroscopy procedures have been accompanied by public health concerns, resulting from the increased radiation exposure to both patients and health care personnel.
- The CNA urges you to take necessary steps to look at these recommendations.

MS. NANCY PERKINS: With reference to the September 30th exemption letter. I would just like to again comment on Item number 3 that the permitted licentiate who is directing the non-permitted individual shall document at each facility,

where operating under this exemption, that the individual has received training consisting of all of the following.

- My objection is to the word "training". As previously individuals have said that it is vague. It contains no hours whatsoever. It's not specific. And the word "competency" is never indicated, when, in fact, in October of 2013, the RHB took the bold move to change the regulations to recognize JRCERT-approved schools with required modern curriculum - it's very specific – that requires competencies.

DR. MARK WARFORD: I'm Dr. Mark Warford, Doctor of podiatric medicine and I am a member-at-large of the Board of Directors of the California Podiatric Medical Association.

- I would like to commend the board on passing the most recent motion that does allow non-permitted persons to move the equipment or the patient while it is not energized.

MS. TERI BRAUN-HERNANDEZ: According to your regulations for the non-permitted, you're saying that they can pan the table, they can move the patient, they can reset the fluoro timer, but technically what's really happening is that we are changing the technical factors when we are moving the patient, because during the whole procedure, there could be seven, ten minutes worth of fluoro, where we're raising the table up, lowering the table down. It's just not moving the equipment in and out. We're actually moving it and operating it.

MR. BOB ACHERMANN: Bob Achermann with the California Radiological Society, just a just a point of clarification.

- We don't know yet what RHB will do with the recommendation, but theoretically, if followed, the September 30th version and Item 4 that language will be replaced with the language read by Dr. Butler regarding whether the equipment was energized or not. Is that correct?

COMMITTEE MEMBER BUTLER: Maybe I can clarify quickly. Basically, it is the September 30th letter, exempting the fourth bullet point, taking that out.

XII. CLOSING COMMENTS

Chairperson Taylor thanked everyone who assisted with, attended, and participated in the meeting. She then acknowledged that the CDPH will continue to partner with the regulated community in an effort to better serve the citizens of California and maintain the focus on public health and safety.

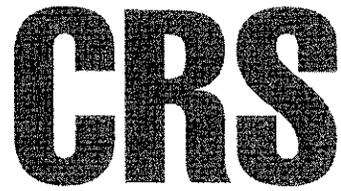
Chairperson Taylor provided information about the next RTCC meeting to be held in the Los Angeles area of Southern California on April 8, 2015.

Chairperson Taylor adjourned the meeting at 4:44 p.m.

XIII. APPENDICES

Attached are three letters received by the Radiologic Health Branch that were read aloud during the October 29, 2014 RTCC Meeting.

1. Letter from the California Radiological Society - October 24, 2014:
"Comments Re Exemption to Title 17, section 30450(a) (1) positioning of patients during fluoroscopy."
2. Letter from the American Federation of State, County and Municipal Employees, AFL – CIO (AFSCME) Local 3299 – October 29, 2014:
"Local 3299"
3. Letter from the California Nurses Association – October 28, 2014:
"Re: October 29th Agenda items Related to Fluoroscopy."



CALIFORNIA RADIOLOGICAL SOCIETY

A CHAPTER OF THE AMERICAN COLLEGE OF RADIOLOGY

October 24, 2014

Frieda Y. Taylor, M.S. Chairperson
Radiologic Technology Certification Committee
Radiologic Health Branch, MS 7610
P.O. Box 997414
Sacramento, Ca. 98599-7414

Comments Re Exemption to Title 17, section 30450(a) (1) positioning of patients during fluoroscopy

Dear Ms. Taylor,

We are writing to indicate the California Radiological Society's opposition to the changes contained in your revised exemption document dated September 30, 2014. This proposal would exempt non-permitted individuals under certain conditions from the need to obtain a fluoroscopy permit in order to move equipment or position the patients when under the direct oversight of a licentiate with either a Fluoroscopy Supervisor and Operator Permit or a Radiology Supervisor and Operator Certificate. We oppose both the logic and wisdom in the use of RHB authority to exempt these individuals from the need for a fluoroscopy permit.

An earlier version of this policy claimed that this change with respect to fluoroscopy was to align California regulators definition of fluoroscopy with the FDA definition stating that it was a "technique" and not a "procedure". Though that rationale is apparently abandoned in the revised policy statement we would like to point out that FDA makes no such distinction. The FDA regulation does state in Title 21, Code of Federal Regulations (21 CFR), Part 1020.30(b);

(b) Definitions. As used in this section and 1020.31, 1020.32, and 1020.33, the following definitions apply: ...Fluoroscopy means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission"

Elsewhere on the FDA's web site under main page on fluoroscopy: "Fluoroscopy is a type of medical imaging that shows a continuous X-ray image on a monitor, much like an X-ray movie. During a fluoroscopy procedure, an X-ray beam is passed through the body." Source:

<http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/ucm115354.htm>

So technically the FDA identifies fluoroscopy as both a type of medical imaging and a technique. The important factor is that **fluoroscopy is a source of ionizing radiation** and the purpose of the Radiation Control Law is to license such equipment and personnel who apply ionizing radiation to humans for

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medical purposes. In addition the FDA approves equipment and does not regulate or license personnel who operate ionizing radiation equipment.

The dangers of the misapplication of fluoroscopy are well known and the creation of an exemption for certain personnel to position equipment or the patient would directly undo patient protections that are found in section 30450(a) (1) and (a) (2) requiring only permitted individuals to perform these activities. RHB would seek to replace that permitting process with an unspecified promise of sufficient training and oversight that has no specific curriculum or hours of training and experience. We thought it would be appropriate to reference an existing American College of Radiology (ACR) standard on the performance of fluoroscopic procedures.

ACR–AAPM TECHNICAL STANDARD FOR MANAGEMENT OF THE USE OF RADIATION IN FLUOROSCOPIC PROCEDURES”, states:

Source: <http://www.acr.org/~media/f22c9d1ff46f43aab001f9ed0466b7e9.pdf>

“Fluoroscopy is frequently used to assist in a wide variety of medical diagnostic and therapeutic procedures, both within and outside of radiology departments. Fluoroscopic equipment capabilities have changed dramatically in recent years. The same fluoroscope may provide a number of operational modes, each of which is tailored to a specific clinical task. Modern fluoroscopic equipment is capable of delivering very high radiation doses during prolonged procedures. There have been reports of serious skin injuries in some patients undergoing certain fluoroscopically guided procedures [1-3]. Interventional procedures that do not result in a skin injury are not risk free to the patient. The risk of a stochastic injury later in life is elevated for pediatric patients who have a longer projected life span and are more radiosensitive in the first decade of life than are adults [4]. Therefore, the use of fluoroscopy in medical institutions must be proactively managed so that the levels of patient radiation exposures are appropriate for the medical demands of the procedures, taking into account risks and benefits. Management of the use of radiation must also ensure adequate safety of the medical personnel involved in these procedures. The intent of this standard is to assist physicians, Qualified Medical Physicists, radiologic technologists, and other ancillary personnel in achieving the above goal. Additional information regarding patient radiation safety in imaging is available from many reliable sources, including the Image Gently® for children (www.imagegently.org) and the Image Wisely® for adults (www.imagewisely.org) websites.”

References for this paragraph:

REFERENCES

1. Koenig TR, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: part 2, review of 73 cases and recommendations for minimizing dose delivered to patient. AJR 2001;177:13-20.
2. Koenig TR, Wolff D, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: part 1, characteristics of radiation injury. AJR 2001;177:3-11.
3. Shope TB. Radiation-induced skin injuries from fluoroscopy. Radiographics 1996;16:1195-1199.

We would respectfully request that this policy change be withdrawn and undergo review by the RTCC for possible revision. Existing regulation of personnel involved in the performance of fluoroscopy

procedures is necessary to assure adequate patient protection. The stated purpose of the policy is to address the concern that " existing regulations create an unsafe patient environment during certain surgical procedures". The presence of permitted fluoroscopy personnel does not create an unsafe environment and to the contrary enhances patient safety. RHB seeks to replace that protection with self enforcing education, experience and oversight that does not provide the same assurances. If one were to utilize this logic you could argue that since the operator/supervisor of a CT unit could attest to the competency of supporting personnel there would be no need for the presence of a certified RT. That is not the purpose or function of the Radiation Control Law.

We appreciate the opportunity to submit comments and look forward to working with RHB on this important policy discussion.

Sincerely,



Janak Raval, MD, FACR
President



Roger S. Eng, MD, MPH, FACR
Past President

LOCAL 3299

Frieda Y. Taylor, M.S., Chairperson
Radiologic Technology Certification Committee
California Department of Public Health
Sacramento, CA 95814

October 29, 2014

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Dear Ms. Taylor:

On behalf of 13,000 patient care technical workers at the University of California's five Medical Centers, AFSCME Local 3299 registers its concern over the Radiologic Technology Certification Committee's (RTCC) consideration to allow medical personnel not certified in fluoroscopy to position and operate fluoroscopy equipment. Weakening the standards by expanding who can operate such potentially dangerous equipment *without* proper certification will put both patients and medical personnel in California at risk.

Fluoroscopic equipment uses ionizing radiation to produce real-time moving images of the internal structures of a patient. Due to the length of a typical procedure and extended period of exposure, patients often receive a relatively high-absorbed dose. When not properly monitored and operated by someone certified in fluoroscopy, the slightest mistake could cause serious, radiation-induced injuries to patients, as well as unnecessary scatter radiation exposure to the operator and everyone else in the room.

It is for this very reason that the RTCC's consideration to possibly allow medical personnel not certified to position and operate fluoroscopy equipment could put California patients and medical personnel at risk of unnecessary exposure to radiation—even under the supervision of a physician. The specialized procedures that call for the use of fluoroscopy demand a higher degree of attention and expertise. Currently, physicians licensed and trained to use fluoroscopy employ the safest standards to protect their patients' health and safety. And, that includes certified Radiologic Technologists—trained in all technical factors and positioning considerations, and who understand how changing angles or tube/intensifier configurations can increase patient doses—to assist them.

Lowering the standards that currently ensure operators of fluoroscopy equipment have the proper education and training will put California patients and medical personnel at risk. In the name of patient and worker safety, we urge you to continue to require that only medical personnel certified in fluoroscopy be allowed to use extremely dangerous fluoroscopic equipment.

Sincerely,



Kathryn Lybarger, President
AFSCME Local 3299



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NURSES
ASSOCIATION

A Voice for Nurses. A Vision for Healthcare.



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Nurses
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October 28, 2014

Frieda Y. Taylor M.S.
Chairperson
Radiologic Health Branch
California Department of Public Health
Facsimile: (916) 341-7136

Re: October 29th Agenda Items Related to Fluoroscopy

Dear Ms. Taylor and RTCC Committee Members:

The California Nurses Association represents registered nurses who provide specialized care to patients in surgical suites, interventional radiology, and cardiac catheterization laboratories throughout California. As licensed professionals they are aware of the importance of certification and licensure as elements of consumer protection in the practice of radiology and radiography.

We understand that the Radiologic Technology Certification Committee may be considering changes that would allow non-radiologic personnel to operate fluoroscopy equipment in surgical suites and interventional radiology settings such as cardiac catheterization laboratories. Non-radiologic personnel would include physicians who are not radiologists, procedure technicians and registered nurses. We are very concerned when we hear that any procedure involving the use of fluoroscopy would be performed without personnel specifically certified to operate this equipment.

The Nation Cancer Institute (NCI) noted:

“The growing use and increasing complexity of [interventional fluoroscopy] procedures have been accompanied by public health concerns resulting from the increasing radiation exposure to both patients and health care personnel. The rise in reported serious skin injuries and the expected increase in late effects such as lens injuries and cataracts, and possibly cancer, make clear the need for information on radiation risks and on strategies to control radiation exposures to patients and health care providers.”¹

According to NCI:

“[M]ost interventional procedures require high quality images, long fluoroscopy time or both. Using appropriate operating parameters for x-ray machines will lower radiation doses to patients, and therefore to operators and assistants as well. It is critically important to adequately train operators and their assistants to use equipment that provides acceptable image quality along with the maximum possible dose-reduction, and to have

¹ <http://www.cancer.gov/cancertopics/causes/radiation/interventionalfluoroscopy/page1>

Frieda Y. Taylor M.S.
Chairperson
Radiologic Health Branch
California Department of Public Health
October 28, 2014

equipment regularly inspected and maintained. Physicians, technologists, medical physicists, fluoroscopy equipment manufacturers and medical and governmental organizations share the responsibility to optimize radiation doses to patients undergoing interventional fluoroscopy.”²

With these risks to patients and health care providers in mind, we respectfully suggest that the RTCC support the use of Certified Radiology Technologists only in any setting using fluoroscopy since these technicians have been specially trained in the use of this equipment. If you have any questions, please contact me at (916) 446-5019.

Sincerely,

CALIFORNIA NURSES ASSOCIATION/
NATIONAL NURSES UNITED



Donald W. Nielsen
Director, Government Relations

cc: Brendan White

² Id., p. 5