

Exposure Rates From Fluoroscopic Units

There are three regulatory parts in California that must be observed for fluoroscopic exposure rates, and there appears to be a good deal of confusion among operators, service personnel, physicists, and even the inspectors. The real (complicated) answer goes like this:

1. For All Fluoroscopic Equipment - Title 17 §30307(a)(7)(A)

With your equipment in its normal clinical operating mode, and with the California Standard Phantom (20 cm of Lucite) in the beam, and with the beam collimated to not less than 6 ¼ square inches, the exposure rate shall be as low as is practicable and shall not exceed 5 R/min.

And, pray tell, what is the normal clinical operating mode? Depends on the room, doesn't it? Many physicists and inspectors assume a typical "normal" mode would be an air contrast BE, for example.

2. For Fluoro Equipment Manufactured **after 8/1/74** AND Equipped with Automatic Exposure Rate Controls (AEC) - Title 17 §30307(a)(7)(B)

- a. *This equipment shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of 10 R/min except during recording of fluoroscopic images, or when an optional high level control is provided.*

In other words, if there is NO high level control then 10 R/min is the maximum allowable exposure rate in any equipment operating mode.

- b. *But when there IS an optional high level control provided, the unit may not operate at any combination of tube potential and current which will result in an exposure in excess of 5 R/min unless the unit is operating in the high level mode. And when operating in the high level mode, there must be a continuous audible alarm to tell the operator that they are in the high level mode.*

So with an optional high level control, what is the maximum exposure rate allowable, 10 R/min ? Nope, we need to keep going to find this answer.

3. For Fluoro Equipment Manufactured **after 8/1/74** AND NOT Equipped with Automatic Exposure Rate Controls (AEC) - Title 17 §30307(a)(7)(C)

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This equipment shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of 5 R/min except during recording of fluoroscopic images, or when an optional high level control is provided.

But there is no mention of what the maximum allowable is when in the optional high level mode. Is it 10 R/min ?? Nope !!! Keep reading – one more piece of the puzzle to go.

4. Title 17, Article 4, §30305(a)(4) says you must also comply with the federal regulations found in 21 CFR, Chapter 1, Subchapter J, Part 1020, Sections 1020.30, 1020.31, and 1020.32.
 - a. Section 1020.32 says, *for fluoro equipment manufactured after 5/19/95 which can be operated at any combination of tube potential and current that results in an exposure rate greater than 5 R/min shall be equipped with Automatic Exposure Control (AEC), **and***
 - b. *fluoro equipment shall not be operable at any combination of tube potential and current that results in an exposure rate greater than 10 R/min, **except***
 - c. *when in a cine mode, **or***
 - d. *when an optional high level control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that results in an exposure rate greater than 20 R/min.*

Now it's all clear – like mud !!

The bottom line is the allowable exposure rate depends upon the age of the equipment and whether or not it is equipped with AEC and whether or not it is equipped with a high level control and the mode is which the equipment is being operated.

These regulations pertain to all fluoro units: over-table; under-table; c-arms; mobile c-arms; tomo units; cysto units; angio units; cath units; EP units; and so forth.

I have taken the liberty to paraphrase from Title 17 and 21 CFR, but I believe I have correctly interpreted these venerable regulations.

I recommend you print this information to hardcopy and keep it on file. In the event you are faced with someone who tells you otherwise, provide them with a copy for their reading pleasure.