

# CARES and State Regulations

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# Who regulates radiation in the US?

11 Federal Agencies  
with some regulation  
of radiation

50 states plus at  
least three  
additional local  
entities

Various professional  
organizations,  
councils and groups

- CRCPD and OAS
- AAPM, ACR, ASRT, ASTRO

# Who regulates?



## Federal Entities

- US Food and Drug Administration - regulates the manufacture of medical devices
- US Nuclear Regulatory Commission- Regulates the use of Radioactive Material in Federal facilities and non-agreement states



# Who Regulates?

## States and Local Entities

- Regulate the use of both x-ray devices and Radioactive Material in their state
- Regulate/approve licensure for physicians, technologists and physicists in their state
- Can be multiple state agencies involved

# How does this apply to gonadal and fetal shielding?

FDA has petitioned to remove the shielding recommendation in CFR

46 of 50 states currently have regulations directly or indirectly referencing fetal and/or gonadal shielding

Each state's process to change regulation is different-usually takes about one year to change a state's regulations

CRCPD's suggested state regulations have "model" regulations for states to adopt- IF THEY WANT, some states are required to adopt verbatim-others can revise

# CRCPD Suggested State Regulation Part F- Shielding - note NO reference to gonadal/fetal

## MEDICAL DIAGNOSTIC AND INTERVENTIONAL X-RAY AND IMAGING SYSTEMS

### Section F.3 General and Administrative Requirements

- a.vi. A sufficient number of protective apparel (e.g., aprons, gloves, collars) and shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with x-ray operations.
- a.vii. All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with their lead equivalence.

# Sample Regulation: Louisiana (X-Ray Regs)

## 603 General and Administrative Requirements

603.A.6. Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, ***except for cases in which this would interfere with the diagnostic procedure.***  
*(what we call the “escape clause”)*

Most states have this “escape clause” language in their existing regulations.

# What are states doing?

Some are beginning the rulemaking process to remove gonadal shielding from their regulations

Some are dealing with facilities on a case by case basis

Some are not enforcing their current regulation on gonadal shielding (using the escape clause)

Some are not changing anything



# What should my facility do?

First- contact you state radiation control office

- [https://www.aapm.org/government\\_affairs/licensure/default.asp](https://www.aapm.org/government_affairs/licensure/default.asp)
- Find out what they are doing with regards to gonadal shielding

Have a plan

- Prepare the changes that you hope to make to your procedures
- Present these to you state agency

Ask for an exemption to the current regulation if applicable

- Get a written exemption to keep for future inspections

# State regulations apply to many different types of facilities



# Why are you telling me this?

Education of ALL of these is crucial

Regulations do not exist in the ideal bubble

Most facilities that are registered with a state DO NOT have a radiologist or physicist on site and/or on staff to help with this

Many facilities do not have a registered x-ray technologist

Gonadal and Fetal shielding is NOT ALL shielding

# So what can happen?

No changes are needed to the CRCPD Suggested State Regulations, Part F since gonadal and fetal shielding are not mentioned specifically

Some states are changing the requirement for gonadal and fetal shielding but this takes time.

Ask for an exemption from you state requirement-be ready to justify why

# So what happens?

There are lots of people involved-Cares is doing an excellent job with this

It is important that we deliver our “message” in a positive manner

The “message” we deliver needs to be cognizant of all levels of understanding

Thank you!

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