

# Regulations and Gonadal Shielding

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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

(As of May, 2022; no action has been taken on this petition)

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



# State Regulation Status Update:

- ▶ As of May, 2022;
- ▶ Vermont has updated regulation to remove reference to gonadal shielding
- ▶ New Jersey will accept exemptions to the requirement and are planning to change their regulations
- ▶ Utah and Vermont require shielding to be available if requested
- ▶ South Carolina and Louisiana are updating regulations with gonadal shielding references removed
- ▶ Nebraska and Florida have issued guidance/information about not using shielding that will interfere with the exam

# What has been the push back at the state level?

- ▶ In all states, the pushback is coming primarily from technologists
- ▶ Physicists are agreeing with the recommendations and helping with regulation issues
- ▶ RSO's seem to be following the physicists lead
- ▶ Some states have discussed training on this issue especially as it in regards to other types of shielding

# 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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