

Computed Tomography Issue Submittal Form

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ONE ISSUE PER FORM

- WAC 246-226-001 Authority
- WAC 246-226-005 Purpose and scope
- WAC 246-226-007 Relationship to other regulations
- X WAC 246-226-010 Definitions, abbreviations, and acronyms
- WAC 246-226-020 Equipment requirements
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Description of Concern (cite subsection as appropriate):

(4) What does "Not applicable to helical scan acquisition." mean in this context. CTDIvol, with its correction for pitch factor was designed to give a rough absorbed dose estimate for helical acquisitions.

Description of Solution (cite subsection as appropriate):

Redefine

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Kalpana Kanal

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Description of Concern (cite subsection as appropriate):

(6), "CT medical director", unclear what this needs to be...

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

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Description of Concern (cite subsection as appropriate):

(12), recommend change:

Description of Solution (cite subsection as appropriate):

""DLP (dose length product)" means the product of the average CT DIvol and the scan length of a group of scans. This number can be calculated over the entire CT procedure to give an estimate of the total absorbed dose to a reference phantom."

Public Health Significance:

Potential Costs (Licensees or Department):

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Description of Concern (cite subsection as appropriate):

(37) Technique factors -- should effective mAs (like for Siemens) also be defined - it causes confusion

Description of Solution (cite subsection as appropriate):

Include definition

Public Health Significance:

Potential Costs (Licensees or Department):

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Description of Concern (cite subsection as appropriate):

CT Protocol is not defined.

Description of Solution (cite subsection as appropriate):

Define CT Protocol as "setting and parameters that fully describe a CT examination.

Use CT Protocol in several areas throughout the regulations where "CT Procedure" is used.

- WAC 246-226-040 (2)(c) Change to "Send each CT protocol page"
- WAC 246-226-040 (3) Change to "the registrant shall establish CT protocols"
- WAC 246-226-040 (3)(a) "Display pediatric CT protocols"
- WAC 246-226-040 (3)(b) "from changing CT protocols" and "Documentation of CT protocol"
- WAC 246-226-040 (4) "to make CT protocol"
- WAC 246-226-040 (5) "The registrant shall review all CT protocols"

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Jeremy L. Corwin

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Description of Concern (cite subsection as appropriate):

(3) this definition of CTDI is somewhat convoluted, providing a standard equation is appropriate.

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

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Description of Concern (cite subsection as appropriate):

(11) change to 'as a function of position along the scan direction.'

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

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Description of Concern (cite subsection as appropriate):

(1)(a) requires a visible signal that indicates when exposures have terminated. It is more appropriate to have a visible signal that represents when exposures are being made.

Description of Solution (cite subsection as appropriate):

Alter language of section to say "a visible signal that indicates the production of x-rays" or something similar. Most scanners are already equipped in this manner, and this is likely the intention of this section, but the wording is unclear.

Public Health Significance:

The operator should be aware of when the equipment is exposing the patient for the entire duration of the exposure in case of any abnormality so that they may attempt to stop the exposure.

Potential Costs (Licensees or Department):

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Description of Concern (cite subsection as appropriate):

WAC 246-226-030 (2) and (4) specifies that “exposure does not exceed dose limits”. Exposure and dose are two different quantities.

Description of Solution (cite subsection as appropriate):

Change the regulations to read “to ensure dose does not exceed dose limits”

Public Health Significance:

Potential Costs (Licensees or Department):

No additional costs.

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Description of Concern (cite subsection as appropriate):

WAC 246-226-030 (2) specifies that a survey shall be conducted within 12 months. There is no need to wait 12 months as a physicist is required to evaluate the new system immediately or within 30 days. See WA 246-226-090.

Description of Solution (cite subsection as appropriate):

Change the regulations to read "Within 30 days" instead of "Within 12 months".

Public Health Significance:

Discrepancies with inadequate shielding can be found rather fast (30 days) compared to one year, possibly saving exposure to folks that were not expecting it.

Potential Costs (Licensees or Department):

No additional costs.

Submitted By: Jeremy L. Corwin

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Description of Concern (cite subsection as appropriate):

"(1) For the purposes of this section, the estimated patient dose is equal to the DLP. DLP is calculated by multiplying the CTDI_{vol} by scan length."

I think this will lead to more misunderstanding in the field. Patient dose (absorbed dose or effective dose) is not equal to DLP. It is proportional to DLP, but not equal. Saying "estimated patient dose" is equal to DLP will be misleading for providers and patients.

Description of Solution (cite subsection as appropriate):

Recommend changing all references to:

"estimated patient dose" to "patient-specific x-ray technique" or "patient-specific x-ray flux"

Public Health Significance:

Potential Costs (Licensees or Department):

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Description of Concern (cite subsection as appropriate):

Reporting DLP values as estimated patient doses will cause confusion. If DLP values are to be communicated to the patient, it should be clear that they do not represent the specific patient's dose.

Description of Solution (cite subsection as appropriate):

Simply removing language that equates dose and DLP would suffice. Though there are simple methods to approximate effective dose from DLP, the relationship is complicated and many assumptions are made. Providing the DLP information if requested is appropriate, but it should be clear that the numbers do not represent the individual patient dose.

Public Health Significance:

For many patients, particularly pediatrics, the DLP as reported by the scanner can give a very distorted picture of the dose and risk incurred by the procedure. This can cause unnecessary concern and anguish for these patients and their families. If a patient or their guardian is to make an informed decision regarding the use of ionizing radiation, the risks need to be clearly communicated, rather than a number which may not be directly applicable to the particular patient.

Potential Costs (Licensees or Department):

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Description of Concern (cite subsection as appropriate):

(1) I am a little uncomfortable with just requiring DLP for the dose that needs to be reported. CTDIvol and DLP are both often very inaccurate indicators of patient dose (they are primarily a means of assessing CT output or comparing the dose implications of protocols and protocol changes).

Description of Solution (cite subsection as appropriate):

The California regulations require CTDIvol and DLP "or "the dose unit as recommended by the AAPM". In doing so, I believe that they left the door open for using SSDE (Size Specific Dose Estimates) as the dose unit to be reported. It seems to me that the industry is moving quickly to advocate SSDEs as the best unit for reporting dose estimates in a patient record. SSDEs are still dose "estimates", but they are considerably closer to actual patient dose than either CTDIvol or DLP. Consequently, it makes sense to me that the Washington regulations incorporate similar language so that the regulations do not become outdated as soon as SSDE is accepted.

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Larry Neubauer

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- Other category

Description of Concern (cite subsection as appropriate):

Requiring that the “Estimated Dose” (defined as DLP in this section) be recorded for every exam and be made available to the patient within 10 days of a request) is problematic. CTDIvol and DLP are effective parameters for comparing one scanner to another or one protocol to another, but they are at best a very poor indicator of dose for a specific patient. Since these values are based on either a 16cm or 32cm circular acrylic phantom and actual patients vary greatly in size, shape, and composition, it is misleading to call this value the “estimated dose” and to allow the patient to think that is an approximation of their dose.

Description of Solution (cite subsection as appropriate):

It would make sense to require that both CTDIvol and DLP be recorded for each exam, but it does not seem appropriate to provide it to patients as “estimated dose” . Currently, the profession is moving rapidly toward recommending a new dose parameter called the Size Specific Dose Estimate (SSDE), which provides an estimated dose that is based on the effective diameter of patient (which is determined from measurements of a patient’s AP and Lateral dimensions). SSDE is likely to become the dose metric of choice in the near future and the Washington draft CT regulations, as they are currently written, do not allow for this parameter to be used.

Public Health Significance:

Providing DLP to the patient as an “estimate dose” is confusing and misleading.



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Potential Costs (Licensees or Department):

It would be costly to licensees to have to spend time and effort explaining to patients why the “estimated dose” that is provided to them is not actually a good estimate of their dose.

Submitted By: Lawrence Neubauer

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Description of Concern (cite subsection as appropriate):

(3) (a) display pediatric CT procedures, even if possible use is very low

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

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Description of Concern (cite subsection as appropriate):

(5) after initial review, review just up to 6 of the most common and be informed of significant changes to others

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Kalpna Kanal

Computed Tomography Issue Submittal Form

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Description of Concern (cite subsection as appropriate):

WAC 246-226-040 (5) specifies that all CT protocols shall be reviewed annually. Many scanners have up to 100 protocols, with many of them not used frequently. An annual review of all protocols would require more time on the system and hence less time for patients. Current guidance (AAPM Practice Guideline 1: CT Protocol Management and Review Practice Guideline) recommends that all protocols be evaluated initially and then the major protocols (clinically significant protocols) be evaluated annually.

Description of Solution (cite subsection as appropriate):

Change the regulations to read that all protocols will be reviewed upon installation (or within 1 year of these regulations). Each facility shall eliminate protocols that are not used. A protocol review will be conducted annually on the clinically significant protocols (Pediatric Head, Pediatric Abdomen, Adult Head, Adult Abdomen, High Resolution Chest, and Brain Perfusion) and any protocols that have been changed since the initial review. If the facility does not perform the exams listed above then additional protocols must be selected for review, either the most frequently performed or higher-dose protocols, so that a total of at least six protocols are reviewed annually.



ISSUE # 14

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Computed Tomography Issue Submittal Form

Public Health Significance:

Potential Costs (Licensees or Department):

There will be reduced time spent on the scanner and reduced time by the CT physician, Medical Director, CT technologist, and physicist in management of the protocols.

Submitted By: Jeremy L. Corwin

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Description of Concern (cite subsection as appropriate):

(5)(a) For the protocol reviews the "Radiation Safety Officer" is not included. The concern is that for the larger institutions with designated Radiation Safety Officers who are not necessarily physicians (i.e. physicist) this is with the scope of practice of the Radiation Safety Office/Radiation Safety Committee.

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: John Gough

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Description of Concern (cite subsection as appropriate):

Reference levels are noted in the table but are not referred to nor regulated. These will lead to confusion.

Description of Solution (cite subsection as appropriate):

Eliminate the Reference Levels column of the table in WAC 246-226-050.

Public Health Significance:

Potential Costs (Licensees or Department):

None.

Submitted By: Jeremy L. Corwin

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Description of Concern (cite subsection as appropriate):

Clarify the assumed age/weight for pediatric head limit (suggest matching the ACR limits). Also, specifically delineate the assumed CTDI phantom size (16- or 32-cm phantom) for each limit and reference level.

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Kalpana Kanal

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Description of Concern (cite subsection as appropriate):

2A, "A 1500 mGy or larger dose of ionizing radiation as estimated by the CT X-ray system's software, or as calculated by a qualified medical physicist, delivered to any organ or tissue of a patient within a time period of 24 hours."

How will a site estimate 1500 mGy to an organ. Should this just be a CTDIvol limit?

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Kalpana Kanal

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Description of Concern (cite subsection as appropriate):

Section 060 exceeds the authority of the Department of Health (DOH) while exposing the DOH and facilities that perform imaging procedures to legal implications. CT events are not classified under state law as 'serious reportable events' and DOH does not have the authority at this time to classify CT events as reportable. Washington State adopted 29 serious reportable events identified in Chapter 70.56. These events have been recognized by the National Quality Forum.

Information, data, conversations, etc. between the DOH and other bodies is discoverable and open to public disclosure rules as noted in the draft rule. It is not clear how the DOH would track 'injurious health effects,' identify trends, or provide meaningful assistance while ensuring information and material remain free from discovery. Information that becomes discoverable may undermine the intent of this section. Additionally, it is not clear what role, if any, the DOH should play in a facilities conducting and using internal root cause analysis to improve patient safety.

Quality improvement and patient safety is a serious issue and one which is receiving wide spread attention. The proposed patient safety efforts under 060 will fall short of their intended goal(s) as it lacks the ability to coordinate state wide quality improvement efforts, aggregate meaningful trend data, and promote system wide change as part of a 'just culture'.



ISSUE # 18B

FOR DOH USE ONLY

Computed Tomography Issue Submittal Form

Description of Solution (cite subsection as appropriate):

The DOH and other stakeholders should acknowledge and support safe imaging initiatives already under way in Washington State. WSHA is leading a 'Safe Imaging' initiative in Washington and has broad support from a range of stakeholders who are committed to improving quality and patient safety. These efforts are already under way, have the ability to aggregate state wide data to identify trends and are well positioned to support state wide change. WSHA staff would like to present our current initiatives around safe imaging to the CT Advisory Committee.

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Ian Corbridge (WSHA)

Computed Tomography Issue Submittal Form

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- Other category

Description of Concern (cite subsection as appropriate):

The current section (2) defines an event as either (a) ≥ 1.5 Gy organ dose (b) unanticipated permanent functional damage/hair loss/erythema. The former requires foreknowledge of accumulated 'max z-location CTDIvol' and integration of studies over a 24 hr period. Getting actual organ dose is a complicated process that is not immediately available. The latter assumes the hospital is aware of deterministic tissue effects after a patient potentially departed the hospital/clinic. In short, this requirement is practically un-followable.

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Kalpana Kanal

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Description of Concern (cite subsection as appropriate):

Section 070, specifically subsection (b) stipulates requirements for medical physicists which could: 1) limit the ability of newly graduated medical physicists to practices in Washington State, 2) limit the available workforce of medical physicists in Washington State, especially in rural areas, and 3) compromise access to essential services.

Furthermore, subsection (b) stipulates that medical physicists must 'hold a graduate degree from an accredited institution in medical physics.' If a graduate degree from an accredited institution is required, why does the draft language specify specific courses a medical physicist must have taken? If these are important concepts then wouldn't these course be a part of a graduate program?

Description of Solution (cite subsection as appropriate):

- Strike existing language regarding work year requirements or if research supports a residency/training program then speak to the value of entities supporting such as program as appropriate/feasible.
- Strike language regarding specific course requirements.

Public Health Significance:

Ensuring access to medical physicists and associated services throughout Washington State.

Potential Costs (Licensees or Department):

Submitted By: Ian Corbridge (WSHA)

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Description of Concern (cite subsection as appropriate):

Continuing education credits for qualified medical physicists – Regarding CE, the document you reference is for board certified by the ABR, and I believe it is only for doctors.

Description of Solution (cite subsection as appropriate):

A better reference would be the ACR CT program accreditation requirements which specify that 15 CEs are required every 3 years but only one of them must be in CT.

Public Health Significance:

Potential Costs (Licensees or Department):

n/a

Submitted By: Department of Health on behalf of Physics Group

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Description of Concern (cite subsection as appropriate):

The last sentence of section 246-226-070 (3)(C) implies that a physicist who qualifies under provision (3)(C) would no longer be qualified after a specified date, which does not make sense.

Description of Solution (cite subsection as appropriate):

It is recommended that the last sentence of this section be omitted to avoid confusion.

Public Health Significance:

There does not appear to be a public health impact to making this change.

Potential Costs (Licensees or Department):

There is no cost to making this change.

Submitted By: Lawrence Neubauer

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Description of Concern (cite subsection as appropriate):

(1) (c) and (e) Laser printer quality control should only be applicable to sites that use printed images for primary interpretation. There is no need for quality control on the printer units at these intervals if the site has a legacy printer.

Description of Solution (cite subsection as appropriate):

Include language that exempts sites who do not use printed images for primary interpretation

Public Health Significance:

Potential Costs (Licensees or Department):

Labor costs for these tasks.

Submitted By: Kalpana Kanal

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Description of Concern (cite subsection as appropriate):

246-226-090 (2) (j) specifies that a performance evaluation must evaluate Dosimetry, including "Patient radiation dose for preventative CT procedures." I am unsure what a CT preventative procedure is and why the dosimetry would need to be evaluated for these specific procedures if the protocols are to be reviewed annually.

Description of Solution (cite subsection as appropriate):

Eliminate (J)(ii), Patient radiation dose for preventative CT procedures.

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Jeremy L. Corwin

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Description of Concern (cite subsection as appropriate):

There are several tests that are really not valuable and are not currently prescribed by the ACR.

(2)(b) Alignment of Table to Gantry

(2) (c) Evaluation of table and gantry tilt

(2) (n)(v). Dose profile

(2)(p) Deviation of scan increment verses actual scan increment (already tested in (2)(e))

Description of Solution (cite subsection as appropriate):

Eliminate the tests noted above.

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Jeremy L. Corwin

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Description of Concern (cite subsection as appropriate):

(2)(b) I am unaware of a standard way to test the alignment of the table to the gantry, suggest removing this from the requirements on an annual basis

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Kalpana Kanal

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- WAC 246-226-140 Mobile CT x-ray systems used for head and neck imaging
- Other category

Description of Concern (cite subsection as appropriate):

(2)(c). Clarify language to note that table motion and gantry tilt accuracy are evaluated

Description of Solution (cite subsection as appropriate):

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Kalpna Kanal

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- WAC 246-226-001 Authority
- WAC 246-226-005 Purpose and scope
- WAC 246-226-007 Relationship to other regulations
- WAC 246-226-010 Definitions, abbreviations, and acronyms
- WAC 246-226-020 Equipment requirements
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Description of Concern (cite subsection as appropriate):

246-226-090 (1) specifies that a performance evaluation must be conducted initially, before using the CT system. I think we should grant flexibility with the initial performance evaluation. Conducting the initial evaluation prior to clinical use does not give the site time to adjust their protocols/work with applications specialists. I suggest we have an evaluation within 30 days if the system passes all manufacture tests upon installation. This is in agreement with ACR's guidelines, and will also reduce the number of visits by the physicist if the site is accrediting.

Description of Solution (cite subsection as appropriate):

Change (1)(a) to read "within 30 days of installation if the system passes all manufacture installation tests upon installation."

Public Health Significance:

Potential Costs (Licensees or Department):

This will save the facility from needing several different physics evaluations due to one installation.

Submitted By: Jeremy L. Corwin

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Description of Concern (cite subsection as appropriate):

246-226-100 (1)(d) specifies that “the distance in millimeters between the tomographic plane and the reference plane” be posted. I’m not sure why this would need to be posted and what its impact would be.

Description of Solution (cite subsection as appropriate):

Discuss the need for this posting at the meeting.

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Jeremy L. Corwin

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Description of Concern (cite subsection as appropriate):

WAC 246-226-110 (2)

Description of Solution (cite subsection as appropriate):

Change to:

Registrants using PET/CT or SPECT/CT X-ray systems solely for PET or Nuclear Medicine exams, with no diagnostic quality CT examinations or no reimbursement requests for CT exams with CT CPT codes, are exempt from the requirements of this chapter, except that the registrant shall comply with WAC 246-226-090, Performance evaluation.

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Kalpna Kanal

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Description of Concern (cite subsection as appropriate):

I am unsure why PET/CT, SPECT/CT, and CT Sim are exempt from these regulations, particularly when some of these systems obtain diagnostic CT's. These systems use CT technology, and can give doses commensurate with diagnostic CT, and sometimes are used for diagnostic CT exams. It is unclear why they would not be subject to dose limits, protocol management, operational requirements, etc.

Description of Solution (cite subsection as appropriate):

Discuss the exemption at the meeting. Determine if there are more relevant factors to exclude a CT scanner from the regulations.

Public Health Significance:

Potential Costs (Licensees or Department):

Submitted By: Jeremy L. Corwin

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Description of Concern (cite subsection as appropriate):

For 246-226-120 and 246-226-130, radiation from CT in PET/CT, SPECT/CT, and CT simulators carries the same health risk as radiation from CT used for other purposes.

Description of Solution (cite subsection as appropriate):

Do not exempt CT scanners in POET/CT, SPECT/CT, and CT simulators from the rules for CT

Public Health Significance:

Many of the patients who have PET/CT, SPECT/CT, or CT simulation are either young or are being diagnosed/treated for curable diseases so are subject to the same long term radiation risks as patients getting CT for other reasons.

Potential Costs (Licensees or Department):

No greater than for other types of CT scanners. Scanners associated with PET/CT, SPECT/CT, and CT simulation all can meet the same requirements as other types of diagnostic CT scanners

Submitted By: William P. Shuman, MD FACR, FSCBTMR