



ISSUE #

FOR DOH USE ONLY

### Computed Tomography Issue Submittal Form

The Department of Health is developing rules for Computed Tomography (CT). In order for proposals to be considered by the CT Advisory Committee, each proposal must be submitted using this form and include a compelling public health reason for the change. Issues raised during meetings do not need to be submitted on an Issue Submittal Form.

**Proposals must be received by the Department of Health no later than 2 weeks prior to meeting.**

#### ONE ISSUE PER FORM

- WAC 246-226-001 Authority
- WAC 246-226-005 Purpose and scope
- WAC 246-226-010 Definitions, abbreviations, and acronyms
- WAC 246-226-020 Requirements for equipment
- WAC 246-226-030 Facility design requirements
- WAC 246-226-040 CT Facility accreditation
- WAC 246-226-050 Operating procedures and conditions of operation
- WAC 246-226-060 Dose limits
- WAC 246-226-070 Required notification of a CT adverse health event
- WAC 246-226-080 CT personnel qualifications
- WAC 246-226-090 Periodic CT performance evaluations and quality control
- WAC 246-226-100 Required records and reports
- WAC 246-226-110 Requirements for low power (5 kW or less) CT scanners and conebeam scanners
- WAC 246-226-120 Requirements for positron emission tomography (PET/CT) or single photon emission computed tomography (SPECT/CT) systems
- WAC 246-226-130 Requirements for CT simulators used exclusively for treatment planning purposes in conjunction with a megavoltage radiation therapy unit
- Other category

#### Description of Concern (cite subsection as appropriate):

(1) Effective July 1, 2014, a registrant that uses a computed tomography (CT) X-ray system for human use shall record the patient dose (CTDI<sub>vol</sub> or DLP) of radiation on every CT study produced during a CT examination. This will be done by either recording the dose within the patient's radiology report or attaching to the radiology report the protocol page that includes the dose of radiation.

(2) The registrant conducting the study shall electronically send each CT study and protocol page that lists the technical factors and dose of radiation to the electronic Picture Archiving and Communications System (PACS).

(3) The displayed dose on the CT console shall be verified annually by a medical physicist to ensure the displayed doses are within 20 percent of the true dose measured in accordance with WAC 246-226-080 (6) below.

(4) For the purposes of this section, dose of radiation shall be defined as one of the following:

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- (a) The computed tomography index volume ( $CTDI_{vol}$ ) and/or dose length product (DLP), as defined by the International Electrotechnical Commission (IEC) and recognized by the federal Food and Drug Administration (FDA).
- (b) The dose unit as recommended by the American Association of Physicists in Medicine (AAPM).
- (5) Six months after the effective date of these rules, the CT registrant shall establish scanning protocols in consultation with a medical physicist. In addition,
- (a) Each registrant shall review all of their CT default protocols every six months to ensure they are correct and are the intended protocols. Comparison should be made to the initial dose assessments that were made at the time of installation and those made during the last annual review by the medical physicist. The protocol review shall be conducted by a combination of the lead CT interpreting/supervising physician, CT medical director or CT Department Manager, the medical physicist and lead CT technologist. The evaluation or review shall determine whether the ( $CTDI_{vol}$ ) from current protocols is appropriate or whether there is an opportunity to reduce the technique and lower the  $CTDI_{vol}$  without an unacceptable sacrifice in image quality. *Written and signed documentation of this 6-month review shall be made and kept available for inspection for each CT unit at the facility.*
- (b) The approved protocols shall ensure that image quality remains at the desired noise level and results in acceptable dose levels according to standards found in WAC 246-226-090. Once approved, the protocols should be recorded and guidelines of variability established. The limits of the variability range shall be approved by the CT medical director or lead CT interpreting/supervising CT physician. Technologists are permitted to adjust protocols as long as they remain within the approved limits of variability. *Any changes in a protocol shall be documented and approved by the lead interpreting/supervising CT physician with signature and date of approval.*
- (c) Procedural, software or engineering measures such as password protection shall be in place that prohibit anyone from changing protocols without approval from the CT medical director, lead CT technologist or lead interpreting/supervising CT physician.
- (d) If the CT system in use at a facility has the capability of automatic tube current modulation or other dose reduction features for CT examinations, it shall be a component of appropriate examination protocols as determined by the lead CT interpreting/supervising physician.
- (e) Pediatric CT protocols shall be available on each CT scanner and used when children undergo CT examinations.
- (f) *Each CT registrant shall assure that CT manufacturer's technical and/or applications representatives are not permitted to make protocol changes or other software changes or upgrades that would impact radiation dose or image quality without the approval of the lead CT interpreting/supervising physician, the lead CT technologist or the medical physicist.*
- (8) The CT operator shall check the display panel before and after performing each scan to make sure the amount of radiation delivered is appropriate for the exam and individual patient. This may be accomplished by reviewing dose indicator devices if available or dose indices such as the technique factors. Dose indicators or indices outside of expected values shall be documented and reviewed by an interpreting physician or medical physicist.

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(9) *Each CT facility shall have a written policy approved by the medical director or lead CT interpreting/supervising physician that establishes internal rules for retaking CT exams, i.e., how many are authorized on a patient, who can authorize additional retakes, etc.*

(10) Staff personnel routinely working with or around radiation sources shall not be required by the registrant to restrain patients during CT examinations. If such procedure is permitted personnel exposure shall not exceed the limits in WAC 246-221-010 or the procedure is prohibited.

(11) When a patient must be held in position for CT, mechanical supporting or restraining devices shall be used unless contraindicated. If the patient must be held by an individual, this individual shall wear protective gloves and a protective apron of 0.5 millimeter minimum lead equivalence and be so positioned that no part of his or her body will be struck by the useful beam and that his or her body is as far as possible from the edge of the useful beam.

(12) Only individuals whose presence is necessary are allowed in a fixed CT scanner room during exposure. Each individual, except the patient, shall be protected by at least 0.5 millimeter lead equivalent aprons or a whole body protective barrier.

(13) Personnel monitoring is required in controlled areas for each individual occupationally exposed to ionizing radiation from CT scanner equipment. Personnel monitoring devices shall be permanently assigned to each occupationally exposed individual. Monitoring shall be continuous during employment as a radiation worker.

(14) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.

(15) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with WAC 246-221-090.

(16) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he or she is exposed as a patient for any medical or dental reason.

(17) A CT scanner shall not be left unattended without locking the apparatus, room, or building in some manner which will prevent use of the apparatus by unauthorized persons.

### **Description of Solution (cite subsection as appropriate):**

Remove manufacturer specific requirements. These are already required in 21 CFR. No need for it in WA rules.

1. Delete 1.
2. Add after PACS - *or may be documented in another electronic system for ease of access when required.*
3. Change 3 to - The displayed CTDIvol on the CT console shall be verified annually by a medical physicist for an adult routine head and adult routine abdomen protocol to ensure the displayed doses are within 20 percent of the measured dose in accordance with WAC 246-226-080 (6) below or within physicist recommendations.

Move this to physics section, 090

Also, could not find WAC 246-226-080 (6)

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4. Move 4 to 1.
5. Combine a and b and modify as follows:

A protocol review committee, consisting of the lead CT interpreting/physician, the medical physicist, and the lead CT technologist shall review all clinically used CT scan protocols at acceptance testing. Thereafter, the following 6 scan protocols (at a minimum) should be reviewed annually:

Pediatric Head, Pediatric Abdomen, Adult Head, Adult Abdomen, High Resolution Chest, Brain Perfusion

Facilities that do not perform all of the exams listed above must select additional scan protocols at their facility (i.e. the most frequently performed or the higher-dose protocols) up to a total of at least six reviewed protocols or more if desired.

Scope of Protocol Review. Acquisition parameters (kV, mA, rotation time, collimation or detector configuration, advanced dose reconstruction techniques, pitch, etc.) should be reviewed to ensure they are appropriate for the diagnostic image quality necessary for the clinical indications for the protocol while minimizing radiation dose. The facility shall review the  $CTDI_{vol}$  for each CT scan protocol and compare the value to the reference value of the ACR CT Accreditation Program, Dose Reference Levels, AAPM CT Protocols, or other published reference values for the appropriate protocols if available. For a facility's routine protocol for an average sized patient, the expected  $CTDI_{vol}$  shall be below these reference values.

Written and signed documentation of this annual review shall be made and kept available for inspection for each CT unit at the facility. Once approved, the protocols should be recorded and any changes in a protocol shall be documented and approved by the lead interpreting/supervising CT physician with signature and date of approval.

(c) Change to - Procedural, software or engineering measures such as password protection, where available shall be in place that prohibit anyone from changing protocols without approval from the CT medical director, lead CT technologist, medical physicist or lead interpreting/supervising CT physician.

(d) Delete

(e) For scanners that may potentially be used to scan pediatric patients (patient age < 18 years), pediatric specific CT protocols shall be available on the CT scanner and used for children undergoing CT examinations.

8. This should be numbered 6.  
Change to - The CT operator shall check the display panel before and after performing each scan to make sure that the technique and/or the amount of radiation to be delivered or delivered is appropriate for the exam and individual patient. This may be accomplished by reviewing dose indicator devices if available or dose indices such as the technique factors.
9. This should be numbered 7.  
Change to - Each CT facility shall have a written policy approved by the medical director or lead CT interpreting/supervising physician that establishes rules for reacquiring additional CT exams under the same



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study (i.e., retakes of the same body region). Departmental Policy shall establish measures to limit repeat exams.

10. This should be numbered 8.

11. This should be numbered 9.

12. This should be numbered 10.

13. This should be numbered 11.

Change to - Personnel monitoring is required in accordance with WAC 225-221-090.

14-16. Delete

17. This should be numbered 12. We would like to bring this up for discussion with whole group. There was a lot of discussion among physicists.

### Public Health Significance:

None

### Potential Costs (Licensees or Department):

None

**Submitted By:** Physicists Group

**Return completed form to:** Michelle K. Austin, Rules Coordinator, [michelle.austin@doh.wa.gov](mailto:michelle.austin@doh.wa.gov)