



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):

Many rules pertain to equipment requirements for manufacturer (21CFR).

- (1) Termination of exposure.
 - (a) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.
 - (b) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by WAC 246-226 (1)(a).
 - (c) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

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- (2) Tomographic plane indication and alignment
 - (a) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.
 - (b) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.
 - (c) If a device using a light source is used to satisfy the requirements of WAC 246-226 (2) (a) and (b), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.
- (3) Beam-on and shutter status indicators and control switches.
 - (a) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.
 - (b) Each emergency button or switch shall be clearly labeled as to its function.
- (4) Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.
- (5) Extraneous Radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by WAC 246-225-040(3) and (4).
- (6) Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.
- (7) Additional requirements applicable to CT X-ray systems:
 - (a) The total error in the indicated location of the tomographic plane or reference plan shall not exceed 5 millimeters.
 - (b) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.
 - (c) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.



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(d) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

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(a)
2. Delete 2
3. Delete 3(a), Move 3b to 1.
4. Move 4 to the section on hybrid (special) systems
5. Change Extraneous to Leakage
6. Delete 6
7. Change 7a to - The accuracy of the laser or optical positioning system must be within 5 millimeters on axial position (z-axis).

Delete 7b

Change 7c to and move to physics section (090) - The deviation of indicated scan increment versus actual increment shall not exceed ± 1 millimeter with any mass weighing between 0 -100 kilograms resting on the patient support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters whichever is less, and then returned to the starting position.

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