

Preliminary Significant Analysis

Chapter 246-226 WAC Radiation Protection – Computed Tomography

June 2016

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SECTION 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

There are 250 hospitals and clinics (registrants) in Washington State using approximately 400 computed tomography (CT) X-ray systems. Currently, anyone using a CT X-ray system must register with the Department of Health (department) as required by chapter 70.98 RCW and chapter 246-224 WAC, Radiation protection – Radiation machine assembly and registration. Under the generally applicable X-ray requirements for the healing arts established in chapter 246-225 WAC, Radiation protection – X rays in the healing arts, the department inspects registered CT X-ray systems for the health and safety of operators and the public. During inspections, the department notes if the registrant is accredited. If so, the department reviews the last medical physicist survey and records typical doses for head and body scans. The department is proposing rules to establish requirements in a new chapter for the safe and effective use of CT X-ray systems for diagnostic purposes. The proposed rules include requirements for facilities, equipment, staffing, operation and maintenance, records, and reporting requirements, which, collectively, are intended to reduce radiation exposure to the public and help prevent incidents of overexposure of patients and staff.

National Perspective

The use of CT technology has grown in recent years in the number of units, the frequency of prescribed scans, and most importantly, the amount of radiation used. In an October 8, 2009 Initial Communication, the U.S. Food and Drug Administration (FDA) acknowledged that 206 patients had been accidentally exposed to excess CT-generated radiation at the Cedars-Sinai Medical Center in California over an 18-month period beginning February 2008. At least 44 more CT-generated radiation overdose incidents were subsequently discovered at Glendale Adventist Medical Center and at Providence St. Joseph Medical Center in Burbank, California. A number of patients at Huntsville Hospital in Alabama were also exposed to excessive CT-generated radiation. The majority of these excess radiation exposures caused injurious adverse health effects. These findings resulted in adoption of strict rules for CT exams and procedures with stringent upper limits on acceptable radiation doses delivered during CT exams by the state of California radiation authority.

As CT technology advanced rapidly, professionals in the industry became aware that children were often times receiving standard adult CT-generated radiation doses. The doses were not adjusted for the smaller body sizes and shapes of pediatric patients and their increased sensitivity to radiation. Failure to adjust CT-generated radiation doses for children often results in radiation exposures three to four times greater than necessary for pediatric patients. For this and other reasons, several states in addition to California have created CT rules including Oregon, Minnesota, Colorado, Utah, Michigan, Nebraska, and Ohio.

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Further investigation by the FDA through 2010 revealed that approximately 385 patients nationwide were exposed to excess amounts of radiation during CT brain perfusion scans at six different hospitals. This finding resulted in the FDA adopting a nationwide initiative to reduce unnecessary radiation exposures resulting from CT and other X-ray imaging procedures.¹ However, there are currently no federal rules for any type of patient CT imaging procedures using gantry-style CT X-ray systems.

Washington State Perspective

In 2005, two professional medical physicists recognized as qualified experts by the department X-ray program found and reported CT patient safety concerns related to 43 facilities surveyed in our state. When compared to the American College of Radiology's (ACR) recommended dose index reference levels, the physicists reported that 60% of the facilities had higher than recommended dose index values for CT head exams, and more than 4% of the facilities had higher than recommended adult abdomen CT dose index values.

In February 2012, at a CT seminar in Tacoma, one of the same two medical physicists pointed out to the audience of CT operators, radiologists, and hospital administrators that he personally was aware of two recent CT patient overexposures that occurred in our state. He went on to say that the State of Washington has no regulations controlling the use of CT.

The department found many of the conditions that could contribute to the findings described above during inspections of CT X-ray systems over an 18 month period beginning in 2013. Examples of findings include inadequate attention to protocol password protection, no designation of a responsible radiologist to oversee protocol selection, and no guidance for re-takes which may lead to overexposure.

On January 1, 2012, Centers for Medicare and Medicaid Services (CMS) began requiring all non-hospital facilities using CT to be accredited by either the ACR or the Intersocietal Accreditation Commission (IAC) in order to receive Medicare reimbursement. This accreditation requirement leaves a gap in complete accreditation since it does not apply to hospitals and facilities that do not receive Medicare reimbursement. The proposed rules will create consistent statewide requirements for all facilities using CT X-ray systems for diagnostic purposes that are compatible with Medicare standards. By establishing CT X-ray system requirements in rule, the department seeks to improve patient and operator safety.

Approach to Rule Making

To develop the proposed rules, the department used a collaborative rule making approach. The department developed an initial draft rule based on recommendations from an advisory committee made up of experts in the field of CT. The advisory committee was composed of a representative cross-section of doctors, radiologic technologists, radiation medical physicists, nurses, and hospital administrators from both urban and rural facilities. The advisory committee met six times over 19 months

¹ <http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm>

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beginning in July 2013. The department further refined the rules for proposal based on an extensive informal review and comment period held in July 2015.

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SECTION 2:

Is a Significant Analysis required for this rule?

RCW 34.05.328(5) requires the department to complete an analysis of a proposed rule when it meets the definition of a “significant legislative rule.” The department determined that many of the rules proposed in chapter 246-226 WAC meet the definition of significant legislative rule because they “make significant amendments to a regulatory program.” Therefore, the department has completed a significant analysis meeting the requirements of RCW 34.05.328(5).

However, the following table identifies rules the department determined do not require analysis based on the exemptions provided in RCW 34.05.328(5)(b) and the definitions found in (c).

Section and Title	Description of Rules	Reason for Determination of Non-significance
246-226-001 Authority, purpose, and scope	Identifies the department’s authority to protect the occupational and public health and safety by establishing requirements for the safe use of CT X-ray systems for diagnostic purposes. The chapter does not apply to treatment using CT X-ray systems.	Interpretive rule: Describes the agency’s interpretation of statutory provisions it administers.
246-226-006 Exemptions	Identifies types of CT X-ray systems that are exempt from requirements of the chapter.	Interpretive rule: Establishes exemptions to the requirements of the chapter the violation of which does not subject a person to a penalty or sanction.
246-226-007 Relationships to other regulations	Aids the regulated community in understanding the relationship of this chapter to other applicable regulations governing the use of ionizing radiation.	Interpretive rule: Describes the agency’s interpretation of statutory provisions it administers.
246-226-010 Definitions, abbreviations, and acronyms	Defines terms used within the chapter so that requirements are clearly understood and consistently applied.	Interpretive rule: The violation of this rule does not subject a person to a penalty or sanction. <i>Definitions are analyzed in context as part of the section-by-section analysis.</i>

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SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The general goal and specific objectives of RCW 70.98.020 is to protect occupational and public health and safety by creating a program of effective regulation of sources of ionizing radiation. The specific objectives of the chapter 70.98 RCW are further identified in RCW 70.98.050(4) and 70.98.080, requiring the department to develop programs for evaluation of hazards associated with the use of ionizing radiation; adopting rules related to controlling sources of ionizing radiation; and requiring people who possess or use a source of ionizing radiation to maintain records relating to receipt, use, storage, transfer, or disposal. The proposed rules implement chapter 70.98 RCW by creating an effective regulatory structure for diagnostic use of computed tomography, a significant source of ionizing radiation.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The rule is needed to protect occupational and public health and safety from overexposure of ionizing radiation related to the diagnostic use of computed tomography. This protection is provided through department oversight of CT X-ray systems, which includes establishing requirements for equipment, facilities, operating procedures, reporting, staffing, quality control, performance evaluation, and recordkeeping. These requirements must be established in rule in order to comply with the statutory directive of chapter 70.98 RCW.

As stated in the introduction, the use of CT technology has grown in recent years in the number of units, the frequency of prescribed scans, and most importantly, the amount of radiation used. The rules are necessary to reduce radiation exposure to patients, operators, and the public; and to help prevent overexposure incidents. If the department does not adopt the rules for the regulation of CT X-ray systems for diagnostic purposes, occupational and public health and safety are not adequately protected.

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SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The following section-by-section cost and benefit analysis includes a description of the proposed rules deemed significant under RCW 34.065.328(5) as well as the associated probable costs and probable benefits. To determine probable costs, the department surveyed the approximate 250 CT X-ray system registrants and 3 medical physicist groups providing services in Washington State. The department received 21 responses. This cost information is summarized and included in the following section-by-section analysis.

Section-by-Section Cost and Benefit Analysis

WAC 246-226-020, Equipment requirements

The significant elements of this proposed rule include equipping CT X-ray systems:

- With a visible signal that indicates when the X-ray exposure is occurring;
- So that the parameters used during a CT procedure are displayed prior to beginning a scan and are visible by the operator from any location scanning can be initiated;
- So that the accuracy of the laser or optical positioning system is within five millimeters maximum deviation on the axial position;
- With an X-ray production indicator of at least one-half second at or near the gantry that is visible from any point outside the gantry opening; and
- So that premature termination of the X-ray exposure by the operator requires resetting the parameters before starting another scan.

All the other requirements of the proposed rule are consistent with existing department or federal requirements and do not require analysis.

Probable Costs

All of the respondents to the department cost survey indicated that their CT X-ray system already has the specified proposed capabilities. For these respondents there will be no cost impact associated with the proposed rule. The equipment requirements proposed in this rule meet industry standards for contemporary CT X-ray systems. The department assumes these standard components are available on CT X-ray systems currently in use by facilities in Washington state.

Probable Benefits

The proposed requirements identified above reduce the risk of harm from unintentional exposure and overexposure to radiation.

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Equipment requirements such as visual “beam-on” indicators alert the operator and other staff when the X-ray beam is turned on. This reduces the chance of unintentional radiation exposure for patients and staff.

Requiring CT parameters to be visible on the control panel prior to initiating the CT procedure will allow the operator to review the machine settings and ensure use of proper protocols for the ordered exam. This is intended to reduce retakes and unnecessary radiation exposure to the patient.

Requiring a laser system that is calibrated to within 5mm of the indicated field is intended to ensure operators can accurately select which region of the body to scan. This prevents unnecessary exposure to the X-ray beam to portions of the body not needing a scan.

By requiring operators to reset parameters before restarting a terminated scan, the proposed rule will help ensure the operator evaluates the need for another scan and reduce the chance of unnecessary radiation exposure.

WAC 246-226-030, Design requirements

The only significant requirement of this proposed rule is for the registrant to complete and keep on file a radiation protection survey of the CT room and surrounding areas consistent with National Council on Radiation Protection and Measurements Report #147 (2004). The survey must be completed within 30 days from first use for new CT X-ray systems, and within two years of the effective date of this chapter for existing CT X-ray systems.

All the other requirements of the proposed rule are consistent with existing department or federal requirements and do not require analysis.

Probable Costs

Fourteen of twenty-one respondents (67%) indicated that they already comply with the proposed facility design requirements. For these respondents there will be no cost impact associated with this proposed rule. The remaining 7 respondents estimated the cost of the proposed rule to range from \$250 (one hour of work) to \$3,028 (19 total hours for a facility with 19 CT X-ray machines). The average estimated cost of the seven respondents is \$1,083.

Probable Benefits

Requiring facilities to conduct a radiation protection survey after the CT X-ray system is installed will ensure that the facility meets the design requirements as indicated in the shielding plan. By conducting a survey, registrants will be able to measure any gaps in shielding created during the construction process and make modifications to eliminate possible occupational or public health risk created by the radiation scatter from the CT X-ray system.

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WAC 246-226-040, Operating procedures

The significant elements of this proposed rule include requiring registrants to:

- Establish a procedure to record and retrieve information (CTDI_{vol}, DLP, and SSDE, when available) for every CT procedure performed and send each protocol page that lists the technique factors electronically to the Picture Archiving and Communication System (PACS).
- Provide estimated patient dose for an individual study within ten business days of a patient request.
- Establish CT procedures for each CT X-ray system within six months of the effective date of the rule. This work must be done in consultation with a qualified medical physicist and a lead interpreting CT physician or lead CT technologist to ensure they are correct for the intended dose and image quality.
- Review CT protocols within 12 months of the effective date of the rule to ensure they are correct for the intended dose and image quality. This work must be done in consultation with a qualified medical physicist and a lead interpreting CT physician or lead CT technologist. The reviews must be conducted as follows:
 - Review all CT protocols upon installation of a CT X-ray system;
 - Annually, review new or changed protocols and protocols for pediatric head and abdomen, adult head and abdomen, high resolution chest, and brain perfusion. If the facility does not perform the specified procedures, the registrant must review the most frequently performed or highest dose protocols so that a total of six protocols are reviewed.
 - The protocol review must include comparing protocols to dose estimates during the last performance review, determine if the protocols are appropriate for the desired test, ensure protocols are optimizing image quality, and determine guidelines of variability for exam protocols.
- Create a written policy, approved by the lead interpreting CT physician, establishing procedures for retaking CT scans.
- Individuals allowed in the CT X-ray system room during exposure must be protected by at least 0.5 millimeter lead equivalent apron or a whole body protective barrier.

All the other requirements of the proposed rule are consistent with existing department or federal requirements and do not require analysis.

Probable Costs

Ten out of twenty respondents (50%) indicated that they already comply with the proposed operating procedures. For these respondents there will be no cost impact associated with this proposed rule. The remaining respondents (10 out of 20) estimated the cost of the proposed rule to range from \$140 to \$32,932. The average estimated cost of the ten respondents was \$7,240. The respondent that provided the \$32,932 estimate was for 10 sites. The average estimated cost without this higher value was \$4,386.

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In addition, two respondents identified protocol review costs associated with WAC 246-226-050, Dose limits (below). For each CT X-ray system, the time needed to ensure operation within the dose limits of section -050 is estimated at 1 to 3 hours with an estimated cost of between \$1,470 and \$3,078. The average estimated cost is \$2,274

Probable Benefits

The proposed requirement to record and retrieve $CTDI_{vol}$, DLP, or SSDE from each CT procedure benefits both the physician and patient by being able to track estimated radiation exposure. Physicians and patients alike need this information to ensure appropriate diagnostic techniques are used over time, and patients don't incur greater risk than necessary for diagnosing medical conditions.

By requiring registrants to review protocols in consultation with a qualified medical physicist, lead interpreting physician or a lead CT technologist, the proposed rules help ensure the protocols are correct for each given exam. Requiring registrants to continually review their CT procedures will aid in dose reduction and accuracy of the images obtained. Technology changes and new practices are regularly implemented into the medical industry. The registrant must also review any changes or new protocols on an annual cycle to ensure all changes and new protocols are performed properly and image quality and patient exposure is optimized.

Placing limitations on new or changed protocols will help to reduce errors in administering CT protocols for specific exams, thus reducing the potential for patient overexposure. Overexposure from unnecessary retakes is one of the most common sources of overexposure identified in the introduction of this analysis. Requiring registrants to establish written procedures and guidelines for retakes and of variability will help limit the potential for unnecessary exposures to radiation.

The proposed requirement to use a lead apron of at least 0.5 mm thickness helps protect operators and others who hold patients during a CT exam from overexposure.

WAC 246-226-050, Dose limits

This section establishes dose limits for adult head and abdomen, and pediatric head and abdomen CT procedures. While this is a significant proposed rule in that it establishes a standard, the phantom exams will be conducted during the annual protocol review required above in WAC 246-226-040. Costs associated with this proposed rule are reflected in the probable costs identified for the annual protocol review requirement above.

Probable Costs

The department assumes all CT X-ray systems are capable of performing below the proposed dose limits. All costs associated with conducting a survey to verify CT performance are captured in the probable costs for WAC 246-226-040 above. Based on the department's assumption, there are no costs associated with this proposed rule.

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Probable Benefits

Creating dose limits for typical exams will aid in reducing radiation exposure to patients across the state. Setting dose limits helps prevent overexposure to patients from a CT X-ray system during a single CT exam.

WAC 246-226-060, CT events

This section only applies to registrants that do not include CT events as part of a required coordinated quality improvement program under RCW 70.41.200 or 70.230.080, those that do not include CT events as part of a department-approved voluntary coordinated quality improvement program under RCW 43.70.510.

All requirements of this proposed rule are considered significant and require registrants to establish procedures for responding to deterministic injurious health effects (as described below). Registrants must:

- Conduct an internal investigation when the $CTDI_{vol}$ exceeds 600 mGy for a pediatric CT procedure, 1500 mGy for an adult CT Procedure or when any CT procedures results in unanticipated hair loss, erythema, and functional damage to an organ or physiological change. The investigation must begin within twenty four hours and be completed within 10 days.
- Complete a root cause analysis in consultation with a qualified medical physicist, the lead interpreting CT physician, the lead CT technologist, and the operator who performed the exam; and
- Make appropriate modifications consistent with the corrective action included in the root cause analysis.

Probable Costs

Seventeen out of twenty-one respondents (81%) indicated they already comply with the proposed CT event requirements. For these respondents there will be no cost impact associated with this proposed rule. Three of the remaining four respondents estimated the cost of the proposed rule to range from \$560 to \$1,575², with an average cost of \$978, to comply with the proposed rule.

Probable Benefits

Setting radiation limits for CT events is beneficial for both the registrant and patients. By requiring a facility to report an exposure that exceeds the proposed thresholds, as well as completing a root cause analysis and making modifications will reduce the risk of the incident reoccurring. The department will review the findings of the root cause analysis and use it as a tool to eliminate potential hazards that are caused by equipment or design error, as well as those caused by procedural error.

² One of the four respondents indicated they did not currently comply with the proposed rule, but did not provide cost estimates.

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WAC 246-226-065, Qualified medical physicist

This proposed rule sets minimum requirements for a physicist to become a qualified medical physicist and perform the duties established in the proposed chapter. All proposed requirements are considered significant and are analyzed below.

A physicist must meet one of the following three initial requirements to become a qualified medical physicist:

- Hold a valid certificate in:
 - Diagnostic radiological physics or radiological physics from the American Board of Radiology;
 - Diagnostic imaging physics from the American Board of Physics; or
 - Diagnostic radiology physics from the Canadian College of Physicists in Medicine.
- Completed the following education and experience requirements:
 - Hold a graduate degree in medical physics, radiological physics, physics, or another relevant physical science or engineering discipline, including formal course work in the biological sciences; and
 - At least three years of documented experience in a clinical CT environment.
- Have independently evaluated at least three CT X-ray systems consistent with this chapter in the three years prior to the effective date of this chapter.

In addition, a qualified medical physicist must earn at least fifteen continuing medical education units in the three years preceding any department review or inspection. At least:

- Half the units must be accredited by Accreditation Council for Continuing Medical Education or an equivalent accreditation; and
- One of the units must pertain to CT.

The qualified medical physicist must also meet one of two continuing experience requirements in the two years preceding any department review or inspection. The qualified medical physicist must have either:

- Independently evaluated at least two CT X-ray systems consistent with the requirements of the proposed chapter; or
- Evaluated at least five CT X-ray systems consistent with the requirement of the proposed chapter under the direct supervision of a qualified medical physicist.

Probable Costs

Twenty out of twenty-one respondents (95%) indicated they already comply with the qualified medical physicist requirements. For these respondents there will be no cost impact associated with this proposed rule. The remaining respondent stated the proposed rule would cost an estimated \$5,000 annually for continuing education. This cost is only applicable to facilities who employ a qualified medical physicist to perform the activities identified in the proposed chapter.

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Probable Benefits

Establishing qualifications to perform the complex evaluations and surveys required by the proposed chapter, and to consult with registrants on establishing protocols and procedures, and completing root cause analyses helps prevent overexposures to patients and staff from ineffectively shielded CT X-ray systems, improperly functioning CT X-ray systems, and procedural errors.

The proposed requirements are consistent with the most current ACR accreditation standards for medical physicists.

WAC 246-226-070, Staffing requirements

All proposed requirements of this section are considered significant and are analyzed below.

The proposed rule establishes staffing requirements for registrants to:

- Provide training to CT X-ray system operators within 6 months of employment and annually thereafter;
- Employ or contract with a qualified medical physicist that meets the requirements of WAC 246-226-065 to perform the activities of the qualified medical physicist specified in the proposed chapter; and
- Appoint a lead interpreting CT physician and a lead CT technologist to work cooperatively to:
 - Develop, implement, and enforce policies, procedures, and other registrant requirements;
 - Ensure the physician is present and immediately available when contrast is administered;
 - Implement the quality control program required in WAC 246-226-080;
 - Ensure compliance with the recommendations of the qualified medical physicist; and
 - Oversee all CT-related materials required by the proposed chapter.

Probable Costs

Seventeen out of twenty-one respondents (81%) indicated they already comply with the proposed staffing requirements in their survey response. For these respondents there will be no cost impact associated with this proposed rule. Three of the remaining four respondents estimated the cost of the proposed rule to range from \$2,508 to \$15,200, with an average cost of \$7,703³. The respondent that provided the \$15,200 estimate was for 10 sites. The average estimated cost without this higher value is \$3,954.

Probable Benefits

The proposed rule will help protect patients and staff from overexposure by requiring registrants to employ or contract with medical staff meeting department licensing

³ One of the four respondents indicated they did not currently comply with the proposed rule, but did not provide cost estimates.

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requirements and whose scope of practice includes the duties identified in the proposed chapter (see definitions of “lead interpreting CT physician” and “lead CT technologist”).

Requiring training for operators within six months and annually thereafter is intended to maintain minimum competency levels for operators who meet department licensing requirements and whose scope of practice includes the duties identified in the proposed chapter (see definition of “operator”). Meeting minimum competency levels is important in reducing unnecessary radiation exposure to patients and staff.

WAC 246-226-080, Quality control program

All proposed requirements of this section are considered significant and are analyzed below.

The proposed rule requires the registrant to establish, document, and enforce a quality control program. The program must be created in consultation with a qualified medical physicist and be implemented prior to using the CT X-ray system. The quality control program must include the manufactures recommendations and include:

- Measurement of water CTN and standard deviation on each day of clinical use;
- Artifact evaluation on each day of clinical use;
- Weekly printer quality control of wet laser hardcopy for primary interpretation;
- Monthly visual checklist;
- Monthly printer quality control of dry laser hardcopy for primary interpretation;
- and
- Monthly display monitors quality control.

Probable Costs

Nineteen of twenty-one respondents (90%) indicated they already comply with the quality control program section. For these respondents there will be no cost impact associated with this proposed rule. The remaining respondents (2 out of 20) estimated the cost of the proposed rule to range from \$11,946 to \$14,660, with an average cost of \$13,303.

Probable Benefits

To ensure that a sufficient quality control program is in place, the proposed rule requires the registrant to work in consultation with a qualified medical physicist along with meeting the standards set by the manufacturer. The quality control program must include a measurement of water CTN and standard deviation on each day of clinical use. It is important to measure the CTN number daily to ensure the scanner is quantifying the beam attenuation properly. Artifact evaluation must be done to ensure there are no imperfections in the image that are not represented on the patient or image receptor. The overall benefit of the proposed rule requires daily, weekly, and monthly quality control checks to maintain diagnostic quality of printed images.

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WAC 246-226-090 Performance evaluation

All proposed requirements of this section are considered significant and are analyzed below.

This section requires registrants to hire or contract with a qualified medical physicist to conduct a performance evaluation to assess the quality and safety of the CT X-ray system and its operation. The evaluation must be conducted:

- Within thirty days of installation of a CT X-ray system;
- Annually thereafter; and
- After any change, replacement, or reconfiguration of components that could cause a change in the radiation output or image quality.

The qualified medical physicist must provide the registrant with a performance evaluation within 30 days of completing the evaluation that includes:

- A summary of the evaluation that addresses all components listed in WAC 246-226-090(2);
- Recommendations for improvements, if any; and
- Type of radiation detection instrument or system used, including the date of the last calibration.

Probable Costs

Nineteen out of twenty respondents (90%) indicated they already comply with the proposed performance evaluation requirements. For these respondents there will be no cost impact associated with this proposed rule. The remaining two respondents estimated the cost of the proposed rule to be \$2,600 to \$6,370, with an average cost of \$4,485.

Probable Benefits

The benefit of requiring a registrant to employ or contract with a qualified medical physicist to evaluate the quality and safety of the CT X-ray system is the need for expertise in assessing the CT X-ray system performance. A medical physicist will conduct performance evaluations on the CT X-ray system to ensure that it is operating at an efficient and safe level. The physicist will evaluate radiation output and image quality to ensure the patient is receiving a nominal amount of radiation for the images produced, thereby preventing overexposure to patients and staff.

WAC 246-226-100, Required records and reports

All proposed requirements of this section are considered significant and are analyzed below.

The proposed rule requires registrants to maintain written information regarding the operation and calibration of the CT X-ray system including dates of last calibration and location of results, the most recent quality control program results and evaluation schedules.

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The registrant must also maintain the following records for the specified time period:

- The most recent radiation protection survey and radiation shielding plan for as long as the CT X-ray system is in use;
- Written approval of the most recent annual review of each CT X-ray system with date and signature of the registrant, qualified medical physicist, and lead interpreting CT physician;
- The most recent performance evaluation;
- Records documenting the qualifications of all personnel who worked with the CT X-ray system during the preceding three years;
- Training log for three years; and
- Root cause analysis and corrective action plans for at least ten years.

Probable Costs

Nineteen out of twenty-one respondents (90%) indicated they already comply with the proposed required records and reporting requirements in their survey response. For these respondents there will be no cost impact associated with this proposed rule. The remaining two respondents estimated the cost of the proposed rule to be \$105 to \$400, with an average cost of \$253.

Probable Benefits

By requiring the facility to maintain the identified records for the specified time periods and make them available to the department upon request, the proposed rule improves compliance with the requirements of the proposed chapter and support the beneficial effects of the requirements.

Probable Cost and Probable Benefit Summary

The use of CT technology has grown in recent years in the number of units, the frequency of prescribed scans, and most importantly, the amount of radiation used. There are currently no regulations that govern the use of CT. The proposed rules establish requirements in a new chapter for the safe and effective use of CT X-ray systems for diagnostic purposes that will help reduce radiation exposure to the public and help prevent incidents of overexposure to patients and staff. The proposed rules include requirements for facilities, equipment, staffing, operation and maintenance, records and reporting requirements. Although there are costs associated with several of the components of the program, as identified in the section-by-section analysis above, the benefit of establishing regulations to promote the safe and effective use of CT X-ray systems for diagnostic purposes outweighs these costs. Based on the preceding analysis, the department has determined the total probable benefits of the proposed rules outweigh the total probable costs.

SECTION 6:

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Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

The department considered alternate versions of the rule. In considering each requirement, the department chose the version that is the most protective of public health and the least costly for stakeholders. Below are alternatives considered during the rule making process.

Third party accreditation requirements for all CT facilities

This alternative rule would have required all registrants who have a CT X-ray system to hold ACR accreditation or an equivalent. It was determined that this alternative rule would put an undue burden on rural businesses to obtain and hold accreditation. Minimum rule requirements under an existing department program were determined to be protective of public health without placing undue burden on registrants.

Additional staff requirements for operating CT X-ray systems

The department considered additional registrant staffing requirements for operators of CT X-ray systems. However, the department determined the burden additional requirements would have placed on rural facilities serving populations with limited access to CT services did not outweigh the benefit of additional public health protection beyond existing professional licensing requirements. Instead, the department agreed with the advisory committee recommendation to include the option for registrants to require additional staffing requirements to meet their own needs.

Based on this analysis, the department determined the proposed rule is the least burdensome alternative for those required to comply that achieves the goals and specific objections of the underlying statutes.

SECTION 7:

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The proposed rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

SECTION 8:

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Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The proposed rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The proposed rule does not differ from any federal regulation or statute. To verify this, the department provided the proposed rules from the U.S. Food and Drug Administration, and Centers for Medicare and Medicaid Services staff for review.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable federal, state, or local laws governing the diagnostic use of CT X-ray systems.

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Appendix A – CT Advisory Committee Participants

Radiologic Technologists

- Chuck Cromwell, Group Health Cooperative
- Tamara Sloan, Providence, St. Mary Medical Center, Walla Walla

Radiology Managers

- Bette Drescher, Group Health Cooperative
- Bart Thompson, Good Samaritan Hospital
- Angela Steinbach, Inland Imaging

Rural Hospitals

- Steven B. Schindler, Providence, Stevens County Ministries
- Joy Iverson, Summit Pacific Medical Center

Medical Doctors

- Marie Lee, Virginia Mason Clinic, Radiology Department
- Jonathan Medverd, Washington State Radiological Society
- William P. Shuman, University of Washington
- Janathan Swanson, Seattle Children's Hospital

Medical Physicists

- Jeremy L. Corwin, Corwin Health Physics Inc.
- John Gough, Swedish Medical Center
- Kalpana M. Kanal, University of Washington
- Larry Neubauer, Neubauer Medical Physics
- Gene Wollan, Health Physics Northwest

Mobile CT

- John Connolly, Alliance Imaging

Hospital Administrators

- Jennifer Brown, Seattle Cancer Care Alliance
- Mark Kochan, Evergreen Health
- Jim Aberle, Yakima Valley Memorial Hospital

Associations

- Ian Corbridge, Washington State Hospital Association

Preliminary Significant Analysis

Appendix B – Resources considered during rule development

- Michigan CT Rules-http://www.michigan.gov/lara/0,4601,7-154-11407_35791-259201--,00.html
- American College of Radiology (ACR) Accreditation Standards-
<http://www.acr.org/Quality-Safety/accreditation/CT>
- California Law SB 1237, HSC 115111, 115112, 115113-
<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=115001-116000&file=115105-115115>
- Intersocietal Accreditation Commission (IAC) Standards and Guidelines for CT Accreditation-http://www.intersocietal.org/ct/seeking/seeking_welcome.htm
- Conference of Radiation Control Program Directors Suggested State Regulations, Part F.11
- Conference of Radiation Control Program Directors Board of Directors Position Paper
- The Joint Commission, <https://www.jointcommission.org/>