Preliminary Small Business Economic Impact Statement

Chapter 246-226 WAC

Radiation Protection – Computed Tomography

June 2106

SECTON 1:

Describe the proposed rule, including: a brief history of the issue; an explanation of why the proposed rule is needed; and a brief description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

There are 235 hospitals and clinics (facilities) 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 protect – 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 X-ray system rules including Oregon, Minnesota, Colorado, Utah, Michigan, Nebraska, and Ohio.

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 in 43 facilities surveyed in our state. When compared to the American College of Radiology's (ACR) recommended dose index reference levels, 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.

Approach to Rule Making

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.

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 technologies, 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

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.

SECTION 2:

Identify which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS) codes and what the minor cost thresholds are.

Table A:

NAICS Code	NAICS Business Description	# of businesses in WA	Minor Cost Threshold = 1% of Average Annual Payroll	Minor Cost Threshold = .3% of Average Annual Receipts
621512	Diagnostic Imaging Centers	137	$9,336	$7,701
622110	General Medical and Surgical Hospital	89	$722,465	$557,047
622111	Office of Physician (except mental health specialist)	3,178	$11,602	$7,192

SECTION 3:

Analyze the probable cost of compliance. Identify the probable costs to comply with the proposed rule, including: cost of equipment, supplies, labor, professional services and increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or revenue.

The department surveyed all 235 registrants (entities with registered CT X-ray systems in the state). The department also surveyed three medical physicist groups that provide service to registrants in the state to assess the potential cost of the proposed rule. The survey asked questions about each of the proposed sections and asked participants to identify if they already comply with the proposed rules, or if not, to provide cost estimates to comply. Table 1 below shows the cumulative cost of the proposed rules for the 22 respondents. For more information about the specific rule sections, please refer to the Significant Analysis that the department developed for this proposed chapter.

Table 1: Cumulative Cost of the Proposed Rules	
Respondent 1	$1500
Respondent 2	0
Respondent 3	0

Respondent 4	0
Respondent 5	245
Respondent 6	2250
Respondent 7	1890
Respondent 8	15573
Respondent 9	0
Respondent 10	0
Respondent 11	1500
Respondent 12	2136
Respondent 13	2250
Respondent 14	19100
Respondent 15	0
Respondent 16	21820
Respondent 17	0
Respondent 18	560
Respondent 19	15450
Respondent 20	7480
Respondent 21 (ten sites)	59288
Respondent 22	0
Total	**$151,402**
Average cost for all respondents	$6,882
Average for all respondents reporting costs	$10,814
Average cost excluding respondent with 10 sites	$7,086

The department assumes that no businesses will lose sales or revenue by implementing the proposed rules.

SECTION 4:

Analyze whether the proposed rule may impose more than minor costs on businesses in the industry.

Minor cost threshold (1% payroll) *$9,336*
Minor cost threshold (3/10% of receipts) *$7,192*

As defined in chapter 19.85 RCW, and based on the information above, the proposed rule or portions of the proposed rules may impose more than minor costs on businesses in the industry. The remainder of this document meets the requirements of RCW 19.85.030 and RCW 19.85.040.

SECTION 5:

Determine whether the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Based on cost estimates received from survey respondents, the department assumes many of the costs of the proposed rule are comparable regardless of business size. Therefore, the department assumes the proposed rules are likely to impose a disproportionate impact on small businesses.

SECTION 6:

If the proposed rule has a disproportionate impact on small businesses, identify the steps taken to reduce the costs of the rule on small businesses. If the costs can not be reduced provide a clear explanation of why.

Modifications to the proposed rules were made to balance the burden of reporting injuries with the necessity to improve patient safety and reduce the incidence of medical errors (CT events) that contribute to injuries. These changes include exempting registrants who include CT events in another department-approved coordinated quality assurance program from the event reporting requirements. The proposed exemption allows small business to take advantage of existing reporting processes rather than creating a new process for the purposes of the proposed rules alone.

Though the proposed rules follow national standards quite closely, they were modified to reduce staffing requirements established in national standards to balance patient safety with patient access to services in rural and acute access areas of the state. This is also an important modification to be consistent with department authority related to the regulation of health professionals.

Overall, the department is proposing rules that provide the least burdensome requirements that still protect occupational and public health and safety.

SECTION 7:

Describe how small businesses were involved in the development of the proposed rule.

As described in Section 1: Approach to Rule Making, the department worked closely with an advisory committee to develop the proposed rules. The advisory committee included representatives from both urban and rural areas specifically to include small business perspectives in the development of the proposed rules. In addition, the advisory committee began development of the proposed rules from the basis of national standards and Medicare reimbursement requirements specifically to create consistent statewide requirements for all facilities, including small businesses that currently receive Medicare reimbursement for services and assumedly meet those requirements. The department further refined the rules for proposal based on an extensive informal review

and comment period and cost survey which included all registrants and outreach to facilities in rural and acute access areas of the state.

SECTION 8:

Identify the estimated number of jobs that will be created or lost as the result of compliance with the proposed rule.

The department assumes no jobs will be created or lost as a result of the proposed rules.