Fiscal Impact Analysis for Proposed Rules
NC Division of Health Service Regulation
Radiation Protection Section

Agency:	NC Radiation Protection Commission
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Nature of Impact:	Registrant-Private Entity Impact – YES State Government Impact – YES Local Government Impact – NO Federal Government Impact– NO Substantial Economic Impact – YES
Authorizing Statute:	*G.S. 104E-7* *G.S. 104E-11* *G.S. 104E-12*
Rule Title:	10A NCAC 15 .0611 COMPUTED TOMOGRAPHY (CT) X-RAY SYSTEMS (The proposed rule text is attached)

Need for Adoption

The Section's regulations are designed for the reduction of hazards associated with the use of radiation. In recent years, technology and equipment used for diagnostic medical imaging has become significantly more complex.

Computed Tomography delivers high quality imaging that is of significant benefit to patients and for this reason it represents one of the most important tools for diagnostic medical imaging. However, it also represents the largest contributor to an increase in population radiation exposure based on NCRP Report 160 from the National Council on Radiation Protection and Measurements.[1] The report concluded that medical tests were responsible for almost 50 percent of all radiation exposure experienced by Americans and half of that exposure was from CT scans. These data reflect a dramatic increase in the number CT scans performed each year – and the proposed Rule mandates qualified equipment operators and routine equipment testing to assure optimal image quality with appropriate radiation dose.

[1] National Council on Radiation Protection and Measurements: Report No. 160 "Ionizing Radiation Exposure of the Population of the United States", retrieved from *http://www.ncrppublications.org/reports*.

Much progress in reducing this risk has been made in recent years, and the shift toward improved patient safety, especially as it relates to CT scanning, is highly encouraging and worthy of further consideration at this time. There is ample evidence to suggest that we must remain vigilant in the use of imaging that employs ionizing radiation to avoid a very small increase in cancer risk to exposed individuals and the general population owing to rising average per-capita doses. The National Council on Radiation Protection and Measurement's report indicated that, as of 2006,average annual background exposure per capita in the United States has almost doubled over the previous quarter century, with essentially all of the increase deriving from medical imaging, especially CT. The problem is real, not being ignored, and is being dealt with proactively. Focused attention on this issue has blossomed over the past few years and has been quite effective in preventing escalation of imaging-related radiation exposure into a much larger problem.

The observed problems with CT scans in the past several years reflect a lack of quality assurance and/or a lack of administrative controls. These regulations seek to ensure high quality CT imaging that is appropriate with respect to professional bodies such as the American College of Radiology's (ACR) recommendations. These regulations will implement Quality Assurance (QA) and training requirements that are currently being employed by many facilities in North Carolina. Some facilities are obligated to meet these standards since accreditation by a CMS designated accrediting organization is required to qualify for reimbursement from Medicare. This Rule will apply to all human diagnostic use of CT for facilities whether they are accredited or not. The Rule does not apply to uses of cone beam CT, veterinary CT, CT simulation, and CT attenuation correction.

Currently, the provisions in the NC Regulations for Protection Against Radiation that apply are not specific to the use of CT equipment. Applying the current regulations to the use of CT is difficult for registrants and regulators.

Summary of Proposed Rule

Rule 10A NCAC 15 .0611 proposes to simplify compliance with regulations and reduce the hazards associated with the use of computed tomography (CT) x-ray machines. The Radiation Protection Section based the proposed Rule on the CRCPD Suggested State Regulations, requirements for CT accreditation from the American College of Radiology (ACR), and equipment performance standards from the American Association of Physicists in Medicine (AAPM).

The proposed new requirements include input and review by the .0600 CT Working Group. The Working Group was comprised of representative stakeholders in the use of CT systems. It included experts in many areas associated with CT operation, evaluation, manufacturing, and servicing.

Summary of Impacts

Although these changes will impact state government and private entities, most of the impacted facilities have programs in place to meet these standards. Many facilities are currently meeting accreditation standards to qualify for reimbursement for procedures utilizing CT equipment from the Centers for Medicare and Medicaid Services (CMS). The facilities that do not currently implement these standards would incur the most costs to meet the requirements.

The most significant impacts are from requirements for training, system performance evaluations, routine quality control, and operation standards.

These changes may also result in a cost-savings for some facilities. This Rule addresses some safety issues with the use of CT x-ray machines that may benefit facilities by reducing radiation exposure to their operators, other employees, and members of the public that may be near machines in operation. A reduction in radiation exposure will reduce the chances for injuries and lower the risks for radiation induced cancers. The training requirements for operators and qualified experts should reduce the potential for procedure failures. This in turn would result in a reduced potential for litigation related to misdiagnosis or over-exposure.

These changes should result in benefits to our Section. The clarification of the requirements for CT use should shorten the time needed for inspections, enforcement, and result in staff timesavings for Section inspectors and registrant operators.

There is only one state government CT facility impacted by this Rule. This state government facility is not accredited. Although we anticipate this state facility meets most of the new requirements, all potential impacts created by this Rule are included for demonstration of possible costs.

The Section does not expect the proposed rules to affect patient access to CT services. A GAO report on Medicare Imaging Accreditation (14-378) does not show a correlation between access to CT services and the requirement of accreditation for reimbursement (a costlier requirement than the proposed rules). It attributes reductions in CT exams performed to other factors such as reduced reimbursements and increased physician and patient awareness of the risks associated with radiation exposure. [2]

Analysis: Costs

Impact of Proposed Rule 10A NCAC 15 .0611(b)(1), (b)(2) and (b)(3) - Definitions

Purpose: Establish definitions for terms that apply to the use of CT x-ray systems.

Impact: The definitions should not have any impact other than clarifying the new Rule.

Benefit to the public interest: The new definitions define terms that only apply to this new Rule. They are in addition to the existing definitions of this Section. The definitions clarify terms that are specific to CT x-ray systems and will simplify the understanding of this Rule.

Impact of Proposed Rule 10A NCAC 15 .0611(c)(1) – Equipment and Installation Requirements

Purpose: This directs the registrant to reference 10A NCAC 15 .0117(a)(3) for CT x-ray system's equipment and installation requirements, which are incorporated by reference, from the Code of Federal Regulations 21 CFR 1020.33.[3]

Impact: These are existing federal requirements for the manufacturing of CT x-ray systems and will not create any impact.

Benefit to the public interest: This addition makes it easier for the general public and x-ray stakeholders to understand and use this Rule.

[2] Medicare Imaging Accreditation GAO-14-378. (2014) retrieved from http://www.gao.gov/assets/670/662658.pdf

[3] Code of Federal Regulations: (CFR) (21 CFR 1020.33), retrieved from *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.33*

Impact of Proposed Rule 10A NCAC 15 .0611(c)(2) – Equipment and Installation Requirements

Purpose: To establish a requirement for aural communication between the patient and the operator for CT x-ray systems. This requirement does not exist in the current Rule for other types of x-ray systems and is only applicable to CT.

Impact: This should have very little impact on facilities. Although aural communication is not required by 21 CFR 1020.33, all manufactures accommodate this standard and almost all machines meet this requirement by default. Costs to install or repair a communication system should be minimal to moderate based on estimates provided by stakeholders we surveyed ($50-$1000). This requirement can save costs to the registrant by reducing patient radiation dose and time required to scan patients.

Benefit to the public interest: This requirement improves safety for the patient and may put patients at ease during the scan. This requirement should reduce repeat exposures and lower patient radiation dose.

Summary of Estimated Costs of Rule 10A NCAC 15 .0611 (c)(2), Based on 5% of machines (27 out of 540) needing repair or installation of aural communication device in any year. Cost Range is $50-$1000.00 per machine. These number and cost assumptions are based on the input of stakeholders, our best professional judgment, and inspection experience.

	Cost
Registrant-Private Entity-26 machines	$1300-$26000.00
Local Government	$0
State Government-1 machine	$50-$1000.00
Federal Government	$0
Total	$1350-$27000

Impact of Proposed Rule 10A NCAC 15 .0611(d) – Personnel Requirements

Purpose: To establish training requirements for CT operators.

Impact: Although most current CT operators meet this requirement, this Rule requires specific credentials for operators that impacts all registrants utilizing CT x-ray systems. The Rule additionally allows for operation of CT machines by individuals in training that are under supervision of a qualified operator. These training requirements do not apply to operation of the unit for testing or maintenance purposes. There are potential costs for training existing operators or hiring qualified individuals.

Benefit to the public interest: This requirement should reduce unnecessary radiation exposure and repeat exposures and lower patient radiation dose.

Summary of Estimated Costs of Rule 10A NCAC 15 .0611 (d) Due to accreditation and insurance reimbursement requirements, very few operators do not meet this training requirement. Based on stakeholder input we estimate that less than 5% of operators (68 out of 1364) do not meet the requirements of this new Rule. The estimated costs are based on $20/hour pay rate difference between qualified and non-qualified operators. ($20/hour X 40 hours X 52 weeks X 68 operators=$2,828,800)

There is also a quantifiable cost of training per operator per facility. Medical Technology Management Institute, MTMI, is a worldwide provider of medical image training. MTMI provides a CT training course for operators that costs $1000.00 for a 5-day course.[4] This is a one-time cost.

	Cost due to pay difference between trained and untrained operators.	Cost for CT Training Course per operator.	Cost for CT Training (5 days)
Registrant-Private Entity-67 operators out of 1364	$2,787,200	67 operators X $1000.00= $67,000	Approximately $43.00 per hour X 67 operators= $2881.00 X 40 hours of time spent in training= $115,240.00
Local Government	$0	$0	$0
State Government-1 operator out of 1364	$41,600	1 operator X $1000.00= $1000.00	Approximately $43.00 per hour X 1 operator= $43.00 X 40 hours of time spent training= $1720.00
Federal Government	$0	$0	$0
Total	$2,828,800.00	$68,000.00	$116,960.00

[4] Medical Technology Management Institute, MTMI CT Training Course, retrieved from *https://www.mtmi.net/course/ct-training-course-technologists*

Impact of Proposed Rule 10A NCAC 15 .0611(e) – System Performance Evaluations

Purpose: To establish the minimum equipment tests to be performed by the CT QE at least annually on the CT system. This is a new requirement that is based on the SSRs, standards and tolerances from the AAPM, and accreditation requirements from the ACR.

Impact: Based on feedback from CT QEs that perform system performance evaluations in NC, the cost for annual testing would be in the range of $1000 - $3000 per scanner per year. There are additional costs to the facility because of the down time of the CT equipment. The time required to evaluate the equipment can be from 2 to 3 hours per scanner annually. Facilities that are currently accredited are required to have annual system performance evaluations. We approximate that out of 341 total CT facilities, 219 are accredited. There will be nominal costs related to the maintenance of records required for documentation of the testing.

Benefit to the public interest: The benefit to the public interest of an annual system performance evaluation is that the potential for procedure failures is greatly reduced. This reduces the chance for misdiagnosis for the patient and litigation against the facility.

Summary of Estimated Costs of Rule 10A NCAC 15 .0611 (e) Due to accreditation and insurance reimbursement requirements, most machines are already evaluated annually. The cost for evaluations will not be a new cost for most facilities. Based on stakeholder input we estimate that less than 2% of machines (11 out of 540) do not meet the requirements of this new Rule. (Average cost of annual evaluation of each machine = $1500) (11 machines X $1500 = $16,500)

	Cost
Registrant-Private Entity-10 machines out of 540	$15,000
Local Government	$0
State Government-1 machine out of 540	$1,500
Federal Government	$0
Total	$16,500

Impact of Proposed Rule 10A NCAC 15 .0611(f) – Routine Quality Control (QC)

Purpose: To establish the minimum requirements for developing and conducting quality control tests for CT equipment. This is a new requirement that is based on the SSRs, standards and tolerances from the AAPM, accreditation requirements from the ACR and manufacturers' recommendations.

Impact: Based on feedback from stakeholders and the working group, the cost related to developing and implementing a routine QC program would be a one-time cost in the range of $400-$800. The testing equipment required for the QC, such as a phantom, is typically provided by the manufacturer with the purchase of a new or refurbished machine. The working group agreed that the manufacturer/seller not providing the phantom is unlikely, but the cost for a phantom is between $4000-$10000. Since this is an unlikely occurrence, this cost is not factored into the total cost of this requirement.

There are costs to the facility related to the time it takes the operator to conduct the routine QC tests. The time required for the facility to conduct the routine QC is about 10 minutes for each scanner for every day of use. Most facilities will operate the CT equipment between 200 to 364 days per year. Each machine will typically require between 33 and 60 hours of operator time per year to conduct the tests. On average qualified CT operators, earn a wage of about $30 per hour. Total compensation costs, including benefits, is estimated at $43.00 per hour based on the Bureau of Labor Statistic's September 2016 Employer Costs of Employee Compensation data.

There are also additional costs to the facility because of the down time of the CT equipment while conducting the QC tests and small costs related to the maintenance of records required for documentation of the testing.

Facilities that are currently accredited are required to conduct routine QC. We approximate that out of 341 total CT facilities, 219 are accredited.

Benefit to the public interest: The costs related to a routine QC program are an investment in safe and proper use of a CT scanner. The testing helps to ensure that the equipment is operating within manufacturer specifications and provides evidence that the facility is operating in a safe manner. This can reduce the impact of litigation in the occurrence of an adverse patient event.

Summary of Estimated Costs of Rule 10A NCAC 15 .0611 (f) Due to accreditation and insurance reimbursement requirements, most facilities have established a quality control program (QC) that meets the requirements of this new Rule. Most facilities are provided the quality control program recommendations and equipment (phantom etc.) by the manufacturer. The cost for setup and testing will not be a new cost for most facilities. Based on stakeholder input we estimate that less than 2% of facilities (7 out of 341) and machines (11 out of 540), will not have a quality control program approved and implemented, and should incur a one-time cost. (Initial setup of QC program per facility average = $400-$800). (7 facilities X $400-$800 = $2800-$5600) (Ongoing QC program review average = $400 per year per facility). (7 facilities X $400 = $2800) (Conducting daily/routine QC tests =$43 per hour X 33-60 hours per year =$1419-$2580). (11 machines X $1419 - $2580=$15609- $28380).

	Cost
Private Entity- 6 facilities out of 341 Private Entity- 10 machines out of 540	Initial set up of QC Program= $2400-$4800 QC Program Review= $2400 Operator Conducting QC= $14190-$25800
Local Government	$0
State Government- 1 facility out of 341 State Government- 1 machine out of 341	Initial set up of QC Program= $400-$800 QC Program Review= $400 Operator Conducting QC= $1419-$2580
Federal Government	$0
Total	Initial set up= $2800-$5600 QC Program Review= $2800 Operator Conducting QC= $15609-$28380

Impact of Proposed Rule 10A NCAC 15 .0611(g) – Operating Requirements

Purpose: To require information that must be available to a CT operator during use of the machine and while performing routine QC.

Impact: There should be no costs related to maintaining this information for operators.

Benefit to the public interest: The benefit to the public interest of requiring availability of this information will ensure QC testing and machine operation is conducted properly. This will improve image quality and reduce the potential for procedure failures. This reduces the chance for misdiagnosis for the patient and litigation against the facility.

Analysis: Aggregate Benefits

Lower Radiation Exposure and Avoided Cancer Incidence:

The primary benefit of the proposed rule is that patients will undergo exams on equipment that will be tested routinely to assure optimal image quality with appropriate dose. Furthermore, computed tomography scans will be performed by appropriately trained individuals. Estimates of reduced cancer risk are based on the following assumptions but are speculative.

Based on the literature, CT is responsible for approximately 25% of population radiation exposure[5] and 2% of the cancers incurred.[6] The expectation and assumption is that the proposed rules will reduce patients' exposure to radiation and that this benefit will be seen primarily in non-accredited facilities verses accredited facilities, although benefit will be seen in both. As a result of reduced radiation exposure, the proposed rules are expected to reduce the number of future cancer diagnoses. DHSR assumes that the new training, oversight, and quality control measures required by the proposed rules will ultimately reduce NC's population radiation exposure from CT by 4%. The benefit parameters used include the median age of a CT patient being 50 years and the average age for cancer diagnosis being 68-70 years of age. Baseline cancer incidence projections, based on the literature on CT use trends and technology developments[7] and existing trends in cancer incidence per 100,000 population in NC,[8] suggest a slight annual increase in cancer attributable to CT between the years of 2017-2021 if the proposed rules do not go into effect.

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[5] National Council on Radiation Protection and Measurements: Report No. 160 "Ionizing Radiation Exposure of the Population of the United States", retrieved from *http://www.ncrppublications.org/reports*.

[6] Cancer Risks Associated with External Radiation From Diagnostic Imaging Procedures: (Feb 3, 2012), retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3548988/

CT Radiation Dose: Trending in the Right Direction: Volume 261, Issue 1 (2011), retrieved from http://pubs.rsna.org/doi/full/10.1148/radiol.11111319

[7] CT Radiation Dose: Trending in the Right Direction: Volume 261, Issue 1 (2011), retrieved from http://pubs.rsna.org/doi/full/10.1148/radiol.11111319

[8] CDC and National Cancer Institute. State Cancer Profiles – North Carolina 2009-2013 Incidence Rates. Retrieved from: https://statecancerprofiles.cancer.gov/

DHSR quantified the cost of implementing the rules in years 2017-2021 as well as the associated cancer reduction benefits that occur in years 2036-2040. Based on information from subject matter experts and industry literature, this analysis estimates that the proposed rules would prevent approximately 41 new cases of cancer per year. Cancer related benefits are assumed to be seen in years 2036-2040 based on a 20-year latent period due to the time of exposure and the onset of the disease. This is only an average. Post Rule implementation, it is projected that in 2036-2040, some cancer patients would have premature death while others would have gone through treatments for the 5 year period. Industry literature indicates that lung and colon cancers are the most common cancers caused by CT radiation[9] and this analysis assumes that patients benefiting from the proposed rules would have contracted lung or colon cancer. 60% of cancer patients will die from lung/colon cancer within 5 years of diagnosis,[10] statistically, and the life loss value is estimated at $8,800,000 per individual in 2016 dollars.[11] This is applied to all prevented deaths. The other 40% that survive at least 5 years post diagnosis will have the average cost of cancer treatment, at $19,142/year/person (discounted at 7% in 2016$),[12] applied to the avoided cancer incidence projection to help quantify these values. It is demonstrated that there will be an increase in the benefit of avoided premature death along with other avoided costs because the deaths and the treatment costs for each cohort are annualized, reaching full benefits in year 2040.

See the table below for a summary of quantified benefits of reduced radiation exposure. This analysis does not quantify the indirect benefits of avoided cancer incidence, such as avoided pain and suffering or the effects on family and caretakers. See the Risk Analysis section for an analysis of the impact of the proposed rules under different assumptions about the number of avoided cancer diagnoses, the number of avoided premature deaths due to cancer, and the timing of the benefits.

Avoided Cancer Incidence Projections	**2036**	**2037**	**2038**	**2039**	**2040**
NC cancer incidence attributable to CT	962	967	972	977	982
Annual reduction in radiation exposure due to rules	4.2%				
Estimated cancer diagnoses avoided post-rule	41	41	41	41	41
Average 5-yr mortality rate, colon and lung cancer	59%				
5-yr survivors	17	17	17	17	17
Avoided premature deaths, annualized	5	10	14	19	24
Value of avoided medical costs, 5-yr survivors (discounted at 7%, 2016$), annualized	329,239	671,023	1,025,810	1,394,064	1,776,259
Value of avoided productivity loss, 5-yr survivors (discounted at 7%, 2016$), annualized	13,459	27,260	41,411	55,921	70,796
Value of avoided premature deaths (2016$)	42,409,050	85,031,874	127,866,888	170,911,611	214,162,996

[9] Cancer Risks Associated with External Radiation From Diagnostic Imaging Procedures: (Feb 3, 2012), retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3548988/

[10] http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-047079.pdf

[11] U.S. Environmental Protection Agency, (2016). *Guidelines for Preparing Economic Analysis.* Retrieved from https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses

[12] Mariotto et al, (2010). *Projections of the Cost of Cancer Care in the United States:2010–2020.* J Natl Cancer Inst 2011;103:117–128. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3107566/pdf/djq495.pdf

Lower Inspection and Enforcement Costs:
The Section inspects most of the facilities impacted by this Rule on a three-year frequency. The Section expects to inspect 114 of these facilities each year. A conservative estimate, based on variability of inspection times and previous inspection experience, would be that these changes could reduce the inspection time and enforcement time by 30 minutes per inspection, thusly saving the Section 59.5 hours of working time per year. This example would also save the registrant on inspection time. The cost savings for the agency would be equal to $1668.97 based on a midpoint inspector salary rate of $28.05[13] per hour X 59.5 hours saved per year.

The reduced time needed for inspections and enforcement would result in time savings for facilities impacted by this Rule. This would save these facilities $2558.50 annually. This estimate is based on a midpoint CT operator salary rate of $30 per hour ($30 per hour X 43% for benefits = $43 per hour[14]) X 59.5 hours saved per year.

Lower litigation costs:
The training requirements for operators and qualified experts should reduce the potential for procedure failures. This in turn would result in a reduced potential for litigation related to misdiagnosis or over-exposure. Estimated litigation costs for a misdiagnosis claim, including legal fees and expert witness fees but excluding damages, are approximately $100-200,000.[15] This type of litigation has been so infrequent that it would be a minor contributor to the benefit. For the purpose of this analysis, we are expecting that no events will occur within the next five years due to the extreme infrequency.

Regulatory clarity:
The regulated community will benefit from greater rule clarity. The proposed changes will make it easier for registrants to understand and implement the rules.

Analysis: Summary

The impacts estimated in Table 2 of this analysis are based on the following totals of facilities, machines, and operators.

# of CT Facilities	# of CT Machines	# of Accredited Facilities (Estimated)	# of Private Businesses	# of State Gov. Facilities	# of Local Gov. Facilities	# of Operators per Facility (Est. Avg.)	# of Operators (Total)
341	540	219	339	2 (1 machine and 1 operator per facility)	0	4	1364

[13]State of NC Salary Plan: retrieved from *http://s3.amazonaws.com/oshr.ncgovstaging.fayze2.com/s3fs-public/migrated_files/Guide/CompWebSite/2014%20Salary%20Plan%20Book.pdf*
[14]Bureau of Labor Statistic's September 2016 Employer Costs of Employee Compensation data: Table 14, retrieved from *http://www.bls.gov/news.release/ecec.t14.htm*
[15] Cost estimate based on the experience of a medical malpractice attorney in private practice.

IMPACT ANALYSIS, 2016$										
Year	**2017**	**2018**	**2019**	**2020**	**2021**	**2036**	**2037**	**2038**	**2039**	**2040**
COSTS						Cancer reduction due to rule implementation in 2017-21				
Private Registrant Compliance	3,158,587	3,090,347	3,216,183	3,342,051	3,467,955					
State Registrant Compliance	49,020	45,582	45,624	45,667	45,711					
Total Costs	**3,207,607**	**3,135,928**	**3,261,806**	**3,387,718**	**3,513,665**					
BENEFITS										
Private Registrant										
Inspection/Enforcement		2,457	2,507	2,558	2,610					
Lower litigation Costs	U*	U*	U*	U*	U*					
State Registrant										
Inspection/Enforcement		44	45	46	47					
Lower litigation Costs	U*	U*	U*	U*	U*					
State - DHSR										
Inspection/Enforcement		2,333	2,380	2,428	2,478					
Operator Training Providers	69,000									
Patients - avoided cancer										
Avoided cost of care Avoided						329,239	671,023	1,025,810	1,394,064	1,776,259
productivity loss Avoided						13,459	27,260	41,411	55,921	70,796
indirect cancer costs						U*	U*	U*	U*	U*
Avoided premature death						42,409,050	85,031,874	127,866,888	170,911,611	214,162,996
Total Benefits	**69,000**	**4,834**	**4,932**	**5,032**	**5,134**	**42,751,747**	**85,730,157**	**128,934,110**	**172,361,596**	**216,010,051**
Net Impact	**(3,138,607)**	**(3,131,095)**	**(3,256,875)**	**(3,382,687)**	**3,508,532)**	**42,751,747**	**85,730,157**	**128,934,110**	**172,361,596**	**216,010,051**
Present Value, 2016$	(2,933,278)	(2,734,819)	(2,658,580)	(2,580,635)	(2,501,535)	11,821,214	22,154,302	31,139,275	38,904,281	45,566,647
Net Present Value, 7% discount rate	**136,176,873**									

* U signifies unquantified impacts

Summary of Estimated Costs of Rule 10A NCAC 15 .0611 by Rule Provision

Rule #	Estimated Total Cost	Impact Description
.0611 (a)	None	Introductory Statement of Scope
.0611 (b)	None	None
.0611 (c)(1)	None	None
.0611 (c)(2)	$1350-$27000	Based on 5% of machines (27 out of 540) needing repair or installation of aural communication device in any year. This estimated total cost is based on a range of $50-$1000.00 for correction or installation of equipment based on stakeholder input.
.0611 (d)	Pay Difference Costs $2,828,800	Due to accreditation and insurance reimbursement requirements, very few operators do not meet this training requirement. Based on stakeholder input we estimate that less than 5% of operators (68 out of 1364) do not meet the requirements of this new Rule. The estimated costs to meet the new requirements are based on $20/hour pay rate difference between qualified and non-qualified operators. ($20/hour X 40 hours X 52 weeks X 68 operators=$2,828,800)
.0611 (d)	Training Costs $68,000	It is estimated, based on stakeholder input, that approximately 5% of operators (68 out of 1364) will require CT Training. This is a quantifiable cost of training per operator per facility. Medical Technology Management Institute, MTMI, is a worldwide provider of medical image training. MTMI estimates the cost of CT Training for operators to be approximately $1000.00 per operator. This is a one-time cost.
.0611 (d)	Training Time Costs $116,960	Approximately $43.00 per hour X 68 operators= $2924.00 X 40 hours (5 days) of time spent in training= $116,960.00
.0611 (e)	$16,500	Due to accreditation and insurance reimbursement requirements, most machines are already evaluated annually. The cost for evaluations will not be a new cost for most facilities. Based on stakeholder input we estimate that less than 2% of machines (11 out of 540) do not meet the requirements of this new Rule. (Average cost of annual evaluation of each machine = $1500) (11 machines X $1500 = $16,500)
.0611 (f)	Initial Setup $2800-$5600	Due to accreditation and insurance reimbursement requirements, most facilities have established a quality control program (QC) that meets the requirements of this new Rule. Most facilities are provided the quality control program recommendations and equipment (phantom etc.) by the manufacturer. The cost for setup and testing will not be a new cost for most facilities. Based on stakeholder input we estimate that less than 2% of facilities (7 out of 341) and machines (11 out of 540), in any one year, will not have a quality control program approved and implemented. (Initial setup of QC program per facility average = $400-$800). (7 facilities X $400-$800 = $2800-$5600) (Ongoing QC program review average = $400 per year per facility). (7 facilities X $400 = $2800) (Conducting daily/routine QC tests =$43 per hour X 33-60 hours per year =$1419-$2580). (11 machines X $1419=$15609 – 11 machines X $2580=$28380).
	Program Review $2800	
	Operator conducting QC $15609-$28380	
.0611 (g)	None	None
Annual Total	**$3,052,819-$3,094,040**	**This is an estimate of the potential annual cost range for all facilities in a given year created by this new Rule. Most facilities will incur little true cost since they currently meet the new requirements.**

Alternatives

Two alternatives will be presented:

Alternative 1: Do not adopt Rule .0611

The first alternative is to not adopt Rule .0611.

The Section's current Rules for all types of X-ray machines, that do not specifically address CT machine use, would remain applicable. The Section would continue to regulate use of CT machines and operators with Rules that do not address the safety issues that are unique to CT. The Section has utilized the current Rules to address increased radiation dose and missed diagnosis, although they are not adequate to properly regulate these issues.

This option would have little impact on accredited facilities. Not implementing the Rule may significantly reduce the costs for non-accredited facilities that would not have to meet the proposed Rule .0611. However, the non-accredited facilities may be negatively impacted by the loss of the potential benefit meeting these standards could provide. These include reducing radiation exposure that could result in a reduced potential for litigation related to misdiagnosis or over-exposure.

Not implementing this Rule would have a negative impact on the Section's time needed for inspections and enforcement.

Alternative 2: Adopt Rule that Requires Accreditation for all CT

The second alternative is to require all facilities that provide CT services to maintain accreditation of those services. Facilities that maintain accreditation would be expected to have reduced patient exposure and improved image quality over non-accredited facilities. Accreditation requires rigorous review by a CMS approved organization to ensure the facilities meet nationally accepted standards for quality assurance and safety.

Although this would have little impact on facilities that are currently accredited, there would be a significant increase in costs to non-accredited facilities. These facilities would not only have to meet the standards of the proposed Rules but would also have increased costs related to obtaining the accreditation. The requirements for accreditation would be more stringent and increase costs compared to the proposed Rule. Based on a Government Accountability Office (GAO) report 14-378. (2014), the cost of accreditation as of January 2013 ranged from $1800 to $3800 per machine. There are also costs related to preparing an application and reapplying if the application fails. Accreditation of CT machines expire after three years and must be renewed to continue services. Requirements for accreditation are also more stringent and costly than the proposed Rules.[16]

Requiring accreditation would potentially have a positive impact on the Section's inspection process. The Section would expect less compliance issues for facilities that are accredited compared to non-accredited facilities.

[16] Medicare Imaging Accreditation GAO-14-378. (2014) retrieved from http://www.gao.gov/assets/670/662658.pdf

Requiring accreditation would also be costlier to facilities that may wish to cease providing CMS reimbursable services. These facilities would not have the ability to end accreditation to reduce their costs related to CT.

The Section estimates that up to 36% of the 341 CT facilities are not accredited.

Rationale for Adopting Rule .0611 Over the Alternatives

Based on input from stakeholders, the X-ray Surveillance Advisory Committee, and the CT Working Group adopting the new Rule .0611 was the best option for the Sections oversight of use of CT machines. Although the analysis potentially shows a substantial impact from adopting this Rule, the impression is that the true impact will be much less than the potential impact. This impression is based on the majority of existing facilities holding accreditation and currently meeting the proposed standards of the Rule. The Section also believes that the number of accredited facilities is actually higher than what has been confirmed based on observations during inspections of these facilities.

Risk Analysis:

The assumptions made in this analysis are based on the Section's most recent facility registration information, stakeholder input, and inspection findings. Also data from recent studies on the impact of CT radiation exposure on cancer incidence and radiation induced cancer incidence were utilized. Many of the impact costs are given in ranges to account for uncertainties in some of the estimates.

Because of the inherent uncertainties in in this type of analysis a sensitivity analysis was conducted. This allows us to understand how different the impact of this Rule would be if the assumptions made were off base. The sensitivity analysis strongly supports that with even with a reduction of the effect of the rules on CT radiation exposure (lowering the number of prevented cancers); the long term benefits outweigh the costs to implement the Rule. Net benefits are also seen when there is a lower than expected five-year mortality rate for patients with colon or lung cancer. It is also believed that the estimates for the reduction in radiation exposure used in this analysis are conservative and the true reductions could be significantly higher. The sensitivity analysis shows that a greater reduction in radiation exposure than expected, would result in an increase in the benefits of this Rule.

Rate of cancer incidence attributable to CT	1%	**2%**	3%
Net Present Value	61,384,013	**136,176,873**	210,969,732

Median age of CT scan patient	40	**50**	60
Net Present Value	62,632,948	**136,176,873**	280,848,904

Net Present Value 2-way Analysis		**Average 5-yr cancer mortality rate**				
		0%	20%	40%	**59%**	80%
Change in radiation exposure (post-rule)	0.0%	(13,408,847)	(13,408,847)	(13,408,847)	(13,408,847)	(13,408,847)
	-0.5%	(13,047,650)	(7,162,065)	(1,276,480)	4,314,826	10,494,690
	-1.0%	(12,686,453)	(915,283)	10,855,887	22,038,499	34,398,228
	-4.2%	(10,360,389)	39,313,259	88,986,907	**136,176,873**	188,334,203
	-7.0%	(8,352,093)	74,046,098	156,444,290	234,722,572	321,240,674
	-10.0%	(6,184,913)	111,526,789	229,238,492	341,064,609	464,661,897

Other things to consider that may change the projected results are:

The CT industry has undergone tremendous growth since the current Rules were adopted. However, the level of growth may increase or decrease significantly based on advancements in medical imaging technology. A change in the growth rate for CT will impact the assumptions used in this analysis.

Many of the true impacts of this Rule will only affect non-accredited facilities. The Section does not have a completely accurate source for the total number of accredited facilities or the patients examined with accredited machines. Only facilities confirmed to be accredited were included in this total number. Although it is suspected that more facilities are accredited, this analysis assumes they are non-accredited.

Changes in insurance and government policies may also significantly impact the assumptions made within this analysis.

10A NCAC 15 .0611 is proposed for adoption as follows:

10A NCAC 15 .0611 COMPUTED TOMOGRAPHY (CT) X-RAY SYSTEMS

(a) This Rule provides special requirements for human diagnostic use of computed tomography (CT) x-ray equipment. The uses of Cone Beam CT, Veterinary CT, CT Simulation, and CT attenuation correction shall be exempt from this Rule. The provisions of this Rule are in addition to, and not in substitution for, the Rules in Sections .0100, .0200, .0600, .0900, .1000, and .1600 of this Chapter.

(b) The following definitions shall apply to this Rule:

(1) "CT qualified expert (CT QE)" means an individual who is registered or is providing service for a registered facility where they are employed, as required by Section .0200 of this Chapter. The individual shall have the following education and experience:

(A) a master's or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and

(B) three years work experience in a clinical CT environment. The work experience shall be supervised and documented by a board certified medical physicist; or

(C) certification in the specific subfield(s) of medical physics with its associated medical health physics aspect by an appropriate national certifying body and shall abide by the certifying body's requirements for continuing education.

(2) "general supervision" means the activity is performed under the qualified supervisor's overall direction and control but the qualified supervisor's physical presence is not required during the activity.

(3) "personal supervision" means overall direction, control and training of an individual by a qualified supervisor who must be physically present during the activities performed by the supervised individual.

(c) Equipment and Installation Requirements

(1) CT x-ray systems shall meet the requirements of 21 CFR 1020.33 as incorporated by reference in Rule .0117(a)(3) of this Chapter.

(2) The operator of a CT scanner shall be able to maintain aural communication with the patient from a shielded position at the control panel.

(d) Personnel Requirements

Individuals who operate CT x-ray systems shall:

(1) hold (CT) registration with the American Registry of Radiologic Technologists (ARRT); or

(2) be a Registered Technologist (R.T.) by the ARRT with registration in radiography (R) or a Certified Nuclear Medicine Technologist by the Nuclear Medicine Technology Certification Board; these individuals shall document training and experience that is equivalent to that required to attain (CT) registration with the ARRT; or

(3) be in training under the personal supervision of an individual that meets the requirements of Paragraph (d) of this Rule; and

(4) be specifically trained on the operational features of the unit.

(e) System Performance Evaluations

(1) Performance evaluations of the CT x-ray system shall be performed by, or under the general supervision of, a CT QE who assumes the responsibility for the evaluation.

(2) The performance evaluation of a CT x-ray system shall be performed within 30 days of installation and at least every 14 months.

(3) Performance evaluation standards and tolerances shall meet manufacturer's specifications or standards and tolerances for the CT x-ray system from the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM). These standards and tolerances may be found at no charge on the ACR and AAPM websites.

(4) The performance evaluation shall include the following as applicable to the design of the scanner:

(A) geometric factors and alignment including alignment light accuracy, and table increment accuracy;

(B) image localization from a scanned projection radiograph (localization image);

(C) radiation beam width;

(D) image quality including high-contrast (spatial) resolution, low-contrast resolution, image uniformity, noise, and artifact evaluation;

(E) CT number accuracy;

(F) image quality for acquisition workstation display devices;

(G) a review of the results of the routine QC, as set forth in Paragraph (f) of this Rule; and

(5) The performance evaluation shall also include the evaluation of radiation output and patient dose indices for the following clinical protocols if performed:

(A) pediatric head;

(B) pediatric abdomen;

(C) adult head;

(D) adult abdomen; and

(E) brain perfusion.

(6) Evaluation of radiation output shall be performed with a dosimetry system that is calibrated. The dosimetry system shall have been calibrated within the preceding two years by persons registered to provide such services pursuant to Rule .0205 of this Chapter.

(7) The performance evaluation shall be documented and maintained for inspection by the Agency. The documentation shall include the name of the CT QE performing or supervising the evaluation, as well as any other individual(s) participating in the evaluation under the general supervision of the CT QE. The documentation shall be retained for 14 months.

(f) Routine Quality Control (QC)

(1) A routine QC program for the CT system shall be developed by or have written approval by a CT QE and include:

(A) instructions for the routine QC;

(B) intervals for QC testing;

(C) acceptable tolerances for the QC tests;

(D) use of a water equivalent phantom to evaluate each day of clinical use: noise, CT number accuracy, and artifacts; and

(E) routine QC tests that may be performed in place of system performance evaluations after equipment repairs or maintenance. This shall include the process for obtaining approval from the CT QE prior to conducting testing.

(2) The duties in the routine QC program, as described in Part (f)(1) of this Rule, shall be conducted by individuals that meet the requirements of Part (d) of this Rule or individuals approved by the CT QE.

(3) The routine QC shall be documented and maintained for inspection by the Agency. The records shall be retained for 14 months.

(g) Operating Requirements

The following information shall be accessible to the CT operator during use of the machine and while performing routine QC:

(1) instructions on performing routine QC;

(2) a schedule of routine QC;

(3) any allowable variations set by the CT QE for the indicated parameters;

(4) the results of the most recent routine QC completed on the system; and

(5) established scanning protocols.

History Note: *Authority G.S. 104E-7; 104E-11; 104E-12;*
Eff. Oct 1, 2017.