**Fiscal Impact Analysis of Permanent Rule Amendment and Readoption**

**Agency**

Department of Health and Human Services
Division of Health Service Regulation
Radiation Protection Section

**Contact Persons**

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**Impact Summary**

| | |
|---|---|
| Federal Government: | No |
| State Government: | Yes |
| Local Government: | Yes |
| Regulated Community: | Yes |
| Substantial Impact: | Yes |

**Rules with Proposed Changes**

Rule Readoption with Substantive Changes:

| | |
|---|---|
| 10A NCAC 15 .0601 | PURPOSE AND SCOPE |
| 10A NCAC 15 .0602 | DEFINITIONS |
| 10A NCAC 15 .0603 | FACILITY RESPONSIBILITIES |
| 10A NCAC 15 .0604 | OPERATOR REQUIREMENTS |
| 10A NCAC 15 .0605 | OPERATING REQUIREMENTS |
| 10A NCAC 15 .0606 | AREA REQUIREMENTS |
| 10A NCAC 15 .0607 | MACHINE REQUIREMENTS |

**Rules Proposed for Repeal**

Rule Repeals Through Readoption:
10A NCAC 15 .0608; .0610 - .0611

*See text in Appendix

**Rulemaking Authority**

G.S. 104E-7; 104E-12(a); 104E-20
21 CFR Chapter I Subchapter J

## Purpose

The rules in 10A NCAC 15 regulate the use of radioactive materials and radiation machines in the State of North Carolina pursuant to G.S. 104E. Rules in Section .0600 of Chapter 15 regulate all registrants who use radiation machines in the State of North Carolina.
Pursuant to G.S. 150B-21.3A, Periodic Review and Expiration of Existing Rules, all rules are reviewed at least every 10 years, or they shall expire. As a result of the periodic review of the Rules in Chapter 10A NCAC 15, Radiation Protection, 10A NCAC 15 Section .0600 had seven rules, .0601- .0607, that were determined to be "Necessary with Substantive Public Interest" and that will be readopted with this rulemaking action. Three Rules, Rules 10A NCAC 15 .0608, .0610, and .0611 were determined to be "Necessary with Substantive Public Interest" and will be repealed through readoption with this rulemaking action. The requirements in these rules were incorporated into the substantive changes in the proposed rules for readoption, therefore these three Rules are not necessary.

As mandated by G.S. 150B-19 (4), the agency may not adopt a rule that repeats the content of a law, a rule, or a federal regulation. To comply with this mandate, the federal regulations in 21 CFR Subchapter J[1] are proposed for incorporation by reference, including subsequent amendments and editions. This incorporation is specifically reflected in the proposed amendments to Rule .0607(b).

This fiscal note provides an evaluation of the costs and benefits associated with these regulatory changes.

## Introduction

Pursuant to its statutory authority, the North Carolina Department of Health and Human Services (DHHS), through the Division of Health Service Regulation (DHSR) and its Radiation Protection Section (RPS), exercises regulatory oversight of radiation machines and radiation-generating devices (RGDs) operated within the State of North Carolina. In accordance with the requirements of G.S. 150B-21.3A, which mandates the periodic review and readoption of existing rules, the RPS has proposed comprehensive amendments and reorganizations to the Rules in 10A NCAC 15, Section .0600.

The primary objective of the proposed rule readoptions is to update, clarify, and improve the structure of existing requirements. The RPS has reorganized the Rules for improved logical sequencing, enhanced consistency, and simplified compliance for regulated entities. This reorganization includes the retitling of rules, making technical changes, repealing unnecessary or obsolete provisions, and updating terminology to current regulatory and industry standards.

The current rules codified for 10A NCAC 15 .0601, .0605, and .0606 were last amended on May 1, 1993. Rule .0602 was last amended on June 1, 1993. Rules .0603, .0604, .0607, .0608, .0609, and .0610 were last amended on January 1, 1994. Rule .0610 was subsequently amended on October 1, 2017. Several of these provisions have remained unchanged since their initial adoption, reflecting a significant need for modernization to align with evolving technology and current standards of practice.

Substantively, the proposed amendments incorporate new language establishing operational and competency-based requirements for individuals operating radiation machines. These requirements, which are not presently reflected in the existing administrative code, are derived from prevailing national models, most notably the Suggested State Regulations for Control of Radiation (SSRCR) published by the Conference of Radiation Control Program Directors (CRCPD). The SSRCR, originally issued in

[1] Code of Federal Regulations: (CFR) (21 CFR) retrieved from: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-J

1974 and last comprehensively revised in 2015,[22] has long served as the foundational framework for state-level radiation safety regulation across the United States. The proposed revisions align North Carolina's rules with the SSRCR's most current provisions, particularly those found in Parts B and F.

The proposed rule amendments further introduce required training, certification, or licensure standards for radiation machine operators. These standards are designed to be equivalent to or inclusive of the requirements imposed by the relevant North Carolina professional licensing boards for dental, chiropractic, podiatric, and veterinary practitioners, as well as nationally recognized credentialing bodies such as the American Registry of Radiologic Technologists (ARRT). The proposed framework includes formal didactic education, supervised clinical training, and successful completion of a standardized examination. The adoption of these provisions will ensure that all operators possess a uniform and verifiable level of technical proficiency and clinical competency. The majority of U.S. states mandate licensure or certification for individuals operating radiation machines, yet North Carolina is one of only four states that currently do not require such credentials.

The readoptions and accompanying amendments are the product of an extended consultative process involving the Radiation Protection Commission, the X-ray Surveillance Advisory Committee, and working groups. They are intended to reduce interpretive burden, increase regulatory compliance, and improve both worker and public safety outcomes. While the RPS acknowledges that these changes may introduce additional compliance costs for certain stakeholders, the anticipated benefits, including reduced radiation exposure due to fewer repeat X-rays, improved diagnostic accuracy resulting from increased image quality, and enhanced regulatory compliance, are expected to outweigh the projected fiscal impact over time.

## Scope of Analysis

This analysis assesses the potential effects of proposed regulatory requirements on entities operating radiation machines, utilizing comprehensive data from the Radiology Compliance Branch's registration database. It evaluates how the proposed rules may impact facilities, machine operators, and patient populations across a range of sectors, including:

- **State Government:** Entities such as state prisons and educational institutions that use radiation machines for patient imaging or instructional purposes.
- **Local Government:** County jails and health departments employing radiation machines for imaging services.
- **Private Sector:** Privately-owned businesses and organizations that operate radiation machines for imaging human or non-human patients.
- **Patients:** Individuals receiving imaging services from these regulated entities.

The analysis considers the anticipated implications for each group, providing a comprehensive understanding of the regulatory impact across state and local agencies, private organizations, and the communities they serve.

## Rule Changes and Anticipated Impacts

The following provides a detailed overview of the proposed changes to each rule and their anticipated impacts.

[2] Conference of Radiation Control Program Directors: (CRCPD), retrieved from https://online.flippingbook.com/view/892080394/

**10A NCAC 15 .0601 - PURPOSE AND SCOPE**
The proposed changes restructure the rule into distinct paragraphs, addressing the organization of the Rules within Section .0600 and clearly stating to whom the requirements apply. These changes are designed to improve clarity and remove ambiguity, making the Rule easier to interpret and apply for regulated parties, agency staff, and the general public. This may, in turn, result in incremental improvement to compliance within the regulated community.

**10A NCAC 15 .0602 – DEFINITIONS**
The proposed changes to this rule involve the relocation, updating, adding, or removal of definitions: Definitions proposed to be removed from this rule are either no longer relevant and unnecessary; or are terms defined in federal regulation that we are proposing to incorporate by reference into Rule .0607(b).

- The following definitions have been relocated from the current Rule .0611: "CT qualified expert (CT QE)", "General supervision", and "Personal supervision".
- The following definitions have been added or updated to align with current or proposed rule language:
  "Area survey", "Cone beam computed tomography", "Dental assistant" "Dental hygienists", "Dental handheld radiation machine", "Diagnostic imaging", "Diagnostic imaging system", "Diagnostic radiation machine", "Extra-oral", "Intra-oral", "Letter of acknowledgment", "Licensed dentist", "Mobile radiation machine", "Notice of registration", "Optimal", "Panoramic", "Phototimer", "Portable radiation machine", "Primary beam", "Protective apparel", "Radiation machine", "Radiation subsystem", "Radiation system", "Radiographic imaging system", "Shielding design", "Stationary radiation machine", and "Structural shielding."

The proposed changes will provide additional clarity for the regulated community, which may result in incremental improvements in compliance.

**10A NCAC 15 .0603 – FACILITY RESPONSIBILITIES**
The proposed changes to this rule consolidate requirements for facilities from Rules .0603-.0608, .0610, and .0611 into a single, clearer rule. Key changes include:

1. Reorganizing existing language for logical sequencing and better comprehension.
2. Adding clarifying language for CBCT and CT radiation machines.
3. Updating terminology and aligning with Suggested State Regulations-Part F.[3]
4. Clarifying record-keeping requirements.

The proposed changes to this rule do not alter the existing rule requirements and standards of practice but instead clarify the specific requirements for registrants responsible for the care, custody, and control of a radiation machine(s). The agency does not broaden the scope of regulation by adding rule language but seeks to reduce the burden on registrants and stakeholders who must comply with this rule by clarifying, in one rule, the requirements each facility must meet. The agency expects the changes to simplify compliance, resulting in an unquantifiable, incremental increase in compliance with this Rule. The agency expects an unquantifiable time savings for the registrants and stakeholders to achieve compliance. The changes could lead to significant, though difficult to quantify, time savings for agency staff guiding registrants on compliance-related inquiries. These proposed changes align with existing requirements, and therefore, the agency expects minimal to no economic impact for registrants using radiation machines.

[3] Conference of Radiation Control Program Directors: (CRCPD), retrieved from: https://crcpd.org/document/part-f-medical-diagnostic-interventional-x-ray-imaging-systems/

**10A NCAC 15 .0604 – OPERATOR REQUIREMENTS**

The requirements currently outlined in Rule .0604 are proposed to be relocated to Rule .0607. The revised language in Rule .0604 consolidates operator requirements for the use of radiation machines, organizing them by modality. This rule establishes general operational and training standards for all operators to ensure the safe use of radiation machines, while also specifying additional training requirements tailored to the various modalities employed in patient imaging.

Key anticipated impacts of these changes include:

1. **Standardization of Competency**
   By aligning operator qualifications with nationally recognized ARRT standards, the proposal ensures that all technologists achieve a consistent level of clinical and technical competency.

2. **Enhanced Patient Safety**
   Certified technologists receive comprehensive training in radiation safety, patient positioning, and imaging protocols, thereby reducing risks to patients and improving diagnostic accuracy.

3. **Reduction in Repeat Imaging**
   Improved training and competency among professionals decrease the likelihood of image retakes, which in turn lowers patient radiation exposure and reduces associated costs for facilities and insurers.

The proposed Rule language represents a significant step towards enhancing safety and competency in the operation of radiation machines. By clarifying requirements, addressing technological advancements, and specifying training requirements for the different modalities, the rule aims to ensure that operators are properly trained to operate radiation machines safely and effectively. Including a grace period for compliance and the requirement to maintain training records demonstrates a balanced approach to implementation, allowing for adaptation while emphasizing the importance of ongoing accountability.

Table 1 lists the number of registered facilities and radiation machines -- by facility type and modality -- that will be affected by the new training requirements in Rule .0604. Data is provided for both State and Local Government, as well as the Private Sector community. The table includes only this subset of facilities and machines because they are the only ones expected to be affected by the new requirements.

**Table 1: Number of Registered Facility Types and Number of Registered Radiation Machines for Each Modality Affected by the New Requirements**

| MODALITY | Dual Energy X-Ray Absorptiometry | | Computed Tomography | | Dental | | Fluoroscopy | | Radiography | |
|---|---|---|---|---|---|---|---|---|---|---|
| FACILITY TYPE | Facilities | Machines | Facilities | Machines | Facilities | Machines | Facilities | Machines | Facilities | Machines |
| | | | | | | | | | | |
| State Government | -- | -- | -- | -- | -- | -- | -- | -- | 1 | 1 |
| Local Government | -- | -- | -- | -- | -- | -- | -- | -- | 2 | 2 |
| Chiropractic | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| Dental | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| Educational | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| Podiatry | -- | -- | -- | -- | -- | -- | -- | -- | 79 | 21 |
| Hospital | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| Physician | 50 | 52 | -- | -- | -- | -- | -- | -- | 281 | 299 |
| Veterinary | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| **MODALITY TOTAL** | 50 | 52 | -- | -- | -- | -- | -- | -- | 363 | 323 |

The agency does not expect chiropractic, dental, or veterinary imaging modalities to be affected, as these entities are already subject to requirements set by their respective North Carolina professional licensing boards. These requirements apply to chiropractic clinics, dental radiation machines used in dental practices, hospitals, surgical centers, and veterinary offices. Modalities such as radiography, including Dual Energy X-Ray Absorptiometry (DEXA or DXA), fluoroscopy, and computed tomography, commonly used at hospitals, hospital-owned imaging centers, independent imaging centers, mobile imaging companies, and pain clinics, typically require ARRT registration for radiation machines to ensure insurance reimbursement. Therefore, the agency does not anticipate any impact on these entities from the new training requirements of this Rule.

**Number of Radiation Machine Operators Affected**
DHHS estimates that approximately 375 radiation machine operators currently practicing without registration equivalent to that of the American Registry of Radiologic Technologists (ARRT) will need to obtain ARRT registration in Radiography. Note that this analysis assumes that one operator is needed for each machine. This includes:

- an estimated 299 operators for radiography machines at physicians' offices.
- one operator for a radiography machine at a state government facility;
- two operators for radiography machines at local government facilities;
- an estimated 52 operators for Dual Energy X-Ray Absorptiometry (DEXA or DXA) machines, all of which are located at physicians' offices; and
- an estimated 21 operators of radiography machines in podiatry that are assumed to lack both ARRT registration and certification from the North Carolina Foot and Ankle Society. These individuals will be required to obtain both credentials to comply with the proposed standards. Of the 85 registered machines in use, it is assumed that approximately 25% of their operators fall into this category. The certification course, which covers both instruction and examination, is offered annually and, beginning in 2026, will be available twice a year at a cost of $225. Since 2015, a total of 293 individuals has completed the certification course.
- The proposal will also affect a portion of future RTs entering the field. New practitioners who do not already hold credentials equivalent to ARRT certification will be required to obtain training and certification that aligns with these nationally recognized standards. According to the Bureau of Labor Statistics, employment of radiologic technologists is projected to grow by 6% nationally from 2023 to 2033, with an estimated 13,000 job openings per year on average over the decade.[4] Many of these openings are expected to result from workforce turnover, including retirements and career changes. In North Carolina, based on the current estimate of 375 radiation machine operators who would need to complete training, an assumed annual turnover or new hire rate of 6% would lead to approximately 23 additional operators per year requiring training under the proposed rule.

**Costs of Rule .0604**
The anticipated per-person costs associated with the new requirements in Rule .0604 were estimated using the following data and reasonable assumptions:

[4] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Radiologic and MRI Technologists, at https://www.bls.gov/ooh/healthcare/radiologic-technologists.htm (visited *June 11, 2025*).

- **Training and Registration**:
    - Initial certification requires completion of an approved educational program (~$5,500 per person in tuition and exam costs) to take the exam to become registered through the ARRT. Note that this estimate assumes that the individual has already completed certain preliminary coursework.
    - Opportunity costs (i.e., time costs) for individuals to complete the required training and exam. We estimated the average number of credit hours required to complete the training is 51.15 hours (over two years) and assumed one hour of instruction per credit hour per week. This brings the estimated total amount of time spent completing the required coursework to about 818 hours per person (spread over two years or 4 semesters).
    - The course and exam for certification through the North Carolina Foot and Ankle Society cost $225.
    - Opportunity costs for individuals to complete the certification through the North Carolina Foot and Ankle Society. We estimated the average amount of time needed to complete this certification is 8 hours.
    - For the purposes of this analysis, opportunity costs were calculated based on an average hourly compensation (wages + benefits) in North Carolina for medical assistants and paramedics, which ranges from $25.35 to $30.42 per hour, respectively.
- **Registration Renewal (ARRT only):**
    - Registration renewal fees of $65 every two years.
- **Continuing Education (ARRT only)**:
    - Tuition costs of between $54 - $200 every two years.
    - Opportunity costs (i.e., time costs) for individuals to complete the required continuing education. We estimated the average amount of credit hours required to satisfy this requirement is 24 hours (every two years) and assumed one hour of instruction per credit hour.
    - For the purposes of this analysis, opportunity costs were calculated based on the average hourly compensation (wages + benefits) in North Carolina for radiologic technologists, which is $39.98 per hour.
- **Labor Cost**:
    - Many urgent care centers and smaller medical facilities in North Carolina currently rely on paramedics or medical assistants to operate radiation machines, even though their qualifications differ from those of RTs. This is reflected in the wage differences among these roles: in North Carolina, RTs have a median hourly wage of $32.29, compared to $24.57 for paramedics and $20.48 for medical assistants. [5] When benefits are included, the median hourly compensation rate is $39.98 for RTs, $30.42 for paramedics, and $25.35 for medical assistants.[6]
    - RTs who obtain this registration may become more marketable, gain a competitive advantage in the job market, and have the potential to command higher salaries compared to non-certified peers. One study estimates that RTs with certification typically earn 4-6% more than their non-certified peers.[7] Employers may incur higher labor costs when hiring registered radiologic technologists, but the decision to offer increased wages is subject to employer discretion or negotiation between the employer and employee. In economic terms, these higher wages represent a transfer from the employer to the employee, reflecting the

[5] Careeronestop-Compare Salaries. https://www.careeronestop.org/Toolkit/Wages/compare-salaries-results.aspx?keyword=Medical%20Assistants%7CParamedics%7CRadiologic%20Technologists%20and%20Technicians&location=North%20Carolina&compareby=loc&view=chart&sortby=annual&sortcolumn=0&sortorder=0

[6] Total hourly wage estimates assumed median hourly wage plus 23.8% in benefits. This benefit amount was derived from the BLS Employer Costs for Employee Compensation - March 2025 data for the health care industry with between 1-49 workers (Table 6).

[7] Timmons, E.J., Thornton, R.J. The Effects of Licensing on the Wages of Radiologic Technologists. *J Labor Res* **29**, 333–346 (2008). https://doi.org/10.1007/s12122-007-9035-9

increased market value of certified labor.
    - There is no data indicating a difference in higher labor costs when hiring a certified podiatry radiation machine operator specifically, but we believe it is reasonable to assume these employers would have the same potential for paying increased wages.
- Initial education, registration, and continuing education costs will be the responsibility of either the operators or their employers. While the exact proportion varies by employer and industry, it is common practice for employers, especially in healthcare, to bear at least part of the cost of required certification and continuing education to maintain a qualified workforce. For this analysis, we did not distinguish between which party would bear these expenses. It is reasonable to assume that some portion of education and certification costs for job-related training would be voluntarily covered by employers. Many employers recognize the value of having certified staff and often invest in employee training to ensure compliance with industry standards, improve workforce competence, and reduce turnover. Some professional organizations such as the ARRT may offer tuition reimbursement and support for continuing education, which some employers may also match or supplement. Additionally, job postings in podiatry and radiologic technology fields often include benefits like tuition reimbursement, indicating that employers are willing to share or fully cover these costs.
- These same per-person tuition and fee costs would apply to individuals entering the field (future hires) as well.

**Table 2: Projected One-Time and Ongoing Costs per Technologist – Rule .0604**

| Category | Modalities | Cost Estimate *per Technologist* | Notes |
|---|---|---|---|
| **Education Costs - ARRT** | Radiography, Podiatry | $5,500 tuition costs;<br>$23,859 opportunity costs | These are one-time costs spread over 2 years. |
| **Education Costs – NC Foot and Ankle Society** | Podiatry | $225 tuition costs;<br>$237 opportunity costs | These are one-time costs. |
| **License Maintenance Fees** | Radiography, Podiatry | $65 | This cost occurs once every two years. |
| **Continuing Education Units** | Radiography, Podiatry | $54-$200 in tuition costs;<br>$1,048 opportunity costs | These costs occur once every two years. |
| **Facility Labor Cost Increase** | Radiography, Podiatry | See wage comparisons in Notes | Median hourly total compensation for NC:<br>• RT $39.98<br>• Paramedic $30.42<br>• MA $25.35 |

**Table 3: Estimated 5-Year Costs for RT Training and Certification Requirements – Rule .0604**

| Sector | RT Type | # of RTs | Year 1 (2026) | Year 2 (2027) | Year 3 (2028) | Year 4 (2029) | Year 5 (2030) | 5-Year PV *per RT* | 5-Year PV Total |
|---|---|---|---|---|---|---|---|---|---|
| **State Government** | Radiography tuition & fees | 1 | $2,750 | $2,815 | $200 | $65 | $200 | $5,384 | $5,384 |
| | *Opportunity costs* | | *$11,753* | *$12,106* | *$1,048* | *$0* | *$1,112* | *$23,207* | *$23,207* |
| **Subtotal – State Gov't** | | | **$14,503** | **$14,921** | **$1,248** | **$65** | **$1,312** | **$28,591** | **$28,591** |
| **Local Government** | Radiography tuition & fees | 2 | $5,500 | $5,630 | $400 | $130 | $400 | $5,384 | $10,769 |
| | *Opportunity costs* | | *$23,507* | *$24,212* | *$2,097* | *$0* | *$2,224* | *$23,207* | *$46,414* |
| **Subtotal – Local Gov't** | | | **$29,007** | **$29,842** | **$2,497** | **$130** | **$2,624** | **$28,591** | **$57,182** |
| **Private Sector** | Radiography tuition & fees | 351 | $965,250 | $988,065 | $70,200 | $22,815 | $70,200 | $5,384 | $1,889,878 |
| | *Opportunity costs* | | *$4,125,394* | *$4,249,156* | *$367,975* | *$0* | $390,385 | $23,207 | *$8,145,602* |
| **Private Sector** | Podiatry tuition & fees | 21 | $57,750 | $63,840 | $4,200 | $1,365 | $4,200 | $5,581 | $117,197 |
| | *Opportunity costs* | | *$246,818* | *$259,193* | *$22,016* | *$0* | *$23,356* | *$23,414* | *$491,685* |
| **Private Sector – potential future new hires** | Radiography tuition & fees | 23 per year | $126,500 | $253,000 | $253,000 | $253,000 | $253,000 | $5,384 | $918,362 |
| **Subtotal - Private** | | | **$5,521,712** | **$5,813,254** | **$717,391** | **$277,180** | **$741,141** | **$28,994** | **$11.56M** |
| **Total – All Sectors** | | | **$5,565,222** | **$5,858,016** | **$721,136** | **$277,375** | **$745,078** | **$28,658 per RT (avg)** | **$11.65M** |
| | | | | | | | | ***25% is direct cost 75% is opportunity cost*** | |

**Notes:**

- Present Values (PVs) are expressed in 2025 dollars using a 7% discount rate. Present Value (PV) is a financial calculation that determines the current value of a series of future costs or payments by discounting them at a specific rate, reflecting the principle that money today is worth more than the same amount in the future. This calculation is required by G.S. 150B-21.4.
- Education costs were split between years 1 and 2, license costs occur in years 2 and 4, CEU costs occur in year 3 and 5, and the $225 certification fee for podiatry RTs occurs in year 2.
- Education per technologist: $5,500 (split $2,750 in year 1, $2,750 in year 2) + opportunity cost of about $12,000 in each of those years.
- License fee per technologist: $65 every two years (incurred in years 2 and 4).
- CEU per technologist: Assumed $200 every two years (incurred in years 3 and 5) + opportunity cost of about

$1,000 in each of those years.

- Opportunity costs for initial education were calculated using the average of the median hourly compensation (wages + benefits) for medical assistants and paramedics, with a 3% annual increase applied. For continuing education units (CEUs), opportunity costs were based on the median hourly compensation (wages + benefits) for RTs.
- If 23 new individuals begin a 2-year program each year, and each program costs $5,500 per individual, the college will have two cohorts enrolled at any given time (first-year and second-year students) beginning in Year 2. 46 students × $5,500 = $253,000 per year in additional tuition costs.
- Note that this table does not capture the unquantifiable costs such as potential wage increases that would be paid by employers and indirect costs to patients if facilities pass on increased operational costs. These unquantifiable costs are difficult to project and will likely vary significantly between different types of facilities and geographic regions.

**Benefits of Rule .0604**

The proposed changes to North Carolina's rules governing the operation of radiation machines introduce standardized training and certification requirements for RTs, aligning with nationally recognized standards such as those of ARRT. These changes are expected to yield significant quantifiable and qualitative benefits for patients, healthcare facilities, and RTs themselves.

Registered radiologic technologists are required to complete extensive education and clinical training in radiologic sciences, including anatomy, radiation physics, radiation protection, and imaging techniques. They must pass certification exams and maintain registration, ensuring up-to-date knowledge and competency. RTs are specifically trained to optimize radiation doses, minimizing exposure for both patients and staff, and are well-versed in radiation biology and safety protocols to reduce the risk of radiation-induced injuries or long-term harm.

In contrast, medical assistants or untrained personnel typically lack this expertise and are, therefore, more likely to produce suboptimal images, increasing the likelihood of misdiagnosis and unnecessary additional imaging and radiation exposure. Unlike medical assistants or untrained personnel, RTs are more likely to possess the expertise required for proper patient positioning, equipment operation, and imaging technique -- critical factors in producing high-quality diagnostic images on the first attempt. This proficiency reduces the need for repeat exposures, thereby lowering both patient risk and healthcare costs.

RTs are held to strict professional and ethical standards, with accountability mechanisms and continuing education requirements that ensure consistent, high-quality care. Their advanced training enables them to manage complications or adverse events associated with radiologic procedures, responsibilities for which untrained personnel may be unprepared.

The anticipated benefits associated with the new requirements in Rule .0604 were estimated using the following data and reasonable assumptions:

- **Reduced Repeat Imaging:**
    - Requiring radiologic technologists (RTs) to be trained and certified is expected to reduce repeat X-rays, generating significant annual cost savings. According to the American Society of Radiologic Technologists, the average repeat/reject rate is 7% for non-registered personnel and 6% for registered RTs, suggesting a 1% improvement with certification.[8] If each of the 375 technologists performs 20 X-rays per week for 50 weeks per year, that results in a total

[8] American Society of Radiologic Technologists. (2015). Radiation Protection Survey. Retrieved from https://www.asrt.org/docs/default-source/research/radiationprotectionsurvey.pdf

of 375,000 X-rays annually (375 × 20 × 50 = 375,000). A one percent reduction in repeat imaging would mean 3,750 X-rays are avoided each year (1% of 375,000 = 3,750). At a cost of $300 per X-ray, this reduction would save $1,125,000 annually (3,750 × $300 = $1,125,000).

- It is possible that the cost savings from reduced repeat imaging alone could approach or exceed the costs (direct plus opportunity) from the new training and certification requirements. To examine this, we conducted an analysis to determine the number of repeated X-rays that would need to be avoided to break even, varying the cost of an X-ray between $100-$300.

  Total 5-Year PV Cost: $11.65M
  Annualized Cost: $2.33M
  - At $100 per X-ray:
    At least 23,300 repeat X-rays per year would need to be avoided to break even.
  - At $300 per X-ray:
    At least 7,767 repeat X-rays per year would need to be avoided to break even.

- The costs associated with repeated X-rays -- and, conversely, the cost savings from avoiding unnecessary repeats -- are typically shared among patients, physicians, and insurers. The exact distribution of these costs depends on the patient's insurance coverage and the specific healthcare setting. Patients may pay out-of-pocket if they have not met their insurance deductible, have a high-deductible plan, or are uninsured. In these cases, they could be responsible for the full cost of each repeat X-ray.
- Physicians or healthcare facilities may incur costs if insurers refuse to reimburse for repeat imaging deemed unnecessary, or if repeat imaging reduces the facility's profit margin, especially in urgent care or outpatient settings.
- Insurance companies generally cover medically necessary X-rays, but higher repeat rates can lead to increased overall healthcare spending, which may ultimately result in higher premiums and out-of-pocket costs for patients in the long run.
- Reducing the repeat X-ray rate would also reduce patient radiation exposure. For example, reducing the repeat X-ray rate by just one percent from 7% to 6% would result in 3,750 fewer unnecessary X-rays each year (relying on the above assumptions) and a meaningful reduction in cumulative radiation dose for patients. Studies consistently show that even modest reductions in repeat imaging rates -- whether achieved through better training, certification, or information exchange -- improve both patient safety and healthcare efficiency.[9,10,11,12] Fewer repeat exposures directly translate to reduced cumulative radiation doses for patients, lowering the risk of radiation-induced injuries and long-term health consequences such as cancer.
- Better-trained RTs are likely to produce higher-quality images, decreasing the likelihood of misdiagnosis or delayed treatment, especially critical in urgent care settings where timely and accurate diagnosis is essential.
- Certified RTs are trained in radiation safety, proper equipment use, and patient positioning, all of which contribute to minimizing unnecessary exposure and procedural complications.

[9] Brower C, Rehani MM. Radiation risk issues in recurrent imaging. Br J Radiol. 2021;94(1126):20210389. doi:10.1259/bjr.20210389.
[10] Tariq Almojadah, Majdi Alnowimi, Essam Banoqitah, & Shyma M. Alkhateeb. (2023). Digital radiography retake rates and effect on patient dose. *Radiation Physics and Chemistry, 210*, Article 110991. https://doi.org/10.1016/j.radphyschem.2023.110991
[11] "Eliminating unnecessary radiation exposure from spinal radiography." Children's National Innovation District, 20 Feb. 2019. Accessed 9 July 2025. https://innovationdistrict.childrensnational.org/eliminating-unnecessary-radiation-exposure-from-spinal-radiography/
[12] Shi HM, Sun ZC, Ju FH. Recommendations for reducing exposure to medical X-ray irradiation (Review). Med Int (Lond). 2022 Jul 12;2(4):22. doi: 10.3892/mi.2022.47. PMID: 36699506; PMCID: PMC9829209.

- **Revenue to Community Colleges:**
    - The estimated potential revenue benefits in the form of tuition are $1,031,250 per year in each of the first two years and $253,000 per year thereafter. Most, if not all, of these training programs will be provided by community colleges, which play a central role in healthcare workforce education and generate significant economic value for both students and the broader community.

- **Operational Benefits:**
    - Improved first-attempt imaging should reduce workflow interruptions, shorten patient wait times, and optimize the use of expensive imaging equipment.
    - Fewer errors and adverse events lower the risk of malpractice claims for healthcare providers and institutions.
    - Standardized, transparent credentialing may increase public trust in healthcare services involving radiation.
    - Uniform training and certification requirements will bring North Carolina in line with most U.S. states, reducing interpretive burden and simplifying compliance for facilities. These benefits are likely to be realized but cannot be quantified.

- **Benefits to Radiologic Technologists (RTs):**
    - With formal certification, RTs are likely to qualify for higher salaries and more competitive positions, as employers increasingly prefer or require credentialed staff. This trend is evident in wage differences among related roles in North Carolina: RTs earn a median hourly wage of $32.29, compared to $24.57 for paramedics and $20.48 for medical assistants. Nationally recognized certification enhances RTs' ability to seek employment across state lines and in higher-acuity settings, increasing job security and career advancement opportunities.
    - Continuing education requirements ensure RTs maintain up-to-date knowledge, further enhancing patient care quality and safety.

**Table 4: Five-Year Present Value of Quantified Benefits (2025 dollars, 7% Discount Rate)**

| Benefit | Annual Value | 5-Year Present Value ($) |
|---|---|---|
| **Reduced repeat imaging** | $1,125,000/year | $4,612,726 |
| **Community college revenue*** | $1,031,250 (Y1-2), $253,000 (Y3-5) | $2,444,216 |
| **Total** | | **~$7.1M** |

**Notes:**

- *If 23 new individuals begin a 2-year program each year, and each program costs $5,500 per individual, the college will have two cohorts enrolled at any given time (first-year and second-year students). 46 students × $5,500 = $253,000 per year in additional revenue.

**Table 5: Summary of Quantified and Unquantified Benefits – Rule .0604**

| Benefit | Quantifiable Impact | Unquantifiable Impact |
|---|---|---|
| **Reduced Repeat Imaging** | Saves ~$1,125,000 annually by avoiding 3,750 unnecessary X-rays (at $300 each) | Lowers patient radiation exposure, improves patient safety, and reduces healthcare system inefficiency |
| **Community College Revenue** | $1,031,250/year (Years 1-2), $253,000/year (Years 3-5+) in tuition revenue | Strengthens community college role in workforce development |
| **Higher Earning Potential for RTs** | Certified RTs earn 4-6% more than non-certified peers | Enhances job security, career advancement, and professional mobility |
| **Operational Efficiencies** | Not quantified | Reduces workflow interruptions, shortens patient wait times, optimizes equipment utilization |
| **Reduced Malpractice Risk** | Not quantified | Fewer errors and adverse events lower risk of malpractice claims |
| **Public Trust and Compliance** | Not quantified | Increases public trust, aligns NC with national standards, simplifies compliance for facilities |
| **Improved Diagnostic Quality** | Not quantified | Decreases misdiagnosis risk and improves patient outcomes |
| **Workforce Quality and Safety** | Not quantified | Ensures consistent training, up-to-date knowledge, and higher standards of care |

**Uncertainties**

Notable uncertainties that could affect the cost and revenue estimates presented in this analysis are as follows:

- **Operator-to-Machine Ratio:**
  The analysis assumes one operator per machine. If facilities use multiple operators per machine or share operators across machines, the number of individuals affected -- and thus total cost -- could change.
- **Future Workforce Growth:**
  The number of new entrants into the field each year is estimated based on current turnover rates and projected job growth. Actual numbers could be higher or lower depending on labor market conditions and healthcare demand.
- **Repeat Imaging Reduction:**
  The projected 1% reduction in repeat X-rays is based on national averages. Actual reductions could vary depending on baseline repeat rates, compliance with new standards, and facility practices.
- **Opportunity Costs:**
  Opportunity costs are calculated using average hourly compensation for medical assistants and paramedics. However, some individuals may not be salaried or may not have benefits, which could lower the true opportunity cost for training and continuing education.

- **Continuing Education Costs:**
  The analysis uses the maximum estimated cost for continuing education units (CEUs) at $200 every two years, but actual costs could be as low as $54, depending on course selection and provider.
- **Wage Impacts:**
  The analysis assumes a potential wage increase for certified technologists, but the extent to which employers will pay higher wages is uncertain and may vary by region and facility type.
- **Indirect and Patient Costs:**
  The potential for increased patient fees if costs are passed on to patients is not quantified.
- **Revenue to Community Colleges:**
  Projected revenue assumes stable enrollment and tuition rates, but these could fluctuate based on demand, program capacity, or changes in educational funding. It should be noted, however, that the tuition rate for North Carolina community colleges has not changed since 2015-16.
- **Unquantifiable Benefits:**
  Many benefits, such as improved patient safety, reduced diagnostic errors, and enhanced public trust, are difficult to express in monetary terms but are likely significant.

**Alternatives Analysis for Proposed Rule .0604**
*Alternative 1: Maintain the Status Quo*

Under this alternative, North Carolina would retain its existing rules regarding operator training for individuals who use radiation machines, making no updates or enhancements. The current rules do not mandate structured training that aligns with national standards, nor do they require formal certification for radiologic technologists (RTs). While the Section has used these rules to address operator training to some extent, they are insufficient to ensure consistent, high-quality training and competency.

Although this alternative to the rule, as proposed, would have no immediate fiscal impact on the state, local governments, or regulated entities, it poses significant and unacceptable risks to public health and safety. The absence of standardized certification requirements perpetuates wide variability in operator training and competency, undermining consistency in radiation safety practices and patient protection. This ongoing lack of clarity will continue to cause confusion among employers and regulators regarding the minimum qualifications necessary to operate radiation machines safely.

Most critically, by failing to require certification for RTs, North Carolina would remain out of step with national standards designed to ensure competency and safeguard patients. This exposes patients and the public to unnecessary risk due to potential errors or unsafe practices by inadequately trained operators. For these reasons, maintaining the current rules is not a viable option, as it fails to protect patients, support workforce quality, or align with best practices in the field.

*Alternative 2: Accept Limited Scope Certification from Other States*

This alternative would permit North Carolina to recognize limited scope x-ray operator certifications from other states with comparable standards, rather than requiring registration exclusively through the American Registry of Radiologic Technologists (ARRT). Limited scope certification programs generally require 12 months of training, compared to 24 months for full ARRT registration, enabling faster workforce entry and helping to address shortages of entry-level imaging personnel.

Currently, North Carolina does not offer any in-state educational programs for limited scope certification. Implementing this alternative would require schools to develop new programs, a process complicated by the lack of existing infrastructure and uncertain demand. Additionally, agency staff would face an increased administrative burden to evaluate and approve out-of-state certifications for equivalency, potentially raising

regulatory oversight costs. There is also a risk that accepting varied training standards could lead to inconsistencies in the quality of care and safety practices if programs do not fully align with North Carolina's expectations. For these reasons, this alternative is not considered viable at this time and was rejected.

**Summary - Rule .0604**

The proposed amendments to Rule .0604 consolidate and clarify operator requirements for the use of radiation machines, aligning state standards with those of the American Registry of Radiologic Technologists (ARRT). We estimate that roughly 375 currently practicing radiation machine operators -- primarily in physicians' offices – will need to obtain ARRT-equivalent registration, with ongoing requirements for continuing education and license renewal.

Overall, implementing these certification and training requirements is expected to enhance patient safety, improve quality of care, and promote standardized practices across medical fields utilizing radiologic imaging. While facilities may incur higher labor costs, these are likely to be offset by savings from reduced repeat imaging, fewer diagnostic errors, and improved patient outcomes, resulting in a net positive fiscal and clinical impact over time.

In preparing this analysis, we intentionally used conservative estimates for costs to avoid underestimating the potential financial impact. Many of the benefits, particularly those related to patient safety and quality of care, are inherently difficult to quantify and are not fully captured in the analysis. Despite these uncertainties, there is a high degree of likelihood that the benefits of the proposed rule amendments will exceed the associated costs, especially as the healthcare system adapts and quality improvements are realized over time.

**10A NCAC 15 .0605 – OPERATING REQUIREMENTS**

The proposed readoption renames the rule title from "Fluoroscopic X-ray systems" to "Operating Requirements". By renaming, this rule's name aligns with the operating requirements proposed in this Rule. This proposed rule readoption is a consolidation of requirements specific to the facility located throughout the current Rules .0603 - .0608, .0610, and .0611. Merging this information into a single rule eliminates any ambiguity regarding who the requirements apply to, clearly informing all registrants that they must meet these requirements. The proposed rule does not eliminate the existing operating requirements for operators of radiation machines but clarifies existing language, contains technical changes, updates terminology, and aligns with industry standards.

**10A NCAC 15 .0606 – AREA REQUIREMENTS**

The proposed changes to this rule consolidate requirements for facilities from Rules .0603-.0608, .0610, and .0611 into a single, clearer rule. Key changes include:

1. Reorganizing existing language for better comprehension and logical sequencing.
2. Adding clarifying language for CBCT and CT radiation machines.
3. Updating terminology and aligning with Suggested State Regulations-Part F.[13]

The proposed changes to this rule do not alter the existing rule requirements and standards of practice but instead clarify the requirements in the area where radiation machines are used. The agency expects the changes to simplify compliance, resulting in an unquantifiable, incremental

[13] Conference of Radiation Control Program Directors: (CRCPD), retrieved from: https://crcpd.org/document/part-f-medical-diagnostic-interventional-x-ray-imaging-systems/

increase to compliance with this Rule. The agency expects an unquantifiable time savings for the registrants and stakeholders to achieve compliance. These proposed changes align with existing requirements, and therefore, the agency expects a minimal to no economic impact for registrants using radiation machines.

**10A NCAC 15 .0607 – RADIATION MACHINE REQUIREMENTS**

The proposed changes to this rule consolidate the radiation machines requirements of Rules .0604-.0607 and .0610 into a single, clearer rule. Key changes include:

1. Reorganizing existing language for better comprehension and logical sequencing.
2. Consolidating and incorporating by reference the federal regulations in 21 CFR Subchapter J.
3. Adding clarifying language for radiation machines not meeting existing requirements.
4. Updating terminology and aligning with Suggested State Regulations-Part F.
5. A proposed new rule specific to radiation machines that are considered new technology or that do not meet equipment requirements in the existing rule language.

The proposed changes to this rule do not alter the existing rule requirements and standards of practice. The agency does not broaden the scope of regulation with the addition of rule language but seeks to reduce the burden on registrants and stakeholders who must comply with this Rule. These proposed changes meet existing requirements for when a user or manufacturer must submit information for review when a machine does not meet existing requirements. Therefore, the agency expects minimal to no economic impact. The agency expects the changes to simplify compliance, resulting in an unquantifiable, incremental increase in compliance with this Rule. The agency expects an unquantifiable time savings for the registrants and stakeholders to achieve compliance. These proposed changes align with existing requirements, and therefore, the agency expects a minimal to no economic impact for registrants using radiation machines.

10A NCAC 15 .0601 is proposed for readoption with substantive changes as follows:

## SECTION .0600 - ~~X-RAYS IN THE HEALING ARTS~~ RADIATION MACHINES

Codifier's Note: 10 NCAC 03G .2700 was transferred to 15A NCAC 11 .0600 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

### 10A NCAC 15 .0601 PURPOSE AND SCOPE

~~This Section establishes requirements for x-ray equipment by or under the supervision of an individual authorized by and licensed, in accordance with state statutes, to engage in the healing arts or veterinary medicine The provisions of this Section are in addition to, and not in substitution for, the provisions of Sections .0100, .0200, .0900, .1000, and .1600 of this Chapter.~~

(a) Before installing a radiation machine for use, the registration process shall be initiated in accordance with Section .0200 of this Chapter.

(b) This Section applies to all facilities and service providers using radiation machines for the following:

(1) educational facilities that provide clinical training;

(2) human and veterinary use; and

(3) non-human use, used for forensic medicine, or used by service providers for demonstration purposes.

(4) service providers company who provide operators to end users.

(c) This Section provides additional requirements for the use of radiation machines by or under the supervision of a licensed practitioner authorized by and licensed, in accordance with state statutes, to practice medicine and provide professional services in chiropractic, dentistry, podiatry, research, and veterinary medicine.

(d) This Section provides additional operator requirements to use a radiation machine.

(e) The requirements of this Section are in addition to the provisions in Sections .0100, .0200, .1000, .1100, and .1600 of this Chapter.

*History Note:* *Authority G.S. 104E-7;*
*Eff. February 1, 1980;*
*Amended Eff. January 1, 1994;*
*Transferred and Recodified from 15A NCAC 11 .0601 Eff. February 1, ~~2015.~~2015;*
*Readopted Eff. May 1, 2026.*

10A NCAC 15 .0602 is proposed for readoption with substantive changes as follows:

**10A NCAC 15 .0602 DEFINITIONS**

~~(a) As used in this Section, the following definitions shall apply:~~

~~(1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.~~

~~(2) "Added filter" means the filter added to the inherent filtration.~~

~~(3) "Aluminum equivalent" means the thickness of aluminum, type 1100 alloy, affording the same attenuation, under specified conditions, as the material in question. The nominal composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum and 0.12 percent copper.~~

~~(4) "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.~~

~~(5) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation. Phototimer is described separately.~~

~~(6) "Beam axis" means a line from the source of x-rays through the centers of the x-ray fields.~~

~~(7) "Beam limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.~~

~~(8) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.~~

~~(9) "Changeable filters" means any added filter which can be removed from the useful x-ray beam through any electronic, mechanical or physical process.~~

~~(10) "Contact therapy system" means that the x-ray tube target is put within five centimeters of the surface being treated.~~

~~(11) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.~~

~~(12) "Cooling curve" means the graphical relationship between heat units stored and cooling time.~~

~~(13) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.~~

~~(14) "Diagnostic source assembly" means the tube housing assembly with a device attached.~~

~~(15) "Diagnostic type protective tube housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 mR in one hour when the tube is operated at its leakage technique factors.~~

~~(16) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.~~

~~(17) "Direct scattered radiation" means that radiation which has been deviated in direction by materials irradiated by the useful beam.(See also scattered radiation).~~

~~(18) "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.~~

~~(19) "Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons, negatrons and positrons, liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special unit of exposure is the roentgen.~~

~~(20) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.~~

~~(21) "Filter" means material placed in the useful beam to preferentially attenuate selected radiations.~~

~~(22) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks and structural material providing linkage between the image receptor and the diagnostic source assembly.~~

~~(23) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.~~

~~(24) "Gonad shield" means a protective barrier used to reduce exposure to the testes or ovaries.~~

~~(25) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.~~

~~(26) "Healing arts mass screening" means the examination of human beings using x-rays for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts who is legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. It does not include the use of x-ray tests as a requirement for hospital admission or as a condition of employment.~~

~~(27) "Image intensifier" means a device, including housing, which converts an x-ray pattern into a corresponding light image of higher energy density.~~

~~(28) "Image receptor" means any device, such as fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.~~

~~(29) "Inherent filtration" means the filtration permanently in the useful beam; it includes the window of the x-ray tube and any permanent tube or source enclosure.~~

~~(30) "Installation" means the act of physical movement of a radiographic system from one location to another in conjunction with a change of ownership.~~

~~(31) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.~~

(32) "Leakage radiation" means radiation emanating from a diagnostic or therapeutic source assembly except for:

(A) the useful beam and

(B) radiation produced when the exposure switch or timer is not activated.

(33) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly (i.e., tube housing and beam limiting device) which are used in measuring leakage radiation. They are defined as follows:

(A) for diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mC) or the minimum obtainable from the unit, whichever is larger;

(B) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential; and

(C) for all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.

(34) "Light field" means that area of the intersection of the light beam from the beam limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one fourth of the maximum in the intersection.

(35) "Maximum line current" means the rms (root mean square) current in the supply line of an x-ray machine operating at its maximum rating.

(36) "Mobile equipment" (see x-ray equipment).

(37) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(38) "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").

(39) "Portable equipment" (see x-ray equipment).

(40) "Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.

(41) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for radiation protection purposes, to reduce the radiation exposure.

(42) "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.

(43) "Protective barrier" means a barrier of radiation attenuating material(s) used to reduce radiation exposure. Types of protective barriers are defined in other items of this Rule.

(44) "Protective glove" means a glove made of radiation attenuating materials used to reduce radiation exposure.

(45) "Qualified expert" means an individual who is registered pursuant to Rule .0205 of this Chapter.

(46) "Radiograph" means an image receptor on which the image has been created directly or indirectly by an x-ray pattern and results in a permanent record.

(47) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

(48) "Rating" means the operating limits as specified by the component manufacturer.

(49) "Recording" means producing a permanent form of an image resulting from x-ray photons such as film and video tape.

(50) "Registrant", as used in this Section, means any person who owns or possesses and administratively controls an x-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by the provisions contained in Sections .0100 and .0200 of this Chapter to register with the agency.

(51) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid-scale reading.

(52) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (See also "direct scattered radiation".)

(53) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

(54) "SID" means source-image receptor distance.

(55) "Source" means the focal spot of the x-ray tube.

(56) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

(57) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

(58) "Stationary equipment" (see x-ray equipment).

(59) "Stray radiation" means the sum of leakage and scattered radiation.

(60) "Technique factors" means the conditions of operation. They are specified as follows:

(A) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(B) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and

(C) for all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(61) "Therapeutic type protective tube housing" means the tube housing with tube installed, and it includes high voltage and filament transformers and other appropriate elements when they are contained within that housing.

(62) "Transportation equipment" means x-ray equipment which is installed in a vehicle or trailer.

(63) "Tube" means an x-ray tube, unless otherwise specified.

(64) "Tube housing assembly" means the tube housing with tube installed. It includes high voltage and filament transformers and other appropriate elements when they are contained within the tube housing.

(65) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(66) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

(67) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at the given SID.

(68) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

(69) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices which control the technique factors of an x-ray exposure.

(70) "X-ray equipment" means an x-ray system, subsystem or component thereof.

(A) "Mobile equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(B) "Portable equipment" means x-ray equipment designed to be hand-carried.

(C) "Stationary equipment" means x-ray equipment which is installed in a fixed location.

(71) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(72) "X-ray high voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.

(73) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube housing assembly, a

~~beam limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.~~

~~(74) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this Section.~~

~~(75) "X-ray tube" means an electron tube which is designed for the conversion of electrical energy into x-ray energy.~~

~~(b) Other definitions applicable to this Section may be found in Sections .0100 and .0200 of this Chapter.~~

In addition to definitions found in Rules .0104, .0607(b)(3), (18), and (19), .1001, and .1601 of this Chapter, the following definitions shall apply to this Section:

(1) "Added filter" means the filter added to the inherent filtration.

(2) “Advanced practitioner” means an individual performing medical acts, tasks, or functions as a licensed nurse practitioner in accordance with G.S. 90-18.2 or a licensed physician assistant in accordance with G.S. 90-18.1.

(3) “Area radiation survey” means the evaluation of radiation levels around a radiation machine installation and adjacent areas to ensure compliance to dose limits in accordance with Section .1601 of this Chapter.

(4) “Cone beam computed tomography” is a volumetric imaging modality. Volumetric data are acquired using two-dimensional digital detector arrays and a cone-shaped x-ray beam (instead of fan-shaped) that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

(5) “Clinical training” means hands-on experience or clinical simulation to gain practical knowledge, experience, and skills.

(6) "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 a college or university accredited by an agency recognized by the U.S. Department of Education, and three years of work experience in a clinical CT environment. The work experience shall be supervised and documented by a medical physicist certified in the specialty area of diagnostic medical physics by the American Board of Radiology, the Canadian College of Physicists in Medicine, or the American Board of Medical Physics; or

(B) certification in the specialty area of diagnostic medical physics by the American Board of Radiology, the Canadian College of Physicists in Medicine, or the American Board of Medical Physics and shall abide by the certifying body's requirements for continuing education.

(7) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(8) “Dental assistant” means an individual who works for licensed dentists and meets the education, training, and experience defined by the NC Board of Dental Examiners.

(9) “Dental handheld radiation machine” means a radiation machine used to take dental radiographs, is designed to be handheld during operation, is operated by an individual authorized to take dental radiographs and may be used in multiple locations.

(10) “Dental hygienist” means an individual licensed by the NC Board of Dental Examiners to practice dental hygiene.

(11) “Diagnostic imaging” means visualizing the inside of the body using radiation exposures to determine the cause of illness or injury or to confirm a diagnosis.

(12) "Diagnostic-type protective tube housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 mR in one hour when the tube is operated at its leakage technique factors.

(13) “Diagnostic radiation machine” shall have the same meaning as “Diagnostic x-ray system” as defined in Rule .0607(b)(19) of this Section.

(14) "Entrance exposure rate" means the roentgen per unit time at the point where the center of the useful beam enters the patient.

(15) “Exposure control” shall have the same means as “control panel” as defined in Rule .0607(b)(19) of this Section.

(16) “Extra-oral” means outside the mouth. An extraoral image is produced by exposing, to x-rays, an image receptor positioned outside the mouth.

(17) "Filter" means material placed in the primary beam to preferentially attenuate selected radiation energies.

(18) "General supervision" means the activity is performed under the qualified supervisor's overall direction and control, but the qualified supervisor's physical presence shall not be required during the activity.

(19) "Inherent filtration" means the filtration permanently in the useful beam, including the window of the X-ray tube and any permanent tube or source enclosure.

(20) “Intra-oral” means inside the mouth. An intraoral image is produced by exposing a film, plate, or sensor placed within the mouth to X-rays.

(21) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(22) “Licensed dentist” means an individual licensed by the NC Board of Dental Examiners to practice dentistry.

(23) “Letter of Acknowledgement” means the correspondence provided by the agency acknowledging receipt of a shielding design, in accordance with Rule .0204(b) of this Chapter.

(24) “Mobile radiation machine” shall have the same meaning as “Mobile equipment” in Rule .0607(b)(19) of this Section.

(25) “Notice of Registration” means the correspondence provided by the agency, to the person completing the registration process, containing the information submitted on the agency forms in accordance with Rules .0203 and .0205 of this Chapter.

(26) “Optimal” means desirable or satisfactory.

(27) “Panoramic” means an imaging technique for producing a curved image layer radiograph of maxillary and mandibular dental arches and their supporting structures. This is a curvilinear variant of conventional tomography.

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

(29) "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation that reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated. See also "Automatic exposure control" in Rule .0607(b)(19) of this Section.

(30) “Portable radiation machine” shall have the same meaning as “Portable equipment” in Rule .0607(b)(19) of this Section.

(31) "Position indicating device (PID)" means a device on dental radiation machines used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.

(32) “Primary beam” shall have the same means as “useful beam” as defined in Rule .0607(b)(19) of this Section and is the beam used to make radiographic images.

(33) "Protective apparel" garments made of a radiation attenuating material used to potentially reduce radiation exposure to an individual wearing the item.

(34) "Qualified expert" means an individual registered in accordance with Rule .0205 of this Chapter.

(35) “Radiation machine” as defined in Rule .0103(b)(10) of this Chapter, shall have the same meaning as “x-ray equipment” as defined in Rule .0607(b)(19) of this Section.

(36) “Radiation subsystem” shall have the same meaning as X-ray subsystem in Rule .0601((b)(1()(B) of this Section.

(37) “Radiation system” shall have the same meaning as X-ray system in Rule .0601((b)(1()(B) of this Section.

(38) “Radiograph" means an image receptor on which the image has been created directly or indirectly by an x-ray pattern and results in a permanent record.

(39) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

(40) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.

(41) "Secondary protective barrier" means a barrier sufficient to attenuate stray radiation.

(42) "Secondary radiation" means the sum of leakage and scattered radiation.

(43) “Shielding design” means the floor plan and structural shielding specifications in accordance with current national standards, demonstrating the barriers which will attenuate radiation so that the dose limit requirements of Rules .1601(a)(8) and .1601(a)(15) of this Chapter are not exceeded.

(44) "Stationary radiation machine" means a radiation machine, components, or system installed and used in a fixed location.

(45) “Structural shielding” means materials incorporated into ceilings, floors, walls, or other structures to ensure the dose limit requirements of Rules .1601(a)(8) and .1601(a)(15) of this Chapter are not exceeded.

(46) “Veterinarian” means a veterinarian licensed pursuant to General Statue Chapter 90, Article 11.

(47) “Veterinary technician” means a veterinary technician registered pursuant to General Statue Chapter 90, Article 11.

*History Note:* *Authority G.S. 104E-7;*
*Eff. February 1, 1980;*
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*Readopted Eff. May 1, 2026.*

10A NCAC 15 .0603 is proposed for readoption with substantive changes as follows:

**10A NCAC 15 .0603 ~~GENERAL REQUIREMENTS~~ FACILITY RESPONSIBILITIES**

~~(a) Administrative controls~~

~~(1) The registrant shall be responsible for directing the operation of the X-ray machines which he has registered with the agency. He or his agent shall assure that the following provisions are met in the operation of the X-ray machine(s):~~

~~(A) An X-ray machine which does not meet the provisions of these Rules shall not be operated for diagnostic or therapeutic purposes, if so ordered by the agency in accordance with Rules .0109 and .0110 of this Chapter.~~

~~(B) Individuals who will be operating the X-ray equipment shall be instructed in the safe operating procedures and use of the equipment and demonstrate an understanding thereof to the registrant.~~

~~(C) In the vicinity of each diagnostic X-ray system's control panel, a chart shall be provided, which specifies for all usual examinations and associated projections which are performed by that system, a listing of information including patient's anatomical size versus technique factors to be utilized at a given source-to-image receptor distance. The chart shall also provide:~~

~~(i) type and size of the film or film-screen combination to be used,~~

~~(ii) type and ratio of grid to be used, if any, and focal spot-to-film distance,~~

~~(iii) type and placement of gonad shielding to be used.~~

~~(D) Radiation protection programand rules shall be established and made available to each individual operating X-ray equipment under his control. The operator shall be familiar with these rules.~~

~~(E) Only the professional staff and ancillary personnel required for the medical procedure or for training shall be in the room during the radiographic exposure. Other than the patient being examined:~~

~~(i) All individuals shall be positioned such that no part of the body including the extremities which is not protected by 0.5 mm lead equivalent will be exposed to the primary beam.~~

~~(ii) Professional staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.~~

~~(iii) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least six feet from both the tube head and the nearest edge of the image receptor.~~

(iv) When a portion of the body of a non-occupationally exposed professional staff or ancillary personnel is potentially subjected to stray radiation which would result in that individual receiving one-fourth of the maximum permissible dose as defined in Rule .1604 of this Chapter, additional protective measures shall be employed.

(v) Upon written application to the agency, the agency may waive the requirements in Subparts (a)(1)(E)(ii) and (a)(1)(E)(iii) of this Rule if the registrant demonstrates that such waiver is necessary for best management of patients and will not result in violation of the public and occupational dose limits established in the rules in this Chapter.

(F) Gonad shielding of not less than 0.5 mm lead equivalent shall be used for potentially procreative patients during radiographic procedures in which the gonads are in the direct, or primary beam, except for cases in which this would interfere with the diagnostic procedures.

(G) Individuals shall not be exposed to the primary beam except for healing arts purposes. Such exposures shall have been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other nonhealing arts purposes.

(H) When a patient or film must be provided with auxiliary support during a radiographic exposure:

(i) Mechanical holding devices shall be used whenever medical circumstances permit. Written safety procedures, as required in Part (a)(1)(D) of this Rule shall indicate the requirements for selecting a holder;

(ii) If a human holder is required, radiation protection programas required in Part (a)(1)(D) of this Rule, shall indicate the instructions provided to the holder;

(iii) The human holder shall be protected as required in Part (a)(1)(E) of this Rule;

(iv) No individual shall be used routinely to hold patients or film.

(I) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This includes, but is not limited to, the following requirements:

(i) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

(ii) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(iii) Portable or mobile equipment shall be used only for examinations where it is impractical for medical reasons to transfer the patient to a stationary radiographic installation.

~~(J) All persons who are associated with the operation of an X-ray system are subject to the occupational exposure limits as defined in Rules .1604 and .1638 of this Chapter, and personnel monitoring procedures in Rule .1614 of this Chapter. In addition, when protective clothing or equipment is worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:~~

~~(i) When an apron is worn the monitoring device shall be worn at the collar outside the apron.~~

~~(ii) The dose to the whole body shall be recorded in the reports required in Rule .1640 of this Chapter. If more than one device is used, each dose shall be identified with the area where the device was worn on the body.~~

~~(2) The registrant shall maintain at least the following information for each X-ray machine:~~

~~(A) current registration information and other correspondence with the agency regarding that machine;~~

~~(B) records of surveys and calibrations;~~

~~(C) records of maintenance or modifications which affect the primary beam after the effective date of these Rules, along with the names of persons who performed the service.~~

~~(b) Plans Review. Prior to construction or structural modification, the floor plans and equipment arrangement of all installations utilizing X-rays for diagnostic or therapeutic purposes shall be reviewed by a qualified expert. The registrant shall submit recommendations of the expert to the agency.~~

~~(c) Radiation Survey~~

~~(1) For installations of X-ray equipment after the effective date of this Rule, an area radiation survey shall be performed within 30 days following initial operation of each radiation machine to show compliance with Rule .0604(b) of this Section. This survey shall include:~~

~~(A) a drawing of the room in which a stationary X-ray system is located and radiation levels in adjacent areas; and~~

~~(B) the name of the person approved by the agency performing the survey and the date the survey was performed.~~

~~(2) Any modification to the X-ray room or adjacent areas which could increase the radiation dosage to any individual shall require a new survey.~~

~~(3) Records of this survey shall be maintained in accordance with Subparagraph (a)(2) of this Rule.~~

(a) The registrant shall not allow the operation of a radiation machine for diagnostic imaging not meeting the requirements of Rule .0607(b) of this Section.

(b) Mobile or portable radiation machines shall only be used for radiation exposures where transferring the patient to a stationary radiation machine is impractical for medical reasons. The use of a mobile or portable radiation machine as the primary method for diagnostic imaging at a permanent location, instead of a stationary radiation machine, is prohibited.

(c) If ordered by the agency, radiation machines are subject to impounding by an authorized representative of the agency in accordance with Rule .0107 of this Chapter.

(d) The registrant or their designee shall:

(1) be responsible for directing the operation of the radiation machine(s) registered with the agency;

(2) ensure the provisions of this Section are met during the operation of the radiation machine(s) under their control;

(3) establish radiation protection procedures and make them readily available to individuals who operate the radiation machine(s);

(4) ensure QC is performed if required by the manufacturer or registered service provider, in accordance with the instructions provided; and

(5) establish procedures or provide equipment to operators to control the radiation area during radiographic exposures.

(e) Extraoral cephalometric, cone beam computed tomography (CBCT), and panoramic radiation machines designed for use in dental radiography or for facial diagnostic imaging and chiropractic or podiatry radiation machines shall meet shielding design requirements in Rule .0204(b) of this Chapter, shielding barrier requirements in Rule .0606(a) of this Section, and radiation machine requirements in Rule .0607 of this Section; and

(f) Dental intraoral handheld radiation machine additional requirements for maintenance and evaluation:

(1) Maintenance shall be performed by a registered service provider following the manufacturer's specifications.

(2) The machine shall be evaluated by a registered service provider, in accordance with Section .0200 of this Chapter, after the unit is dropped, visibly damaged, or as requested by the agency. Machines with signs of visible damage, or as requested by the agency, shall not be used until being evaluated by a registered service provider.

(g) Cone Beam Computed Tomography (CBCT) radiation machine additional requirements for system performance evaluations:

(1) Maintain documentation of the established standards, tolerances, and testing results.

(2) Implement actions when the QC results are outside of the limits specified in the QC recommendations.

(3) The CBCT radiation machine shall be evaluated by a registered service provider, in accordance with Section .0200 of this Chapter, within 30 days of:

(A) initial installation; and

(B) when there is any change or replacement of components which, in the opinion of the registered service provider, could cause a change in the radiation output or image quality.

(4) The following information shall be readily available to CBCT operators:

(A) instructions on performing routine QC, including the use of the CBCT phantom;

(B) schedule of routine QC appropriate for the system and allowable variations set by the registered service provider, if required, for the indicated parameters; and

(C) results of at least the most recent routine QC completed on the system.

(h) Dental Cone Beam Computed Tomography (CBCT) radiation machines shall not be used:

(A) as the primary or initial imaging modality when a lower dose alternative is adequate for clinical purposes;

(B) for the sole purpose of producing simulated bitewing, panoramic, or cephalometric images; or

(C) for routine or serial orthodontic imaging.

(i) The uses of Cone Beam CT, Veterinary CT, CT simulation, and attenuation correction shall be exempt from Paragraphs (i) and (j) of this Rule.

(j) Computed Tomography (CT) radiation machine shall meet the following additional requirements for 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 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 the manufacturer's specifications or standards and tolerances for the CT X-ray system from the American College of Radiology (ACR) incorporated herein by reference, including subsequent amendments and editions. These standards and tolerances may be found at no charge on the ACR website at https://www.acr.org.

(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; and

(G) a review of the results of the routine QC, as set forth in Paragraph (j) of this Rule.

(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; and

(D) adult abdomen.

(6) Evaluation of radiation output shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated within the preceding two years by persons registered, in accordance with Section .0200 of this Chapter, to provide such services.

(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 and any other individuals participating in the evaluation under the general supervision of the CT QE. The documentation shall be retained for 14 months.

(k) Computed Tomography (CT) radiation machines shall meet the following additional requirements for routine quality control (QC)

(1) A routine QC program for the CT radiation imaging 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 (1) of this Paragraph, shall be conducted by individuals that meet the requirements of Rule .0604(i)(2) of this Section, 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.

(l) Records shall be maintained by the registrant as follows:

(1) For each radiation machine under the registrant's custody and control:

(A) the state notice of registration and other correspondence with the agency regarding the radiation machine;

(B) the shielding design and the corresponding letter of acknowledgment granted by the agency;

(C) the report of installation, receipt of sale, disposal notification, or transfer of ownership;

(D) an area radiation survey; and

(E) maintenance or modifications that affect the primary beam and documentation of service(s) performed, along with the names of those who performed the service.

(2) For each individual operating a radiation machine, the operator license, certification, or training documentation.

(m) Records shall be available for agency review during inspection.

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*Eff. February 1, 1980;*
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10A NCAC 15 .0604 is proposed for readoption with substantive changes as follows:

**10A NCAC 15 .0604 ~~GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC SYSTEMS~~ OPERATOR REQUIREMENTS**

~~(a) In addition to other requirements of this Section, all diagnostic x-ray systems shall meet the following requirements:~~

~~(1) The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operation instructions are observed."~~

~~(2) Equivalent wording may be used on battery-powered generators; visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.~~

~~(3) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 millirem in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.~~

~~(4) The radiation emitted by a component other than the diagnostic source assembly shall not exceed two millirem in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.~~

~~(5) Beam Quality~~

~~(A) Half-Value Layer~~

~~(i) The half value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in the following table. "Specified Dental System" is any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980. "Other X-Ray Systems" shall be all other x-ray systems subject to this Section.~~

| ~~X-Ray Tube Voltage (kilovolt peak)~~ | ~~Minimum HVL (millimeters of Aluminum)~~ | ~~Minimum HVL (millimeters of Aluminum)~~ | |
|---|---|---|---|
| | ~~Measured Potential~~ | ~~Specified Systems~~ | ~~Other Dental X-ray Systems~~ |
| ~~Designed operating range~~ | | | |
| ~~Below 50~~ | ~~30~~ | ~~1.5~~ | ~~0.3~~ |

| | | | |
|---|---|---|---|
| | 40 | 1.5 | 0.4 |
| | 49 | 1.5 | 0.5 |
| 50 to 70 | 50 | 1.5 | 1.2 |
| | 60 | 1.5 | 1.2 |
| | 70 | 1.5 | 1.5 |
| Above 70 | 71 | 2.1 | 2.1 |
| | 80 | 2.3 | 2.3 |
| | 90 | 2.5 | 2.5 |
| | 100 | 2.7 | 2.7 |
| | 110 | 3.0 | 3.0 |
| | 120 | 3.2 | 3.2 |
| | 130 | 3.5 | 3.5 |
| | 140 | 3.8 | 3.8 |
| | 150 | 4.1 | 4.1 |

If it is necessary to determine such half value layer at an x-ray tube potential which is not listed in the table, linear interpolation or extrapolation may be made. Positive means shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

(ii) The requirements of Subpart (a)(5)(A)(i) of this Rule shall be considered to be met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table:

Filtration Required versus Operating Voltage

| Operating Voltage (kVp) | Minimum total filtration (inherent plus added) (millimeters aluminum equivalent) |
|---|---|
| Below 50 | 0.5 millimeters |
| 50–70 | 1.5 millimeters |
| Above 70 | 2.5 millimeters |

(iii) Notwithstanding the requirements of Subpart (a)(5)(A)(ii) of this Rule, all intraoral dental systems manufactured after December 1, 1980, shall have a

minimum of 1.5 mm aluminum equivalent filtration permanently installed in the useful beam.

(iv) Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

(v) For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

(vi) The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the focal spot of the tube and the patient, such as a tabletop when the tube is mounted under the table and inherent filtration of the tube.

(B) For new x-ray systems installed after the effective date of these Rules and which have variable kVp and selectable filtration for the useful beam, a device shall link the kVp selector with the filter(s), so that the minimum filtration is always present for the kVp selected.

(6) Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected and their location shall be clearly indicated on the master control panel prior to initiation of the exposure.

(7) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a design function of the x-ray system.

(8) The location of the focal spot may be indicated on a readily visible area of the x-ray source housing in the plane parallel to the image receptor when the image receptor is perpendicular to the beam axis.

(9) Technique Indicators

(A) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

(B) Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(C) On equipment having fixed technique factors, the recommendation in Part (a)(9)(A) of this Rule may be met by permanent markings.

(b) Structural Shielding

(1) For stationary diagnostic systems, except for intraoral dental systems which shall meet the requirements of Rule .0607(j) of this Section, structural shielding shall be provided to assure compliance with Rules .1604 and .1611 of this Chapter. The following shall be provided:

(A) All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of 84 inches above the floor;

~~(B) Secondary barriers in the wall, floor and ceiling areas not having a primary barrier or where the primary barrier requirements are lower than the secondary barrier requirements; and~~

~~(C) A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposures.~~

~~(2) When a mobile system is used routinely in one location, the structural shielding in that location shall meet the requirements for stationary diagnostic systems in Subparagraph (b)(1) of this Rule.~~

(a) A radiation machine shall not be permitted for human, non-human, or veterinary use except when used in accordance with the operating requirements of Rule .0605 of this Section.

(b) Operators shall be trained in the operational features and safe use of the radiation machines used.

(c) Individuals who operate a radiation machine shall meet the requirements for the modality of use in Paragraphs (e),f),(g),(h), or (i) of this Rule no later than 36 months after the effective date of this Rule.

(d) Individuals who operate a radiation machine for research purposes or for end-of-life imaging are exempt from the requirements in Paragraphs (e),(f),(g),(h), or (i) of this Rule.

(e) The uses of Cone Beam CT, Veterinary CT, CT Simulation, and CT attenuation correction shall be exempt from the requirement in Subparagraph (i) of this Rule.

(f) Chiropractic

(1) other than the chiropractor, individuals who operate a radiation machine for chiropractic patient care shall be certified by the North Carolina State Board of Chiropractic Examiners as a Certified Chiropractic Assistant – Level 2 in accordance with G.S. 90-143.2 and 21 NCAC 10.0213)(3);

(2) be a Registered Technologist (RT) by the American Registry of Radiologic Technologists (ARRT) with an active registration in Radiography (R); or

(3) be enrolled in a training program for radiography, and under the personal supervision of an individual who meets the requirements of Subparagraphs (1) or (2) of this Paragraph.

(g) Dentistry

(1) other than the dentist, individuals who operate dental radiation machines shall be a licensed dental hygienist;

(2) shall meet radiography requirements for dental assistants as defined by the NC Board of Dental Examiners; or

(3) shall be enrolled in a training program for radiography, and under the personal supervision of an individual who meets the requirements of Subparagraphs (1) or (2) of this Paragraph.

(h) Podiatry

(1) other than the podiatrist, all podiatric radiation machine operators shall complete radiography training and pass an examination provided by the NC Foot and Ankle Society;

(2) shall hold an active registration in Radiography (R) with the American Registry of Radiologic Technologists (ARRT); or

(3) shall be enrolled in a training program for radiography, and under the personal supervision of an individual who meets the requirements of Subparagraphs (1) or (2) of this Paragraph.

(i) Radiography and Fluoroscopy

(1) Radiography

(A) individuals who operate a radiation machine for plain radiography shall be a Registered Technologist (RT) by the American Registry of Radiologic Technologists (ARRT) with an active registration in Radiography (R); or

(B) shall be enrolled in an accredited radiography educational program and under the personal supervision of an individual who meets the requirements of Part (A) of this Paragraph.

(2) Fluoroscopy

(A) individuals who operate fluoroscopy radiation machines shall be a physician as defined in Rule .0103(b)(8) of this Chapter or an advanced practitioner provider (APP) as defined in Rule .0602(2) of this Section under the personal supervision of a physician who has completed training in accordance with Paragraph (l) of this Rule;

(B) shall be an ARRT-registered RT and hold an active registration in Radiography (R); or

(C) shall be enrolled in an accredited educational program for radiography and under the personal supervision of an individual who meets the requirements of Part (B) of this Subparagraph

(3) Angiography

(A) individuals who operate fluoroscopy radiation machines shall be a physician as defined in Rule .0103(b)(8) of this Chapter;

(B) shall be an ARRT-registered RT and hold an active registration in Radiography (R);

(C) shall be a graduate of a post-secondary educational program in interventional cardiac and vascular technology and a Registered Cardiovascular Invasive Specialist (RCIS) by or a Registered Cardiac Electrophysiology Specialist (RCES) by Cardiovascular Credentialing International (CCI); or

(D) shall be enrolled in an accredited educational program and under the personal supervision of an individual who meets the requirements of Part (B) or (C) of this Subparagraph.

(j) Computed Tomography (CT)

(1) individuals who operate a CT radiation machine for diagnostic imaging shall hold an active Computed Tomography (CT) registration with the ARRT; or

(2) shall be enrolled in an accredited educational program and under the personal supervision of an individual who meets the requirements of Part (A) of this Subparagraph.

(k) Dual Energy X-Ray Absorptiometry (DEXA or DXA)

(1) Individuals who operate a DEXA of DXA radiation machine for diagnostic measurement of bone density or body composition as ordered by a physician or APP shall be:

(A) an ARRT-registered technologist with an active registration in Bone Densitometry (DB);

(B) a Certified Bone Densitometry Technologist (CBDT) by the International Society for Clinical Densitometry (ISCD); or

(C) enrolled in an accredited educational program and under the personal supervision of an individual who meets the requirements of Part (A) or (B) of this Subparagraph.

(2) All individuals who operate a DEXA or DXA radiation machine shall receive training specific to the radiation machine used and training in basic principles of radiation protection prior to using the radiation machine.

(l) Veterinary Imaging

(1) other than the veterinarian, all veterinary radiation machine operators shall be:

(A) under the personal supervision of a veterinarian;

(B) be a veterinary technician; or

(C) under the personal supervision of a veterinary technician.

(2) other than a veterinarian, all veterinary radiation machine operators shall be employed or engaged by a veterinarian or the owner of a veterinary facility registered in accordance with Section .0200 of this Chapter.

(m) For individuals other than radiologists, instruction and training to operate fluoroscopic and angiographic radiation machines by physicians and APPs shall include:

(1) radiation quantities and units;

(2) biological effects of ionizing radiation and recognition of symptoms of acute localized exposure;

(3) radiation dose management and optimization of image quality; and

(4) equipment features.

(n) Training records for each operator of a radiation machine shall be maintained and available for agency review during inspection.

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10A NCAC 15 .0605 is proposed for readoption with substantive changes as follows:

**10A NCAC 15 .0605 ~~FLUOROSCOPIC X-RAY SYSTEMS~~ OPERATING REQUIREMENTS**

~~All fluoroscopic X-Ray systems shall meet the following requirements:~~

~~(1) Limitation of primary beam~~

~~(a) The fluoroscopic tube shall not produce X-Rays unless the primary protective barrier is in position to intercept the entire primary beam at all times.~~

~~(b) The entire cross section of the primary beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID.~~

~~(c) Limitation to the Imaging Surface~~

~~(i) The X-Ray field produced by fluoroscopic equipment without image intensification shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot-filming procedures.~~

~~(ii) Image-intensified fluoroscopy and spot-filming shall comply with the following:~~

~~(A) During fluoroscopic or spot-filming procedures, neither the length nor the width of the X-Ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.~~

~~(B) Compliance shall be determined with the beam axis perpendicular to the image receptor. For rectangular X-Ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-Ray field which pass through the center of the visible area of the image receptor.~~

~~(iii) In addition to other requirements of this Rule, equipment manufactured after the effective date of these Rules shall comply with the following:~~

~~(A) Means shall be provided between the source and the patient for adjustment of the X-Ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. This adjustment shall be automatically accomplished except when the X-Ray field size in the plane of the film is smaller than that of the selected portion of the film.~~

~~(B) It shall be possible to adjust the X-Ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID, shall be equal to or less than five centimeters by five centimeters.~~

(C) The center of the X-Ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID.

(2) X-Ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-Ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) Entrance exposure rates shall be limited as required in the following:

(a) Fluoroscopic equipment shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of ten roentgens per minute at the point where the center of the primary beam enters the patient, except:

(i) during recording of fluoroscopic images; or

(ii) when provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) In addition to the other requirements of this Rule equipment manufactured after August, 1974, which does not incorporate an automatic exposure control (e.g., automatic brightness control or ionization chamber control) shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the primary beam enters the patient except during the recording of fluoroscopic images or when provided with an optional high level control.

(c) Compliance with the provisions of Item (3) of this Rule shall be determined as follows:

(i) Movable grids and compression devices shall be removed from the primary beam during the measurement.

(ii) If the source is below the table, the exposure rate shall be measured one centimeter above the tabletop or cradle.

(iii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iv) In a C-arm type fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(d) Periodic measurement of entrance exposure rate limits shall comply with the following:

(i) Such measurements shall be made every two years or after any maintenance of the system which might affect the exposure rate.

(ii) Results of these measurements shall be available or posted where any fluoroscopist may have ready access to them and shall be in the record required in Rule .0603(a)(2)(B) of this Section. Results of the measurements shall include the exposure rate, as well as the physical factors used to determine all data; the name of the person approved by the agency performing the measurements and the date the measurements were performed.

(iii) Entrance exposure rate shall be determined with the attenuation block in Rule .0602(a) in the primary beam.

(4) Radiation transmitted through the primary protective barrier of the fluoroscopic imaging assembly shall comply with the following requirements:

(a) The exposure rate resulting from transmission through the primary protective barrier with the attenuation block in the primary beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgens per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(b) Measurements to determine compliance with Sub item (4)(a) of this Rule shall be in accordance with the following:

(i) The exposure rate resulting from transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters;

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly, positioned 30 centimeters above the tabletop.

(iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters;

(iv) Movable grids and compression devices shall be removed from the primary beam during the measurement;

(v) The attenuation block shall be positioned in the primary beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(5) During fluoroscopy and cinefluorography, X-Ray tube potential and current shall be continuously indicated.

(6) The source-skin distance shall not be less than:

~~(a) 38 centimeters on stationary fluoroscopes,~~

~~(b) 30 centimeters on all mobile fluoroscopes, or~~

~~(c) 20 centimeters for image intensified fluoroscopes during surgical application.~~

~~(7) Fluoroscopic timers shall meet the following requirements:~~

~~(a) Means shall be provided to preset the cumulative on time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.~~

~~(b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on time. Such signal shall continue to sound while X-Rays are produced until the timing device is reset.~~

~~(8) Mobile fluoroscopes, in addition to the other requirements of this Rule, shall provide image intensification.~~

~~(9) Scattered radiation shall be controlled in accordance with the following requirements:~~

~~(a) A shielding device of at least 0.25 mm lead equivalent for covering the Bucky slot during fluoroscopy shall be provided.~~

~~(b) A shield of at least 0.25 mm lead equivalent, such as overlapping protective drapes or hinged or sliding panels, shall be provided to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.~~

~~(c) Upon application to the agency with adequate justification, exceptions from Sub-items (9)(a) or (9)(b) of this Rule may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures.~~

(a) Radiation machines shall only be operated by individuals who meet the operator requirements of Rule .0604 of this Section.

(b) Exposures of individuals to the primary beam:

(1) Individuals shall not be exposed to the primary beam except for diagnostic imaging purposes. Such exposures shall have been authorized by a licensed practitioner as defined in Rule .0103(b)(8) of this Chapter.

(2) Students or candidates in training under the personal supervision of an individual that meets the requirements of Rule .0604 of this Chapter shall not be permitted to perform radiographic imaging unless such exposures have been authorized by a licensed practitioner as defined in Rule .0103(b)(8) of this Chapter.

(3) Deliberate exposure of an individual for training, demonstration, or other non-diagnostic imaging purposes is prohibited.

(4) Radiation exposures for non-human use, used for forensic medicine, or by service providers for demonstration purposes are exempt from Subparagraphs (b)(1) and (2) of this Rule.

(c) The radiation exposure to the patient shall be the minimum exposure required to produce images of optimal diagnostic quality.

(d) Individuals who operate radiation machines shall:

(1) be familiar with the radiation protection program procedures established in accordance with Rule .0603(d)(3) of this Section;

(2) use collimation to limit the primary beam to the area of clinical interest or to the image receptor, whichever is smaller;

(3) use technique factors and dose reduction technologies, according to patient sizes and clinical indication, to optimize patient dose while maintaining optimal image quality;

(4) use mechanical holding devices, whenever medical circumstances permit, when a patient or image receptor must be provided with auxiliary support during a radiation exposure; and

(5) control the area during radiation exposures.

(e) Except for dental handheld radiation machines, individuals who operate radiation machines shall not hold either the X-Ray tube housing or the collimating device during radiation exposures.

(f) No occupational worker shall be designated as the individual who always holds patients or image receptors during radiation exposures. Operators of veterinary radiation machines are exempt from this Rule.

(g) If a human holder is required, they shall be provided with instructions:

(1) for supporting the patient during the radiation exposure;

(2) to wear a lead apron equivalent to 0.25 mm or greater for protection from scatter radiation during the exposure; and

(3) to avoid extremity exposure to the primary beam, or to wear protective gloves equivalent to 0.5 mm of lead or more.

(h) Except for Dual Energy X-Ray Absorptiometry (DEXA or DXA) and intraoral dental handheld radiation machine operators, only the professional staff and individuals required for the medical procedure or those in training shall be in the room of the patient being examined during the radiographic and fluoroscopic exposures.

(1) All individuals other than the patient being examined shall be:

(A) positioned such that no part of the body, including the extremities, which are not protected by 0.5 mm lead equivalent or greater material will be exposed to the primary beam; and

(B) protected from scatter radiation by protective apparel or whole-body protective equipment of 0.25 mm lead equivalent or greater material.

(2) When a mobile or portable radiation machine is used during radiographic or fluoroscopy exposures, patients other than the individual examined who cannot be removed from the room shall be protected from the scatter radiation by:

(A) protective apparel or equipment; or

(B) be positioned so that the nearest portion of the body is six feet or greater from both the tube head and the nearest edge of the image receptor.

(i) CT operators shall have the following made readily accessible during the use of the CT radiation 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.

(j) Intraoral dental radiation machine operators shall use patient and film holding devices when the techniques permit.

(k) Intraoral dental handheld radiation machine operators shall ensure the following additional requirements are met:

(1) When making an exposure, all individuals other than the patient undergoing the procedure remain at a distance greater than six feet from the patient.

(2) Use an individual monitoring device. When protective apparel is required in accordance with Subparagraph (3) of this Rule, the individual monitoring device shall be used in accordance with Paragraph (m) of this Rule.

(3) Wear protective apparel of 0.25 mm or greater lead equivalent material when the backscatter shield is not parallel to the operator while making an exposure.

(l) Veterinary radiation machine operators shall ensure the following additional requirements are met.

(1) A dead-man type of exposure switch shall be provided, tethered with a cord of a length so that the operator can stand out of the primary beam and six feet or greater from the animal during all X-Ray exposures or behind a protective barrier adequate to assure compliance with dose limit requirements of Rules .1601(a)(8) and .1601(a)(15) of this Chapter are not exceeded.

(2) No individual other than the operator shall be in the X-ray room while exposures are being made unless such an individual's assistance is required.

(m) When protective apparel or equipment is used and an individual monitoring device(s) is required, at least one such monitoring device shall be used as follows:

(1) The individual monitoring device shall be worn at the collar, outside the apparel.

(2) If protective equipment is used in place of protective apparel, the individual radiation monitoring device shall be worn on the torso.

(3) A fetal monitoring device shall be worn at the waist. If protective apparel is worn, the individual radiation monitoring device shall be worn under the protective apparel at the waist.

(4) The dose to the whole body shall be recorded in the reports in accordance with Rule .1601(a)(53) of this Chapter. If more than one device is used, each dose shall be identified with the area where the device was worn on the body.

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*Eff. February 1, 1980;*
*Amended Eff. May 1, 1993; May 1, 1992; October 1, 1980;*

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10A NCAC 15 .0606 is proposed for readoption with substantive changes as follows:

**10A NCAC 15 .0606 ~~SYSTEMS OTHER THAN FLUOROSCOPIC AND DENTAL INTRAORAL~~ AREA REQUIREMENTS**

~~(a) Unless specifically provided otherwise by the rules in this Chapter, the requirements in this Rule shall apply to all x-ray systems, except for fluoroscopic and dental intraoral x-ray systems. The useful beam of x-ray systems subject to provisions of this Rule shall be limited to the area of clinical interest or the image receptor, whichever is smaller.~~

~~(1) General purpose stationary and mobile x-ray systems shall meet the following special requirements:~~

~~(A) There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.~~

~~(B) Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.~~

~~(C) Notwithstanding Parts (a)(1)(A) and (B) of this Rule, equipment manufactured before August 1, 1974 may employ fixed cones and diaphragms or variable collimators without beam defining lights.~~

~~(2) In addition to the requirements of Subparagraph (a)(1) of this Rule, all stationary x-ray systems, except equipment originally manufactured before the effective date of this Rule, shall meet the following requirements:~~

~~(A) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;~~

~~(B) The beam limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;~~

~~(C) Indication of field size dimensions and SID's shall be specified in inches or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.~~

~~(3) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.~~

~~(4) Special purpose x-ray systems shall meet the following requirements:~~

(A) These systems shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(B) Such systems shall also be provided with means to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.

(C) The requirements in Parts (a)(4)(A) and (B) of this Rule may be met with a system that meets the requirements for a general purpose x-ray system as specified in Subparagraph (a)(1) of this Rule or, when alignment means are also provided, as follows:

(i) an assortment of removable, fixed aperture, beam limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where each device has clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(ii) a beam limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which each aperture is designated and indicating which aperture is in position for use.

(b) Radiation exposure control devices shall meet the following requirements:

(1) Means shall be provided to terminate the exposure after a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:

(A) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero except during serial radiography, and

(B) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided.

(2) Control over x-ray exposures shall be in accordance with the following requirements:

(A) A control shall be incorporated into each x-ray system such that the operator can terminate an exposure at any time except for serial radiography where means may be provided to permit completion of any single exposure of the series in process.

(B) Each x-ray control shall be located in such a way as to meet the following criteria.

(i) For stationary x-ray systems, the control shall be permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(ii) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, except for equipment originally manufactured before the effective date of this Rule, a signal audible to the operator shall indicate that the exposure has terminated.

(3) When an automatic exposure control (e.g., phototimer) is provided the following requirements shall be met, except equipment originally manufactured before the effective date of this Rule:

(A) Indication shall be made on the control panel when this mode of operation is selected;

(B) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(C) The minimum exposure time for all equipment other than that specified in Part (b)(3)(B) of this Rule shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater;

(D) Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(E) A visible signal shall indicate when an exposure has been terminated at the limits described in Part (b)(3)(D) of this Rule and manual resetting shall be required before further automatically timed exposures can be made.

(4) When four timer tests are performed at identical timer setting equal to 5.0 seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period (Tmax) and the minimum period (Tmin) in accordance with the formula:

$$T > 5(Tmax - Tmin)$$

(c) Source-skin or source-image receptor distance shall meet the following requirement:

All radiographic systems shall be provided with a durable, securely fastened means to limit the source-skin distance to at least 30 centimeters. This is considered to be met when the collimator or cone provides the required limits.

(d) The exposure produced shall be reproducible to within the following criteria:

When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E)is greater than five times the difference between the maximum exposure (Emax) and the minimum exposure (Emin) in accordance with the formula:

$$E > 5(Emax - Emin)$$

~~(e) Standby radiation from capacitor energy storage equipment, when the exposure switch or timer is not activated, shall not exceed a rate of two milliroentgens per hour at five centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.~~

~~(f) Linearity~~

~~(1) When the equipment allows a choice of x-ray tube current settings, the average ratios of exposure to the indicated milliampere-seconds product, i.e., mR/mAs, obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, i.e., /mean of x1 - x2/ < minus 0.10 mean of (x1+ x2), where the mean of x1 and x2 are the average mR/mAs values obtained at each of two consecutive tube current settings.~~

~~(2) Compliance shall be determined at the most commonly used mA stations by measuring mR/mAs at those stations and at one adjacent station to each.~~

~~(g) Timer accuracy~~

~~(1) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.~~

~~(2) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.~~

(a) Structural barriers shall be installed so that the dose limits of Rules .1601(a)(8) and .1601(a)(15) of this Chapter are not exceeded.

(1) Stationary radiation machine systems shall be installed in areas with the following:

(A) primary protective barriers for all walls, floor, ceiling, or other structures that will intercept the primary beam;

(B) secondary protective barriers in the walls, doors, floor, and ceiling areas or other structures that will intercept and attenuate leakage and scatter radiation; and

(C) a window, to include a frame and lead-equivalent glass, meeting the same structural barriers as required by the adjacent barrier, or a mirror system shall be provided so the operator can see the patient from behind the protective barrier during radiation exposures.

(2) Intraoral dental handheld radiation machines shall be used in a controlled area, as defined in Rule .1601(a)(3) of this Chapter and controlled by separating adjacent uncontrolled areas six feet or greater from the patient.

(b) The exposure switch for radiation machines shall be installed meeting the following requirements:

(1) Stationary radiation machine systems shall have the exposure switch permanently mounted:

(A) behind a protected barrier 40 inches (1 meter) from the edge of the control booth; or

(B) so that the operator is required to remain behind the protective barrier area during the entire radiation exposure.

(2) Dental intraoral radiation machines shall have the exposure switch permanently installed so that the operator is required to be:

(A) behind a protective barrier height of 7 feet (2.3 meters) or greater; or

(B) located 6 feet (1.8 meters) or greater from the tube housing assembly.

(3) Mobile, portable, and veterinary radiation machines shall have an exposure switch that allows the operator to stand six feet or greater from the tube during radiation exposures.

(c) Stationary CT radiation machine operators shall maintain aural communication with the patient while the operator is required to remain behind a protective barrier at the control panel.

(d) Use of video monitors that do not have a direct power source is prohibited.

(e) Any mobile or portable radiation machine used in one location or used as a primary imaging system shall have structural shielding in that location that meets the v requirements for stationary diagnostic radiation machines for stationary diagnostic imaging systems in Subparagraph (a)(1) of this Rule.

(f) An area radiation survey shall be performed for installations of radiation machines within 30 days following the initial use to show compliance with Paragraph (a) of this Rule.

(1) This survey shall include:

(A) a scaled drawing of the room in which the stationary radiation machine system is located;

(B) radiation levels in adjacent areas; and

(C) the name of the person, approved by the agency performing the survey, and the date the survey was performed.

(2) Any modification that could increase the radiation dosage for any individual to the following shall require a new survey:

(A) radiation machine configuration;

(B) radiation output; or

(C) occupancy factors if the x-ray room or adjacent areas are changed.

(3) Area radiation survey records shall document compliance with dose limits in accordance with Rules .1601(a)(8) and (15) of this Chapter.

(4) Records of the area radiation survey shall be maintained in accordance with Rule .0603(h) of this Section.

(g) Technique Charts or imaging protocols for each radiation machine not equipped with an operational anatomic programming or phototimer option shall be readily available to the operator of the radiation machine(s). If pediatric and adult patients are imaged, a chart is required for both and shall include the following information:

(1) patient's anatomical size;

(2) technique factors to be used;

(3) source to image receptor distance used; and

(4) type of image receptor.

(h) Each area, as defined in Rule .1601(a)(3) of this Chapter, where a radiation machine is used shall be conspicuously posted with a sign, in accordance with the requirements of Rule .1601(a)(34) of this Chapter, bearing the words "CAUTION – RADIATION AREA", or words having a similar meaning.

(i) Exemptions apply to the following:

(1) intraoral dental radiation machines from Parts (a)(1)(A) and (C) of this Rule.

(2) Dual Energy X-Ray Absorptiometry (DEXA or DXA) and veterinary radiation machines from Subparagraph (b)(1) of this Rule.

(3) dental handheld radiation machines from Subparagraph (b)(2) of this Rule; and

(4) dental radiation machines from Subparagraph (g)(3) of this Rule.

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*Amended Eff. May 1, 1993; November 1, 1989; October 1, 1980;*
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*Readopted May 1, 2026.*

10A NCAC 15 .0607 is proposed for readoption with substantive changes as follows:

**10A NCAC 15 .0607 ~~INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS~~ RADIATION MACHINE REQUIREMENTS**

~~(a) In addition to the provisions of Rules .0603 and .0605 of this Section, the requirements of this Rule apply to x-ray equipment and associated facilities used for dental radiography. Criteria for extraoral dental radiographic systems are covered in Rule .0606 of this Section.~~

~~(b) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-skin distance to not less than:~~

~~(1) 18 centimeters, if operated above 50 kilovolts peak; or~~

~~(2) ten centimeters, if operated at or below 50 kilovolts peak.~~

~~(c) The size of the direct radiation beam shall be limited in accordance with the following rules:~~

~~(1) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:~~

~~(A) If the source-skin distance (SSD) is 18 centimeters or more, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than seven centimeters; and~~

~~(B) If the SSD is less than 18 centimeters, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than six centimeters.~~

~~(2) Effective February 1, 1981, equipment manufactured prior to August 1974 shall be equipped with a lead line open position indicating device with at least 0.79 mm lead.~~

~~(d) The timing device shall comply with the following requirements:~~

~~(1) Termination of the exposure after a preset interval;~~

~~(2) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;~~

~~(3) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided; and~~

~~(4) When four timer tests are performed at identical timer settings equal to five seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period (Tmax) and the minimum period (Tmin) in accordance with the formula:~~

~~T > 5(Tmax - Tmin)~~

~~(5) Effective February 1, 1983, intraoral dental radiographic systems shall be equipped with an electronic timer.~~

~~(6) Timer accuracy~~

~~(A) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.~~

~~(B) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.~~

~~(e) The exposure switch shall comply with the following requirements:~~

~~(1) A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half second or less.~~

~~(2) Each x-ray control shall be located in such a way as to meet the following criteria:~~

~~(A) For stationary x-ray systems installed after the effective date of this Rule, the exposure switch shall be permanently mounted in a protected area (e.g., corridor outside the room) so that the operator is required to remain in that protected area during the entire exposure.~~

~~(B) For stationary x-ray systems without a protected area and installed before the effective date of this Rule, the exposure switch shall be such that the operator shall stand at least six feet away from the tube and out of the direct beam.~~

~~(C) For mobile and portable x-ray systems the switch shall meet the requirements of Part (e)(2)(B) of this Rule.~~

~~(3) For equipment manufactured after August 1, 1974, the x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.~~

~~(f) The exposure produced shall be reproducible to within the following criteria:~~

~~When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E) is greater than five times the difference between the maximum exposure (Emax) and the minimum exposure (Emin) in accordance with the formula:~~

~~E > 5(Emax - Emin)~~

~~(g) Patient and film holding devices shall be used when the techniques permit.~~

~~(h) Neither the tube housing nor the position indicating device shall be hand-held during an exposure.~~

~~(i) Dental fluoroscopy without image intensification shall not be used.~~

~~(j) Structural shielding~~

~~(1) All wall, floor and ceiling areas shall have protective barriers sufficient to meet the requirements of Rules .1604 and .1611 of this Chapter.~~

~~(2) When intraoral x-ray systems are installed in adjacent rooms or areas, protective barriers as specified in Subparagraph (j)(1) of this Rule shall be provided between the rooms or areas.~~

(a) All radiation machines shall be:

(1) registered with the agency in accordance with Rule .0203(a) of this Chapter; and

(2) installed according to the manufacturer's specifications.

(b) Each diagnostic radiographic and fluoroscopic radiation machine and associated components shall comply with the following provisions of 21 CFR Subchapter J, Diagnostic x-ray systems and their major components, which are hereby incorporated by reference, including subsequent amendments and editions. The following parts of 21 CFR Subchapter J apply:

(1) Part 1000, "General;"

(2) Subpart A 1000.1, "General Provisions - General;"

(3) Subpart A 1000.3(a) through (1), and (n) through (s), "Definitions;"

(4) Subpart A 1000.15, "Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968;"

(5) Part 1002, "Records and Reports;"

(6) Subpart A 1002.1(a) and (c)(4), "Applicability;"

(7) Subpart D 1002.31, "Preservation and inspection of records;"

(8) Part 1003, "Notification of Defects of Failures to Comply;"

(9) Subpart A 1003.1, "Applicability;"

(10) Subpart A 1003.2, "Defect in an electronic product;"

(11) Subpart C 1003.21, "Notification by the manufacturer to affected persons;"

(12) Part 1010, "Performance Standards for Electronic Products - General;"

(13) Subpart A 1010.1, "Scope;"

(14) Subpart A 1010.2 (a),(b), and (d), "Certification;"

(15) Subpart A 1010.3, "Identification;"

(16) Subpart A 1010.4(a) and (d), "Variances;"

(17) Part 1020, "Performance Standards for Ionizing Radiation Emitting Products;"

(18) Section 1020.20, "Cold-cathode gas discharge tubes;"

(19) Section 1020.30, "Diagnostic x-ray systems and their main components;"

(20) Section 1020.31, "Radiographic equipment;"

(21) Section 1020.32, "Fluoroscopic equipment;" and

(22) Section 1020.33, "Computed tomography (CT) equipment."

(c) The regulations incorporated by reference in Paragraph (b) of this Rule are available free of charge at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-J for Subparagraphs (a)(1) through (a)(22) of this Rule.

(d) Diagnostic radiation machines and their associated components used on humans and certified in accordance with Paragraph (b)(17) of this Rule shall be maintained to ensure compliance with standards in accordance with Paragraph (b) of this Rule.

(e) Radiation machines that do not meet the requirements of Paragraph (b)(1) of this Rule shall not be sold, installed, or used in this state prior to the agency completing a review of the radiation machine in accordance with Rule .0212(a) of this Chapter.

(f) All radiation machines shall meet the following additional requirements:

(1) The tube housing shall remain stable during radiation exposures unless tube housing movement is a designed function of the radiation machine.

(2) All position locking, holding, and centering devices on radiation machine components and systems shall function as intended by the manufacturer.

(g) Veterinary. Radiation machines used in veterinary medicine are exempt from paragraph (c) of this Rule. The requirements of this paragraph shall apply only to veterinary medicine radiographic installations. Veterinary radiation machine installations shall meet the following requirements:

(1) The protective tube housing shall be of the diagnostic type.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of the image receptor and shall provide the same degree of protection as is required in the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50-70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(4) A device shall be provided to terminate the exposure after a preset time or exposure.

(5) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures or behind a protective barrier adequate to assure compliance with dose limit requirements of Rules .1601(a)(8) and .1601(a)(15) of this Chapter.

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