

**Fiscal Impact Analysis for  
Permanent Rule Amendment with Substantial Economic Impact  
Radiation Protection Rule**

**Agency Proposing Rule Change**

North Carolina Department of Health and Human Services (DHHS)

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**Statutory Authority:**

G.S. 104E-5, G.S. 104E-9, G.S. 104E-10, G.S. 104E-19

**Rule Citation:**

10A NCAC 15 .1106 Radioactive Materials and Accelerator Fee Amounts (Amend)  
(See proposed rule in Appendix)

**Impact Summary:**

State government: Yes  
Local government: No\*  
Substantial impact: Yes  
Private entities: Yes

\*There would be an impact if a local government organization became a licensee.

**Summary of Proposed Rule Amendment:**

The principle change made to this proposed amendment to the fee rule include increasing radioactive materials and accelerator licensing fees and simplifying the rule by reducing the number of fee categories. Other changes made in the proposed rule are:

- to codify that tritium exit lights do not have an annual fee;
- to clarify and codify the Radioactive Materials Branch policy that each separate facility not connected by a common border controlled by the licensee requires a separate license fee for the conduct of licensed activities. This will not apply to temporary jobsites;
- to clarify that licensees issued licenses for multiple activities are responsible for the highest fee category for the activities they are authorized to conduct; and to set annual fees for the possession of active Sealed Source and Device Registration Certificates.

**Overall:**

This fiscal note summarizes the costs and benefits to the regulated community and the citizens of North Carolina for supporting the continued regulatory activities of the Radioactive Materials Branch through increasing fees to fund this program as required by G.S. 104E. The Radiation Protection Section has determined that this rule proposed for amendment has impacts to State Government and the private sector. No impact has been identified affecting county or municipal government entities. However, if a county or municipal government entity obtains a radioactive materials license at some future point in time, there will be an impact to these entities.

**Statement of Need:**

Fully funding all of the regulatory activities of RPS is critical to maintaining the Agreement. For the last three years, the Radioactive Materials Branch has been operating at a deficit.

Left uncorrected, North Carolina could begin to fail to maintain its obligations under the national materials program. In that event, the NRC may elect to place North Carolina under what is called 'heightened oversight'. Heightened oversight is a process through which the NRC gets involved with State officials to correct problems found with a state's health and safety program. In a worst-case scenario, the State may find that it needs to give up agreement state status and revert back to federal control. Absent the worst-case scenario, the costs associated with rebuilding the radiation protection program and reestablishing the Radioactive Materials Branch to meet the standards of the national materials program exceed the cost of maintaining that program by fully funding it at this time.

**Background & Radiation Protection Program Requirements:**

North Carolina's Governor entered into an Agreement with the United States Atomic Energy Commission (now the United States Nuclear Regulatory Commission (NRC)), effective August 1, 1964.<sup>1</sup> This Agreement provided for the discontinuance of NRC regulatory authority and responsibility within the State. For the Agreement to be approved, the NRC had to determine that the North Carolina program for radiation protection was compatible with the federal program and adequate to protect public health and safety. As time passed, the federal program became the national materials program.

As more States became Agreement States and assumed regulatory control over the use of radioactive materials within their borders, the national materials program grew. Currently there are 37 Agreement States and the NRC in the national materials program. In addition, two States are applying for Agreement State status and one State is discussing becoming an Agreement State. With these changes, the NRC is becoming less of a regulator of licensees, and more of a regulator of States insofar as managing a common environment standardized around a core of regulatory expectations shared between all participants in the national materials program.

The North Carolina Radiation Protection Section (RPS) within the Division of Health Service Regulation of the Department of Health and Human Services (DHHS) is the organization charged with maintaining the Agreement with the NRC on behalf of the State. Part of the Agreement requires North Carolina to maintain a radiation protection program that protects the health and safety of the citizens of North Carolina and is compatible with the national materials program.

The NRC periodically inspects Agreement State radiation protection programs through a process known as the Integrated Materials Performance Evaluation Program, or IMPEP.<sup>2</sup> This inspection occurs every four or five years, depending upon the Agreement State's previous IMPEP history. IMPEP outcomes vary depending upon how effectively the Agreement State is performing relative to the expectations of the national materials program. The very best performance results in a rating of 'satisfactory'. Less stellar performance ratings fall between 'satisfactory, but needs improvement' to 'unsatisfactory'. Left uncorrected, a program found to be 'satisfactory, but needs improvement' can be found 'unsatisfactory' at a subsequent IMPEP. The consequences of being found 'unsatisfactory' vary according to the severity of the problems discovered during the review. Consequences range from frequent teleconferences with the NRC, to being placed in a 'heightened oversight' status with more frequent or focused program inspections. The aim of 'heightened oversight' is to give the State the opportunity to correct deficiencies in its radiation protection program. In an extreme case, where the State is unable or unwilling to bring its

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<sup>1</sup> The North Carolina Agreement with the US Atomic Energy Commission can be found at the following link: <https://scp.nrc.gov/special/regs/ncAgreements.pdf>

<sup>2</sup> See <https://scp.nrc.gov/impeptools.html> for more information involving IMPEP.

performance up to the standards of the national materials program, the State can lose Agreement State status.

During the North Carolina IMPEP<sup>3</sup> in 2014 the NRC found the State's performance to be 'satisfactory, but needs improvement.' The specific areas needing improvement were in technical staffing and training, and in the sealed source and device evaluation program. The availability of funds to hire, train, and retain qualified technical staff heavily affects both areas. Between 2009 and 2014, the Radioactive Materials Branch lost six technical staff. Of these, one loss was due to retirement, the other five were to pursue higher paying opportunities in the private sector. At the time that the 2014 IMPEP was conducted, the Radioactive Materials Branch had two unfilled positions. Another issue identified during the 2014 IMPEP concerned the inability of the Radioactive Materials Branch to efficiently track inspections conducted by inspectors and accurately discerning when inspections are due or becoming overdue. This deficiency was attributed to a legacy database system and changing program needs that could not be adequately handled by that database.

Since the 2014 IMPEP the Radioactive Materials Branch has filled all of its vacant positions. Two staff positions previously in a 'no-hire' status were released and staff was hired to fill both positions. All new staff are currently undergoing training and are in various stages of completing that training. RPS has also invested in information technology and information technology staff to assist in database management and modernizing computing and communications technologies, including the ability to work from any location with internet access. Because of this staffing and infrastructure investment, in March of this year (2018) the IMPEP team found that the deficiencies noted during the 2014 IMPEP were largely resolved. The remaining issue concerns staffing and training for the sealed source and device program. The Radioactive Materials Branch has arranged training for technical staff conducting work associated with this program to be conducted in the near future.

This fee rule amendment is necessary for RPS to continue to maintain its role in the national materials program. The North Carolina General Assembly amended, as part of the Appropriations Act of 2009, the North Carolina Radiation Protection Act (G.S. 104E) to require the Department to set fees that provide revenue to offset its costs in performing its duties under the Act. Subsequently, beginning in July 2011, the Department no longer received appropriations from the general fund to support these activities. G.S. 104E-9 empowers the Department with the authority to raise fees to fund RPS activities; G.S. 104E-19(a) directs the Department to set these fees to provide revenue to offset RPS operating costs. These costs include salaries and benefits for staff, purchased services such as office space rental, temporary services, legal services, and per diem costs for travel, supplies and equipment, internet service, all of the expenses normally associated with running a business.

The fees raised by this rule are earmarked to pay for past program expansion to bring Radioactive Materials Branch staffing and technology up to the level necessary to attain a satisfactory rating during IMPEP. There is still work to be done, but the amount of investment required to do so is considerably less than what it has been since 2014 because the bulk of the task is complete. This fee rule is also necessary to reduce and eliminate Radioactive Materials Branch reliance on revenue generated by the Radiology Compliance Branch to meet its budget. The Radiology Compliance Branch regulates the diagnostic and industrial use of X-Ray systems throughout the State. For the last few years the Radioactive Materials Branch has been relying upon transfers between the two Branches to make up for the revenue shortfalls of the Radioactive Materials Branch. The budgetary shortfall currently experienced by the Radioactive Materials Branch is preventing the improvement and expansion of services provided to citizens of the State by the Radiology Compliance Branch. Within the last few months, the Radiology Compliance

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<sup>3</sup> See <https://scp.nrc.gov/reviews.html> and click on the hyperlink for NC on the page to view the results of the North Carolina IMPEP reviews discussed in this fiscal note.

Branch has lost three X-Ray inspectors to higher-paying employers, and hiring and retaining staff is becoming an issue. In addition, a new rule adopted in October 2017, adds more regulatory responsibilities to the Radiology Compliance Branch that require funding.

### **Benefits of Agreement State Status:**

Maintaining the Agreement is beneficial for several reasons. It promotes interstate trade because licensees may start businesses in North Carolina, but market their products nationwide, or plan to expand nationwide. Conversely, it encourages movement to North Carolina because businesses can be confident that their existing radiation protection programs are very likely to be compatible with North Carolina requirements. Also from a business perspective, NRC annual license fees are four to five times higher than the proposed corresponding North Carolina fees, and the NRC charges license amendment application fees, inspection fees, and hourly cost-recovery fees that the State does not charge. It is simply cheaper to do business in North Carolina as an Agreement State than it is to do business under the NRC. Some of these savings are due to the lower pay scale for state employees compared to their federal counterparts, some are due to the differences in the cost of living in North Carolina versus the urban Washington, DC area, some are due to the differences in scope and span of control and regulatory responsibility between the State and National programs. The NRC has many areas of responsibility denied the States by the Agreement, such as regulation of the import and export of radioactive materials, regulation of nuclear power generation, nuclear security on a national basis, dealing with Congress, etc.

Businesses use radioactive material for a variety of purposes. Radioactive medicines are used for the diagnosis of medical conditions and the treatment of disease. Radioactive sealed sources are used to measure the density of asphalt during road construction or to detect water beneath flat roofs. Sealed sources are also used in manufacturing to ensure that containers are consistently filled properly, and in the manufacture of smoke detectors used by business and homeowners save lives. In short, there are many uses for radioactive material that most consumers are not aware of that affect everyday activities.

Other benefits of maintaining Agreement State Status are less easily accounted for from a quantitative standpoint. It is difficult to put a monetary value on the advantages to having access to local regulators. Radioactive Materials Branch inspection staff are regionally based and reside in their assigned regions. Radioactive Materials Branch licensing staff are centrally located in Raleigh. The nearest NRC offices are based in Atlanta, Georgia, or near Washington, DC, several more hours away from North Carolina than their in state based counterparts are. So if a licensee or a member of the public requests assistance from RPS, a member of the Radioactive Materials Branch can be on-site relatively quickly. This proximity fosters a close relationship between RPS and the public. For instance, RPS frequently receives calls from small businesses in the scrap metal recycling industry who have metal shipments sent back to them because of suspected radioactive material. Depending on the caller's needs, a Radioactive Materials Branch staff member can be on site in a few hours or less to assist the caller. RPS does not charge for this assistance. Licensing staff are likewise accessible and RPS puts a premium on accessibility that promotes a close relationship between RPS, the public, and our regulated communities.

RPS also serves as the primary response agency as a member of the State Emergency Response Team for radiological emergencies occurring at nuclear power plants. Radioactive Materials Branch personnel serve on radiological survey teams and field support, and RPS provides technical expertise to State and local government decision makers in support of protective actions broadcast to the public.

### **Negative Impacts of the Loss of Agreement State Status:**

The primary impact our licensees would feel is undoubtedly to the bottom line of their financial balance sheets. As previously mentioned, NRC license fees are four to five times those proposed by RPS. The cost of doing business with the NRC is also higher than doing business with the Radioactive Materials

Branch: the NRC charges application fees for license amendments; the State does not. The NRC charges cost-recovery fees for work performed reviewing license applications and issuing license amendments; the State does not. The NRC charges inspection fees; the State does not. The NRC charges a per-hour cost recovery fee for incident and emergency response, which the State does not charge.

The NRC also evaluates their fee structure annually, and will change fees to address income needs on an annual basis. The proposed fees that are the subject of this fiscal note are set to provide income for the Radioactive Materials Branch for at least the next five years, providing cost stability for our licensees.

Another significant impact would not be financial but to public health and safety; there would no longer be local radiation safety professionals who could respond quickly to incidents, allegations and nuclear emergencies. The Radioactive Materials Branch provides subject matter experts and health physics support and guidance during incidents and emergencies involving radioactive materials and exposure to radioactive sources. This assistance is provided free of charge to licensees and non-licensee members of the public. The NRC charges for these services.

### **Summary and Purpose of Adopting the fee increase:**

Currently, the Radioactive Materials Branch is spending more than it receives in license fees, and has been for the last few years. In 2015, the Radioactive Materials Branch brought in \$1.16 million in receipts, and spent \$1.19 million. In 2016, the Radioactive Materials Branch also brought in \$1.16 million in receipts from license fees, and spent \$1.31 million. In 2017, revenue fell slightly and the Radioactive Materials Branch brought in \$1.13 million, and spent \$1.38 million. The shortfall in income has been made up by borrowing funds from the Radiology Compliance Branch. This limits the ability of both Branches to provide outreach and other services to the public, and is not sustainable over the long run. In the short run, the impact of an underfunded Radioactive Materials Branch is felt now: the Radiology Compliance Branch is understaffed, and the Branch has difficulty recruiting. The Radiology Compliance Branch has three unfilled positions, and is considering a recruitment salary for individuals having 3 – 5 years of work experience in the \$50,000/year range. An X-ray technician employed by UNC Health Care earns an average of \$65,800/year with similar experience.<sup>4</sup>

The fee increase proposed in this rule amendment is set so that the Radioactive Materials Branch will be fully funded until the 2024 – 2025 timeframe. Data from budget reports obtained for this fiscal note indicate that between 2013 – 2017 the average annual change in Radioactive Materials Branch receipts fell about 2.3% per year, while annual expenditures rose 5.2% per year. This 5.2% annual percentage increase in expenditures appears to be caused by the hiring of new employees in 2013 and 2016 when the annual increase in Radioactive Materials Branch expenditures rose by 10% both years. Absent the increases in annual expenditure due to the hiring of new employees in 2013 and 2016, the average annual increase in Radioactive Materials Branch expenditures is closer to 2% per year, which is in line with the inflation rate reported by *Statista* at ~1.3% per year for 2013 – 2017, and projected increases out to 2023.<sup>5</sup> The increased expenditures in 2013 and 2016, as well as a modest increase in 2017, are traceable to the expansion in the Radioactive Materials Branch budget to address staff and training shortfalls after the 2014 IMPEP.

The cause of the fall in Radioactive Materials Branch receipts is less well understood. Some of this shortfall is anticipated to be due to changes in technologies. For example, there is a national initiative to move away from the use of radioactive cesium in irradiating sterilizers because of that materials potential use in a terrorist weapon. Corresponding to this shift in irradiation technology is the growth in the use of X-Ray systems to sterilize materials previously sterilized using cesium. There are also economic issues

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<sup>4</sup> <https://www.indeed.com/salaries/X-ray-Technician-Salaries-at-Unc-Health-Care,-Chapel-Hill-NC>

<sup>5</sup> <https://www.statista.com/statistics/244983/projected-inflation-rate-in-the-united-states/>.

causing a reduction of the number of licensees that affects Radioactive Materials Branch receipts. There has been a reduction in the number of private practice nuclear medicine licensees because of uncertainties about getting paid due to the Affordable Care Act, and changes in the way payments are handled by Medicare and Medicaid. These physicians are still using radioactive materials, but doing so under the umbrella of hospital licenses where the certainty of payment is higher. On the other hand, the net influx of new residents into the State may well result in a higher demand for those services that require a radioactive materials license. In 2017, ~86,000 people moved into the State. Counting births, the State's population rose by ~117,000 persons in 2017.<sup>6</sup> The last time North Carolina experienced population growth like this was in 2010, which coincides with a time when the number of licensees was on the rise. Periods of population growth requires more infrastructure, more services, and greater resources. Although we cannot assume causality, it can be reasonable assumed that the negative trend in the annual number of radioactive materials licensees to cease or reverse in the near term if increasing populations require the use of services and goods that involve the use of radioactive materials.

In response to the 2014 IMPEP, the Radioactive Materials Branch is now fully staffed, and RPS is using a variety of strategies to reduce costs. For example, since home basing staff and moving to a web-based computing environment began, travel costs have dropped significantly. Inspectors are no longer dispatched from Raleigh to traverse the State as often, with accompanying overtime, hotel, and per diem costs. Most regionalized homebased staff can perform their duties during day trips, so the number of overnight trips has fallen.

Table 1 presents projected income, projected expenses, and the projected balance from this rule amendment assuming that the annual increase in expenditures remains at 5.2% and the annual loss in receipts remains at 2.3%. The annual increase in expenditures is set at 5.2% instead of being set at 2% for a variety of reasons. Revenue generated from annual fees go towards supporting RPS administrative functions as well as the activities of the Radioactive Materials Branch. Since the events of 9/11, the Radioactive Materials Branch has assumed increased responsibilities for the security of radioactive material in the State. In 2016, the State adopted 10A NCAC 15 .1700, which incorporates 10 CFR Part 37. 10 CFR Part 37 reflects the NRC's role in securing radioactive material from maleficent use on the national level. Because of the Agreement, this responsibility falls to the Radioactive Materials Branch on the State level. As the national threat environment changes, so do the requirements placed on the agency. This responsibility is increasing, and so, too, are the costs associated with it. There are also special events that need consideration. In 2012, the agency partnered with the N.C. National Guard's 42<sup>nd</sup> Civil Support Team to provide radiological screening and coverage during the Democratic National Convention in Charlotte. The agency anticipates it will fill the same support role during the upcoming Republican National Convention. During the Democratic National Convention the agency borrowed specialized radiation detection equipment from the N.C. National Guard to help fulfill its role for that event. The agency is contemplating purchasing this equipment if it becomes necessary for its supporting role during the Republican National Convention. This equipment will also be useful during other venues where radiation detection is a component of ensuring the safety of the public. Absent these special events there are other considerations that support the 5.2% annual increase in expenses used for this analysis. The agency is planning to conduct a salary equity review which may well impact pay scales in the Radioactive Materials Branch and RPS Administration. The IT infrastructure investment made by the agency is partially paid for from Radioactive Materials Branch revenue. At some point within the timeline covered by the fee increase the agency's mobile laboratory will need to be replaced because the generator required to run cryogenic cooling apparatus for radiation detection and quantification equipment on the vehicle is no longer reliable. This detection equipment must be maintained at liquid nitrogen temperatures or it will not function as needed. Although the mobile lab serves a vital purpose during radiological emergency response activities, the mission for the mobile lab has changed since the vehicle was outfitted and

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<sup>6</sup> <https://demography.cpc.unc.edu/2017/12/20/nc-population-reaches-10-3-million-in-2017/>.

purchased a decade ago. Costs for other activities have also increased. The agency had to replace the vendor who previously calibrated existing radiation detection survey meters used for routine inspections, and instruments used in the field to identify radionuclides during incident response. The previous vendor is no longer able to calibrate these instruments because of technological changes to these instruments. The new vendor is more capable and more expensive than the previous vendor. The Radioactive Materials Branch is also contemplating procuring neutron detection instruments that are useful for homeland security purposes and for confirming radiation profiles around accelerator vaults.

This table also assumes that there was a net loss of 12% in the number of radioactive materials specific licensees the first year that the fee increase is effective. This percentage loss is equal to the percentage loss of licensees between 2011 and 2012 less the average percentage loss of licensees in our surrounding comparative States during this same period when the North Carolina fee rule was amended in 2011 to increase Radioactive Materials Branch fees. The initial value under ‘Projected Expenses’ was calculated by taking data from the 2017 end of fiscal year budget report and multiplying that value by the average annual increase in Radioactive Materials Branch expenditures (5.2%, compounded) for fiscal years 2018 and 2019. The initial value (in bold font) under ‘Projected Income’ represents the first year’s anticipated income from the fee change.

Table 1

| <b>Fiscal Year</b> | <b>Projected Income</b> | <b>Projected Expenses</b> | <b>Projected Balance</b> |
|--------------------|-------------------------|---------------------------|--------------------------|
| 2019 – 2020        | <b>\$1,997,090</b>      | \$1,506,472               | \$490,617                |
| 2020 – 2021        | \$1,951,157             | \$1,584,809               | \$366,348                |
| 2021 – 2022        | \$1,906,280             | \$1,667,219               | \$239,061                |
| 2022 – 2023        | \$1,862,436             | \$1,753,914               | \$108,521                |
| 2023 – 2024        | \$1,819,599             | \$1,845,118               | (\$25,519)               |
| 2024 – 2025        | \$1,777,749             | \$1,941,064               | (\$163,315)              |

Budget surpluses from all RPS Branches go into a non-reverting fund that is used by RPS to pay for non-nuclear power plant emergency response, equipment procurement, maintenance, and calibration costs for the agency, and assisting licensees who cannot pay for decommissioning or source disposal, or to fund other activities to facilitate the agency’s mission to protect the health and safety of the environment and the citizens of North Carolina. A few examples of the use of this fund to help protect the public are:

- In April 2014, the agency spent a little over \$12,600 to dispose of an irradiator possessed by a licensee that went bankrupt;
- In September 2017, the agency paid \$1,250 to dispose of radioactive waste generated by a licensee who was unable to pay for disposal costs prior to terminating their radioactive materials license, and
- When the agency moved from Barret Drive to its present location on Creedmoor Road, monies from the non-reverting fund paid the agency’s disposal costs of a small irradiator and various radioactive items recovered from the public domain.

Assuming that budget surplus balances are carried forward to pay for equipment and non-salary program needs, this fee increase should offset the budget deficit projected for the 2023 – 2024 and 2024 – 2025 fiscal years.

Radioactive Materials Branch monies are spent on personnel salaries and benefits, equipment procurement, maintenance, and calibration, travel for conducting inspections and licensing visits, and non-nuclear power plant emergency response.

### **Fiscal Baseline:**

This scenario assumes that no further fee increases are made, the Radioactive Materials Branch continues to operate with a loss of annual revenue of 2.3% per year, and that costs continue to rise at 5.2% per year. As noted in the previous discussion, in 2017, the Radioactive Materials Branch brought in approximately \$1.13 million in licensing revenue, and spent approximately \$1.38 million in operational costs. This leaves a deficit of approximately \$250,000, which is roughly 22% of revenue for fiscal year 2017. By fiscal year 2021, the deficit is projected to be approximately \$580,100, or over half of the anticipated revenue for that year (~\$1,077,100). Continuing this trend, in 2024 the projected annual receipts are estimated to be half of the projected expenses. Consequently, the deficit at this point is nearly equal to revenue.

At some point along this path, decisions will need to be made regarding the mission and capabilities of RPS. The Radiology Compliance Branch received \$2.06 million in revenue in 2017, and spent \$2.02 million in expenditures. These expenditures include transfers to the Radioactive Materials Branch. Provided that revenue remains flat for the Radiology Compliance Branch between 2019 and 2024, the shortfall in Radioactive Materials Branch revenue can be carried for up to two – three more years.

The next IMPEP is due in 2022, however, given the severity of the Radioactive Materials Branch financial situation by 2021 it is highly likely that the NRC will come early to assess the State's commitment to the Agreement and its ability to carry out its core mission of protecting public health and safety. During IMPEP, technical staffing and training, status of the materials inspection program, and the technical quality of inspections, licensing, and incident and allegation response are core areas for inspection. Each of these rely heavily upon adequate program funding. The only reason this did not come up as an item of concern during the latest IMPEP (in 2018) is because the Radioactive Materials Branch spent the monies necessary to address the staffing and training concerns that rose during the 2014 IMPEP, and the Branch had sufficient funding due to the revenue transfers from the Radiology Compliance Branch. Since this cannot continue, Radioactive Materials Branch staffing will need to be reduced, with concomitant reductions in the Branch's ability to meet its commitments to maintain the Agreement. The frequency of radioactive materials home-office inspections will need to be extended to reduce the number done in any given period of time to reduce costs. This increases the risk that those inspections will be done late. Likewise, the number of field inspections will need to be reduced to reduce costs, and many will be missed. Meanwhile, the number of inspections to be conducted by each inspector will rise as technical staff are released from employment, decreasing the quality of those inspections as less time is devoted to each individual inspection. Licensing will become protracted with fewer staff. Licensees depend upon quick turn-around time for license amendments to facilitate business. Staff reductions will increase the number of licensing actions per staff member, increase the number of mistakes made during license application review and while revising licenses, and the waiting time for a license amendment will lengthen. Licensees will complain about errors on their licenses, the longer wait times for amendments, and business will suffer as a result. For licensees from out-of-state or from NRC regions requiring reciprocal licenses to work inside North Carolina, a long waiting period to get reciprocal recognition of their licenses could eliminate their ability to compete for jobs inside the state. Incident response at non-nuclear power facilities and investigations of allegations will need to be curtailed. This means that the public will not have easy access to an inspector from RPS if they come into possession of material that may be radioactive, or if they have concerns about how a licensee is handling radioactive materials and feel that RPS should investigate.

In such a circumstance, the NRC IMPEP team is highly likely to find the radioactive materials program inadequate to protect health and safety, and North Carolina would enter into a period of heightened oversight and monitoring. During this time, the NRC would be in frequent contact with RPS to encourage RPS to obtain the monies necessary to fund Radioactive Materials Branch activities. Barring success in

fully funding the radioactive materials health and safety program, the State would likely be placed in probation. Probation requires notification of the Governor, the State's Congressional delegation in Washington and any appropriate Congressional committees. Probation also allows the NRC to increase monitoring and oversight of the program.<sup>7</sup> If the State continues to underfund the radiation safety program and improvements are not made during this time, the NRC may elect to extend the probationary period or to suspend<sup>8</sup> or terminate<sup>9</sup> the Agreement. This process may take several years, during which it is anticipated that Radioactive Materials Branch staffing would continue to fall as work demands increase and morale falls and staff positions are eliminated. It is equally likely that the Governor could request termination of the Agreement during the probationary period to cut costs to the State and to facilitate return of the program to the NRC.

There is uncertainty when the transfer of the radioactive materials program from the State to the NRC would occur during the scenario described above. The NRC scheduled a periodic meeting with the Radioactive Materials Branch for circa September 2019 to discuss progress within the program since the last IMPEP, which was conducted in March, 2018.<sup>10</sup> These periodic meetings give the NRC the opportunity to see how the State is performing between IMPEP reviews, and give the State the opportunity to assure the NRC that any necessary actions that need to be taken are being taken, and that the State's radiation protection program continues to be adequate to protect public health and safety. If this fee rule is not adopted, this periodic meeting would be the earliest opportunity for the NRC to learn that the Radioactive Materials Branch faces insolvency in the near future. This would most likely prompt the beginning of heightened oversight of the program and a second periodic review in 2020; with a special IMPEP scheduled early 2021. If the State continued not funding the program and staff layoffs put the radioactive materials program in jeopardy, the special IMPEP could result in the State being put on probation mid-2021 or early 2022. Generally, a State put on probation has a year to correct any deficiencies that caused it to be placed on probation. Depending upon the State's responses to the NRC the Agreement could be suspended or terminated by 2023.

Once control of the radioactive materials health and safety program is transferred to the NRC, our licensees would be subject to those costs. The proposed fees RPS is advocating in 10A NCAC 15 .1106 are set at 20% of the NRC annual fees. Under the NRC, licensees would experience increases in annual fees ranging from 1.5 times their current annual fee to 23 times their current annual fee. A holder of a general license that is not required to register every year would see the most modest increase (154%) while a service provider or a consultant would see the greatest increase (2325%) in annual fees under the NRC. Hospitals and private practice medical clinics offering only diagnostic services would experience a 15 fold increase in annual license fees, while hospitals offering therapeutic care would see their annual license fee go up by a factor of 8.

### **Impact Compared to the NRC:**

Annual license fees come from rule 10A NCAC 15 .1106 for North Carolina, and 10 CFR 170.31 for the NRC. The NRC charges an hourly cost recovery fee of \$263/hour for inspections (10 CFR 170.20), and application fees that depend upon the type of license for license amendments. North Carolina does not charge inspection fees; nor does the Radioactive Materials Branch charge license application fees or cost-recovery fees to its licensees for staff time spent on licensing or inspection activities. Another notable difference between how the NRC and the Radioactive Materials Branch charge for services is that the

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<sup>7</sup> <https://scp.nrc.gov/procedures/sa113.pdf>

<sup>8</sup> <https://scp.nrc.gov/procedures/sa114.pdf>

<sup>9</sup> <https://scp.nrc.gov/procedures/sa115.pdf>

<sup>10</sup> [https://scp.nrc.gov/reviews/18nc\\_imp.pdf](https://scp.nrc.gov/reviews/18nc_imp.pdf)

NRC charges the hourly cost recovery fee for incident response, and may charge inspection fees based upon the specific situation relating to the incident. The Radioactive Materials Branch does not charge fees for incident response.

Costs to North Carolina for the various activities requiring an hourly breakdown were calculated using the average annual Radioactive Materials Branch staff salary by activity multiplied by a factor of 1.4 to cover the cost of benefits provided by the State. For licensing staff this is approximately \$38/hour, and for inspections staff this is approximately \$39/hour.

Administrative costs to Radioactive Materials Branch associated with both inspections and licensing activities is based upon the hourly cost of an administrative assistant and IT staff (database management, end user support, etc.). Administrative support costs approximately \$58 per hour spent on an activity. It is assumed that approximately one-quarter of an hour is spent supporting the Radioactive Materials Branch for licensing and inspections per license (~\$15).

Based upon interviews with Radioactive Materials Branch inspections staff, the average number of hours spent on an inspection depends upon the type of license that is being inspected. For most non-broad specific license inspections, a single inspector may spend 2 - 4 hours preparing for an inspection, 6 - 8 hours conducting the inspection, and another 2 - 4 hours writing up the inspection. When broad licenses are inspected the number of hours spent preparing for, inspecting, and writing up the inspection increases considerably. Approximately 8 - 12 hours are spent preparing for the inspection, then 2 - 4 inspectors will spend 24 - 40 hours conducting the inspection, and approximately 12 - 16 hours will be spent writing up the inspection. For this cost comparison, the same level of effort is credited for inspections conducted by the NRC to determine the cost to the NRC for inspection related activities.

For those inspections that are not conducted annually, the inspection cost is presented as an average annual cost by dividing the estimated cost of the inspection by the inspection frequency. For example, on average, a non-broad license inspection may take 13 hours to prep, conduct, and write up. If the inspection frequency is every 3 years; the annualized hourly cost would be determined by dividing 13 by 3, and then multiplying the result by the inspection fee for that type of licensee.

Table 2 below describes the annual savings by license type based upon the difference in NRC and Radioactive Materials Branch fees and takes into account annualized inspection costs. It assumes that the NRC does not change its fee structure over the next five years.

Estimated Annual Savings per License Type for annual license fees and annualized inspections\*:  
Table 2

| License Type                                | NRC License Fee | Annualized NRC Inspection Fee | Insp Freq | Annualized NRC Fees | Proposed NC Fee | Annual Savings |
|---|-----------------|-------------------------------|-----------|---------------------|-----------------|----------------|
| Broad Medical                               | \$33,800        | \$7,364                       | 2         | \$41,164            | \$6,760         | \$34,404       |
| Broad Research and Development and Academic | \$25,900        | \$7,364                       | 2         | \$33,264            | \$5,180         | \$28,084       |

| License Type  | NRC License Fee | Annualized NRC Inspection Fee | Insp Freq | Annualized NRC Fees | Proposed NC Fee | Annual Savings |
|---|-----------------|-------------------------------|-----------|---------------------|-----------------|----------------|
| Broad Manufacturing and Distribution  | \$30,500        | \$4,909                       | 3         | \$35,409            | \$6,100         | \$29,309       |
| Industrial Radiography  | \$27,000        | \$3,419                       | 1         | \$30,419            | \$5,400         | \$25,019       |
| Well Logging  | \$16,000        | \$1,140                       | 3         | \$17,140            | \$3,200         | \$13,940       |
| Medical without written directive   | \$14,700        | \$1,140                       | 3         | \$15,840            | \$2,940         | \$12,900       |
| Medical with written directive  | \$23,800        | \$1,710                       | 2         | \$25,510            | \$4,760         | \$20,750       |
| Manufacturing and Distribution (including Radiopharmacy)                              | \$11,600        | \$1,140                       | 3         | \$12,740            | \$2,320         | \$10,420       |
| Additional annual Manufacturing fee per active Sealed source and Device Registration  | \$7,400         | n/a                           | n/a       | \$7,400             | \$1,480         | \$5,920        |
| ≥ 10KCi Irradiators   | \$95,700        | \$1,710                       | 2         | \$97,410            | \$19,140        | \$78,270       |
| < 10KCi Irradiators   | \$10,800        | \$684                         | 5         | \$11,484            | \$2,160         | \$9,324        |
| Education and Research and Development  | \$14,800        | \$684                         | 5         | \$15,484            | \$2,960         | \$12,524       |
| Service and Consultant, Portable and Fixed Nuclear Gauges, "Other" (not listed above) | \$9,300         | \$684                         | 5         | \$9,984             | \$1,860         | \$8,124        |
| General License with annual registration  | \$500           | n/a                           | n/a       | \$500               | \$200           | \$300          |
| General License without annual registration   | \$500           | n/a                           | n/a       | \$500               | \$325           | \$175          |

\*Note: this table assumes no future changes in NRC fees. NRC inspection fees are estimated to be \$14,728 for all types of Broad Licenses, and \$3,419 for all other types of Specific Licenses. This assumes

that NRC inspection fees are based on the NRC hourly rate of \$263/hour and that an average of 56 hours is spent per Broad License inspection and 13 hours is spent per Specific License inspection. General License holders are not inspected by the NRC.

A summary of estimated annual savings for all North Carolina licensees by license type for annual fees and annualized inspections based upon the table above are presented in Table 3, below:

Table 3

| License Type  | # NC Licenses | Annual Savings per License Type | Annual Savings for all licenses by type |
|---|---------------|---------------------------------|---|
| Broad Medical   | 5             | \$34,404                        | \$172,020                               |
| Broad Research and Development and Academic   | 10            | \$28,084                        | \$280,840                               |
| Broad Manufacturing and Distribution  | 0             | \$29,309                        |   |
| Industrial Radiography  | 24            | \$25,019                        | \$600,456                               |
| Well Logging  | 0             | \$13,940                        |   |
| Medical without written directive   | 87            | \$12,900                        | \$1,122,271                             |
| Medical with written directive  | 164           | \$20,750                        | \$3,402,918                             |
| Manufacturing and Distribution (including Radiopharmacy)                              | 28            | \$10,420                        | \$291,751                               |
| Additional annual Manufacturing fee per active Sealed source and Device Registration  | 29            | Not inspected                   |   |
| ≥ 10KCi Irradiators   | 4             | \$78,270                        | \$313,078                               |
| < 10KCi Irradiators   | 4             | \$9,324                         | \$37,295                                |
| Education and Research and Development  | 40            | \$12,524                        | \$500,952                               |
| Service and Consultant, Portable and Fixed Nuclear Gauges, "Other" (not listed above) | 253           | \$8,124                         | \$2,055,321                             |

Total first year savings for North Carolina licensees for inspection costs is approximately \$8.8M.

**Annual Savings per License Type for Licensing Activities for a Single Licensing Action:**

Licensing staff interviews indicate that approximately six hours of staff time, on average, is spent on licensing per licensing action for amendments to specific licenses that do not involve new or renewing licenses. It is conservatively assumed that one licensing action per year will be performed by the State for each specific licensee, and that the NRC will also conduct one specific licensing action per year per specific licensee. Please note that for this analysis, RPS costs for administering the general licensing program are ignored. Most general licensees require no assistance from the State after the general license registration is issued, and the annual fees supporting this activity are not being changed in this fee rule.

Based upon the hourly rate for licensing Staff (\$38/hr) and administrative/IT support costs of \$15 per action, each amendment costs the State about \$243. This cost is included in the annual license fee and is not otherwise passed off to North Carolina licensees.

The NRC charges its licensees application fees based upon the license type and a cost recovery fee for staff time based on the NRC hourly rate of \$263/hour for license application reviews. The corresponding cost to NRC licensees for the hourly charge (6 hours) is \$1,578 per licensing action, and license application fees vary from \$58,700 for irradiator licensees possessing  $\geq 10,000$  curies of radioactive material to \$3,000 for an industrial radiography licensee. Savings to North Carolina licensees can be substantial depending upon the type of license that is being amended and the number of amendments performed during the year.

For example, the Radioactive Materials Branch has 664 specific licensees, and licensing staff performed approximately 750 – 800 license amendments over the last year. Conservatively assuming that 700 license amendments are performed over the course of a year, and that all of them are charged the lowest NRC application fee (\$3,000), savings to North Carolina Licensees is estimated to be in excess of \$2M/year. This savings is calculated without the staff-time hourly fee charged by the NRC into account.

#### **Impact Compared to Our Surrounding Agreement States:**

Unlike our relationship with the NRC, there is no danger that North Carolina's radiation safety program will be taken over by another Agreement State; however, it is useful to compare costs between North Carolina and our surrounding states to see where we stand with regard to our fees. Before doing so, it needs to be pointed out that there is no advantage for our licensees that want to conduct business in North Carolina to leave the state because of relative differences between fees. NRC and other Agreement States licensees wishing to conduct business in North Carolina are required to apply for reciprocal recognition of their radioactive materials licenses before entering the State. Reciprocal license fees are the same as North Carolina license fees for the same activity. In addition, reciprocal recognition of NRC and other Agreement State licenses is limited to 180 days of operations within the State, after which time they are required to obtain a North Carolina radioactive materials license. Thus, a licensee leaving North Carolina and moving to a state with lower license fees could effectively pay twice as much as a North Carolina-based licensee to perform similar activities within this State.

For this comparison in Table 4, North Carolina license fees are compared to license fees in South Carolina, Georgia, Tennessee, and Virginia. These states were chosen because they all share a border with North Carolina and should have lower transaction costs to do business in North Carolina than states that do not share a common State border.

The percentage differences noted in the table on the following page do not tell the whole revenue story:

- Georgia charges fees for license applications, which North Carolina does not.
- South Carolina charges cost-recovery fees for licensing, inspections, and special projects in addition to the annual fees for radioactive materials licenses based upon staff-hours spent reviewing applications and conducting inspections or working on special projects.
- Tennessee charges application review fees that are not captured in North Carolina to support licensing activities. In addition, Tennessee has levied special fees for registrants and licensees to cover revenue shortcomings for its radiation protection program.
- Virginia charges application and inspection fees that are not captured in North Carolina in support of those activities.

**North Carolina License Fees Compared to Georgia, South Carolina, Tennessee, and Virginia:**

Table 4

| License Type   | Proposed Fee in .1106 | Georgia  | % diff (NC/GA) | South Carolina | % diff (NC/SC) | Tennessee | % diff (NC/TN) | Virginia | % diff (NC/VA) |
|--|-----------------------|----------|----------------|----------------|----------------|-----------|----------------|----------|----------------|
| Broad Medical  | \$6,760               | \$17,057 | 40%            | \$2,313        | 292%           | \$7,800   | 87%            | \$12,000 | 56%            |
| Broad Academic   | \$5,180               | \$5,439  | 95%            | \$2,313        | 224%           | \$7,800   | 66%            | \$6,000  | 86%            |
| Industrial Radiography                                   | \$5,400               | \$9,583  | 56%            | \$1,344        | 402%           | \$7,800   | 69%            | \$3,500  | 154%           |
| Well logging   | \$3,200               | \$3,774  | 85%            | \$1,125        | 284%           | \$5,200   | 62%            | \$3,000  | 107%           |
| Nuclear Medicine (with written directive)                | \$4,760               | \$3,182  | 150%           | \$707          | 673%           | \$1,700   | 280%           | \$3,750  | 127%           |
| Nuclear Medicine (without written directive)             | \$2,940               | \$3,182  | 92%            | \$588          | 500%           | \$1,700   | 173%           | \$3,750  | 78%            |
| Manufacturing & Distribution (Radiopharmacy)             | \$2,320               | \$6,253  | 37%            | \$1,244        | 186%           | \$7,800   | 30%            | \$6,000  | 39%            |
| Irradiator (>100KCi)                                     | \$19,140              | \$52,133 | 37%            | \$5,995        | 319%           | \$36,000  | 53%            | \$5,000  | 383%           |
| Irradiator (≤100KCi, self-shielded)                      | \$4,500               | \$22,644 | 20%            | \$313          | 1438%          | \$7,800   | 58%            | \$3,000  | 150%           |
| Education, Research                                      | \$2,960               | \$1,813  | 163%           | \$325          | 911%           | \$850     | 348%           | \$1,500  | 197%           |
| General License with annual registration requirements    | \$325                 | \$100    | 325%           | \$338          | 96%            | \$350     | 93%            |          | N/A            |
| General License without annual registration requirements | \$200                 | \$100    | 200%           | \$338          | 59%            | \$350     | 57%            |          | N/A            |

**Impact:**

This rule change has a substantial economic impact, and affects privately owned and State government licensees. Note that there are no local government licensees at this time so no impact is anticipated for local government entities. The expected distribution of increased fees due to this proposed fee rule change is shown in Table 5. Data for the number of licensees used in this table was taken from the Radioactive Materials Branch database.

Table 5

| License Type   | # State Licensees | Est Cost to State | # Local Licensees | Est Cost to Local | # Private Licensees | Est Cost to Private |
|--|-------------------|-------------------|-------------------|-------------------|---------------------|---------------------|
| Broad Medical  | 3                 | \$4,530           | 0                 | \$0               | 2                   | \$3,020             |
| Broad Academic and Research and Development                                | 8                 | \$13,440          | 0                 | \$0               | 2                   | \$3,360             |
| Broad Manufacturing and Distribution                                       | 0                 | \$0               | 0                 | \$0               | 0                   | \$0                 |
| Industrial Radiography   | 0                 | \$0               | 0                 | \$0               | 24                  | \$45,600            |
| Well Logging   | 0                 | \$0               | 0                 | \$0               | 0                   | \$0                 |
| Medical without Written Directive  | 0                 | \$0               | 0                 | \$0               | 87                  | \$173,130           |
| Medical with Written Directive   | 0                 | \$0               | 0                 | \$0               | 164                 | \$305,040           |
| Manufacturing and Distribution (including Radiopharmacy)                   | 1                 | \$70              | 0                 | \$0               | 27                  | \$1,890             |
| Irradiator ( $\geq 10\text{KCi}$ )   | 0                 | \$0               | 0                 | \$0               | 4                   | \$42,560            |
| Irradiator ( $< 10\text{K}$ )  | 2                 | (\$4,680)         | 0                 | \$0               | 2                   | (\$4,680)           |
| Education, Research and Development  | 10                | \$10,600          | 0                 | \$0               | 30                  | \$31,800            |
| Service, Consultant, Fixed and Portable Gauges, 'Other' (Not listed above) | 1                 | \$1,360           | 0                 | \$0               | 252                 | \$342,720           |
| General License with annual registration                                   | 0                 | \$0               | 0                 | \$0               | 0                   | \$0                 |
| General License without annual registration                                | 0                 | \$0               | 0                 | \$0               | 0                   | \$0                 |
| Accelerators   | 12                | \$33,120          | 0                 | \$0               | 85                  | \$234,600           |
| Total Impact   |                   | \$58,440          |                   |                   |                     | \$1,221,960         |

Negative costs shown in parenthesis represent proposed licensing fees that are lower than the existing license fees.

**Alternatives Considered to Fund the Radioactive Materials Branch:**

Several ways of approaching funding the Radioactive Materials Branch were considered by RPS before this rule amendment was proposed.

1. No fee increase:  
The option not to increase fees leads to increased costs for the regulated community because the State's radioactive materials health and safety program will revert back to the NRC. The NRC charges annual license fees that are five times higher than those proposed by RPS. There are also

opportunity costs that are difficult to quantify, such as easy availability of radioactive materials staff to assist the public, with this option. This option is the least desirable of the five funding options considered by RPS.

2. Flat fee increase based upon the current State fees in the Rule adopted in 2011:  
This approach was more complicated than anticipated. If the same percentage increase were applied to all license types equally for the perception of fairness, it was difficult to set this percentage at a level which assured the funds necessary to fully fund the Radioactive Materials Branch. If a set amount for each license type was used, as opposed to a flat percentage, some license fees increased disproportionately. The Radioactive Materials Branch did not use this approach because it ignored operational experience gained over the last 7 years with the various types of licensed activities and their relative differences in risk to health and safety, and the changing level of effort necessary to regulate those activities. It also did not address historically under charged or over charged licensees. Some licensed activities cost more to regulate than others, and some cost less to regulate. Although fees were set in 2011 using the best information at the time to address the relative risks and level of regulatory effort between different licensed activities, this analysis does not reflect current understanding of those risks and the regulatory effort. This approach also did not address the costs of regulating new technologies entering the market after adoption of the fee rule.
3. Step fee increases based upon either the current State fees or the current NRC fees:  
This approach was not favored when it was proposed to our licensees in 2011. Licensees felt that step increases introduced uncertainty into their budgets because they would be not be sure of the fees due each year. Despite several proposed ways of approaching the rule language for step increases, licensees did not find an approach that they favored over a flat increase. There was the perception that their management would interpret each step increase as a new fee increase, which would cause unnecessary stress between management and the programs using radioactive materials. There are also business efficiencies to be considered. It is more efficient to implement and comply with a single fee increase that is in effect for five years than to implement and comply with a series of step increases over that same five year period. It was also felt that a single fee increase promoted business growth in the State because fixed fees provide more cost certainty than a series of step increases in fees, supporting decisions whether to move into the State.
4. Revisit G.S. 104E to allow the use of monies from the General Fund to fund the Radioactive Materials Branch or to offset costs not covered by license fee revenue:  
This approach is counter the language of G.S. 104E-19, which requires that RPS be self-supporting, and runs against the intent of the Legislature when they amended the Statute. This option was dismissed for these reasons.
5. Flat fee increase based upon the current NRC fees:  
This approach is the favored approach for setting Radioactive Materials Branch fees. The large gap between State and NRC fees ameliorates the problem of meeting the funding target required by the Radioactive Materials Branch budget with a fixed percentage increase, which is fair to all licensees. This also addresses the problem of historically under charged and over charged licensees because NRC fees are based upon the most current understanding of the costs and benefits of regulating a wide variety of different activities. In addition, NRC annual license fees are a national standard and many States base their annual license fees on the NRC fee structure.

### **Uncertainties Regarding the Proposed Rule Changes:**

Determining future trends in the growth or loss of the number of licensees in the State is difficult. Historical data indicates that the State experienced a growth rate of about 40% in the number of specific licensees over the nine-year period between 1995 and 2004, averaging about a 4.5% increase per year. In 1995, the earliest date that this data is available online from IMPEP reporting, North Carolina had 538 specific licensees. The State experienced growth in this sector of the economy and by 2004, data from IMPEP reporting indicates that this number grew to 751 specific licensees.

The data in the table below comes from annual reports of the number of licensees in the United States published by the NRC. In 2012, the year after the fee increase became effective, the number of licensees in North Carolina fell from 760 licensees to 622 licensees. This appears to indicate that the 2011 fee increase resulted in an 18% drop in the number of North Carolina licensees. During this same period, other agreement states experienced an average drop of approximately 4% in the number of licensees licensed in those states. Assuming that North Carolina could have experienced a similar 4% drop in the number of licensees in the absence of the fee increase, and taking into account the growth in the number of licensees that occurred between 2012 and 2018, it can be postulated that the fee increase resulted in a net loss of approximately 12% in the number of North Carolina licensees.

### **Annual Number of Licensees for the Following Agreement States:**

Table 6

| State\Year     | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018    |
|----------------|------|------|------|------|------|------|------|------|------|---------|
| North Carolina | 674  | 760  | 760  | 622  | 635  | 615  | 635  | 578  | 578  | 664     |
| South Carolina | 512  | 503  | 520  | 487  | 444  | 465  | 444  | 414  | 405  | No data |
| Georgia        | 419  | 419  | 414  | 391  | 382  | 396  | 382  | 364  | 348  | No data |
| Tennessee      | 603  | 601  | 589  | 576  | 537  | 553  | 537  | 526  | 520  | No data |
| Virginia       | 427  | 424  | 426  | 419  | 397  | 401  | 397  | 398  | 389  | No data |

Data in Table 6 shows that although there was an initial loss in the number of North Carolina licensees the first year after the fee increase in 2011 (in 2012), the population of licensees fluctuates but gradually increases over time. Currently, in 2018, the Radioactive Materials Branch database shows that North Carolina has 664 active specific licensees.

### **Comparison of the 2011 and the proposed 2019 fee increases:**

The current fee rule has 24 different specific license types and 4 “add-on” fees that were invoiced annual license fees. The annual fee for mobile medical practice, water remediation activities, and accelerator licensees included one unit; be that a single medical client site, single water remediation well, or accelerator. “Add-on” fees are fees charged for additional client sites, well sites and accelerators, respectively. The purpose of the “add-on” fee is to recover the cost of conducting inspections at each site listed on the license. In the cases of mobile medical practices and water remediation activities, these costs are greater than other license types because their offices are spread out over a large geographic area. For accelerators, the “add-on” fee covers the cost of inspecting more complex licensed activities; each accelerator at a facility is an individually inspected ‘item’. Unfortunately, the “add-on” approach led to billing inaccuracies. The snapshot of the license database gained just before invoicing each licensee subject to the “add-on” fees was not necessarily accurate. While licensees do not mind not paying a fee if our licensing database is inaccurate, they do mind paying a fee if the database is inaccurate.

To simplify licensing (and by extension, billing) the Radioactive Materials Branch reduced the number of specific license types to 14, restructured which specific license type went into each fee category in the proposed rule, and eliminated the “add-on” fee. This will reduce administrative costs for RPS since recordkeeping is less complicated. RPS based the restructuring upon RPS’s assessment of the health and safety risks associated with dissimilar activities using radioactive materials or sources of radiation. Those activities with similar health and safety risks were placed into the same fee category.

Table 8  
Percent increase in proposed fees from the current fee rule

| License Category  | Current Fee | Proposed Fee | % of Current Fee |
|---|-------------|--------------|------------------|
| Broad Medical   | \$5,250     | \$6,760      | 129%             |
| Broad Academic and Research and Development                 | \$3,500     | \$5,180      | 148%             |
| Broad Manufacturing and Distribution (new license category) | \$3,500     | \$6,100      | 174%             |
| Industrial Radiography                                      | \$3,500     | \$5,400      | 154%             |
| Well Logging  |             | \$3,200      | new fee          |
| Medical without Written Directive                           | \$950       | \$2,940      | 309%             |
| Medical with Written Directive                              | \$2,900     | \$4,760      | 164%             |
| Veterinarian (new license category, included in ‘Other’)    |             | \$1,860      | new fee          |
| Fixed Nuclear Gauge (included in ‘Other’)                   | \$550       | \$1,860      | 338%             |
| Portable Nuclear Gauge (included in ‘Other’)                | \$425       | \$1,860      | 438%             |
| Manufacturing and Distribution, including Radiopharmacy     | \$2,250     | \$2,320      | 103%             |
| per active Sealed Source and Device registration            |             | \$1,480      | new fee          |
| Irradiator ≥ 10KCi  | \$8,500     | \$19,140     | 225%             |
| Irradiator <10KCi   | \$4,500     | \$2,160      | 48%              |
| Laboratory, Academic, Research and Development              | \$1,900     | \$2,960      | 156%             |
| Service/Consultants (included in ‘Other’)                   | \$400       | \$1,860      | 465%             |
| Other (includes license types noted above)                  | \$500       | \$1,860      | 372%             |
| General License without annual registration requirement     | \$200       | \$200        | no increase      |
| General License with annual registration requirement        | \$325       | \$325        | no increase      |
|   |             |              |                  |
| Accelerators* (all)   | \$2,000     | \$4,760      | 238%             |

The percent increases for the licensed activities noted in Table 8 above reflect both the regulatory effort and expense incurred by RPS to regulate these activities, and reflects those activities that have been over or under charged in the past. For example, blood irradiators used in hospitals are relatively simple to inspect from a health and safety aspect, and the risk of occupational exposure is low. The reduction in fees for these irradiators (<10,000 curies, or 10KCi) reflects this risk analysis. Conversely, portable

nuclear gauge licensees conduct most of their operations at construction sites where there is a lot of heavy moving equipment (bulldozers, rollers, dump trucks, etc.) and it is not uncommon for a gauge to be run over and destroyed, or lost during transportation. Although the risk of an occupational exposure from using a portable nuclear gauge is also low during normal operations, these gauges are used throughout the State and locating the field locations where these licensees are working while the gauges are in use is time intensive, with a corresponding increase in cost.

**Sensitivity Analysis for Licensee Growth on Income for the First Year (2019):**

Due to the loss of approximately 12% of the licensees in North Carolina in 2012 after the fee increase in 2011, this sensitivity analysis is bounded by a 15% loss in the number of licensees. The table below shows revenue in the first year after the fee increase under a range of conditions:

Table 9

| <b>Change in the Number of Licensees</b> | <b>Anticipated Revenue</b> |
|--|----------------------------|
| -15%                                     | \$1,965,489                |
| -5%                                      | \$2,196,723                |
| -1%                                      | \$2,289,217                |
| 0%                                       | \$2,312,340                |
| 1%                                       | \$2,335,464                |
| 5%                                       | \$2,427,957                |
| 10%                                      | \$2,543,574                |

Assuming a worst-case scenario where Radioactive Materials Branch loses 15% of the licensee population and there is no subsequent growth in the number of licensees, this fee increase is anticipated to be sufficient until 2023 – 2024. As indicated in the Table 6, above, growth experienced in licensee population numbers after the initial loss in 2012 does not support this worst-case scenario.

**Net Present Value:**

Costs and Benefits, and Net Present Value are provided below:

| <b>TABLE 10. Parameter Table</b>                                     |             |
|--|-------------|
| Expected total revenue at yr 0                                       | \$1,334,061 |
| Expected total revenue at new fees                                   | \$2,312,340 |
| Initial decline in licensees   | 12.0%       |
| Yearly average decline in licensees                                  | -2.3%       |
| Average increase in expenditures                                     | 2.0%        |
| Benefit received by regulated community through cost savings in yr 1 | \$8,800,000 |
| Radiation Salaries in yr 0   | \$1,211,842 |

The costs and benefits as well as calculated net present value of the rule change for all affected parties for Year 0 through Year 5 is described below:

| <b>Table 11a. Costs and Benefits to Parties Affected</b>                        |                     | 2019             | 2020             | 2021             | 2022             | 2023               |
|---|---------------------|------------------|------------------|------------------|------------------|--------------------|
| <b>Year</b>   | <b>0</b>            | <b>1</b>         | <b>2</b>         | <b>3</b>         | <b>4</b>         | <b>5</b>           |
| <b>COSTS</b>  |                     |                  |                  |                  |                  |                    |
| Private Citizens  |                     |                  |                  |                  |                  |                    |
| Program Fees  |                     | \$647,614        | \$632,719        | \$618,167        | \$603,949        | \$590,058          |
| Consequences of program closure   |                     |                  |                  |                  |                  | \$1,337,972        |
| State Gov't   |                     |                  |                  |                  |                  |                    |
| Foregone supplemental funds received by Radioactive Materials Branch from X-ray |                     | \$255,000        | \$260,100        | \$265,302        | \$270,608        | \$276,020          |
| <b>Total Costs</b>  | <b>\$0</b>          | <b>\$902,614</b> | <b>\$892,819</b> | <b>\$883,469</b> | <b>\$874,557</b> | <b>\$2,204,050</b> |
|   |                     |                  |                  |                  |                  |                    |
| <b>BENEFITS</b>   |                     |                  |                  |                  |                  |                    |
| Private Citizens  |                     |                  |                  |                  |                  |                    |
| Avoided costs for regulations under NRC   |                     |                  |                  |                  |                  | \$8,017,906        |
| Time savings from dealing with NC regulators vs federal regulators              | Unquantified        | Unquantified     | Unquantified     | Unquantified     | Unquantified     | Unquantified       |
| Ability to respond to radiation disasters at local level                        | Unquantified        | Unquantified     | Unquantified     | Unquantified     | Unquantified     | Unquantified       |
| State Government  |                     |                  |                  |                  |                  |                    |
| Increase in fees from implementing rules  |                     | \$647,614        | \$632,719        | \$618,167        | \$603,949        | \$590,058          |
| Increased service from available funds for X-ray                                |                     | \$255,000        | \$260,100        | \$265,302        | \$270,608        | \$276,020          |
| Staff time savings from avoiding probation status                               | Unquantified        | Unquantified     | Unquantified     | Unquantified     | Unquantified     | Unquantified       |
|   |                     |                  |                  |                  |                  |                    |
| <b>Total Benefits</b>   | <b>\$0</b>          | <b>\$902,614</b> | <b>\$892,819</b> | <b>\$883,469</b> | <b>\$874,557</b> | <b>\$8,883,984</b> |
|   |                     |                  |                  |                  |                  |                    |
| <b>NET IMPACT</b>   | <b>\$0</b>          | <b>\$0</b>       | <b>\$0</b>       | <b>\$0</b>       | <b>\$0</b>       | <b>\$6,679,934</b> |
| <b>NPV (of all years)</b>   | <b>\$22,560,954</b> |                  |                  |                  |                  |                    |

|   |              | 2019        | 2020        | 2021        | 2022        | 2023        |
|---|--------------|-------------|-------------|-------------|-------------|-------------|
| <b>Year</b>                                     | <b>0</b>     | <b>1</b>    | <b>2</b>    | <b>3</b>    | <b>4</b>    | <b>5</b>    |
| <b>Table 11b. Net Impact by Affected Entity</b> |              |             |             |             |             |             |
| Regulated community                             | \$0          | (\$647,614) | (\$632,719) | (\$618,167) | (\$603,949) | \$7,427,848 |
| NPV (of all years)                              | \$23,497,713 |             |             |             |             |             |
| Radioactive Materials Branch                    | \$0          | \$392,614   | \$372,619   | \$352,865   | \$333,341   | \$314,038   |
| NPV (of all years)                              | \$2,218,883  |             |             |             |             |             |
| X-Ray Branch                                    | \$0          | \$255,000   | \$260,100   | \$265,302   | \$270,608   | \$276,020   |
| NPV (of all years)                              | \$1,939,658  |             |             |             |             |             |

The costs and benefits used in the calculation of the net present value for Year 6 through Year 10 is described below:

| <b>Table 11c. Costs and Benefits to Parties Affected</b>                        | 2024               | 2025               | 2026               | 2027               | 2028               |
|---|--------------------|--------------------|--------------------|--------------------|--------------------|
| <b>Year</b>   | <b>6</b>           | <b>7</b>           | <b>8</b>           | <b>9</b>           | <b>10</b>          |
| <b>COSTS</b>  |                    |                    |                    |                    |                    |
| Private Citizens  |                    |                    |                    |                    |                    |
| Program Fees  | \$576,487          | \$563,228          | \$550,273          | \$537,617          | \$525,252          |
| Consequences of program closure   | \$1,364,731        | \$1,392,026        | \$1,419,866        | \$1,448,264        | \$1,477,229        |
| State Gov't   |                    |                    |                    |                    |                    |
| Foregone supplemental funds received by Radioactive Materials Branch from X-ray | \$281,541          | \$287,171          | \$292,915          | \$298,773          | \$304,749          |
| <b>Total Costs</b>  | <b>\$2,222,758</b> | <b>\$2,242,425</b> | <b>\$2,263,054</b> | <b>\$2,284,654</b> | <b>\$2,307,229</b> |
| <b>BENEFITS</b>   |                    |                    |                    |                    |                    |
| Private Citizens  |                    |                    |                    |                    |                    |
| Avoided costs for regulations under NRC   | \$7,833,494        | \$7,653,324        | \$7,477,297        | \$7,305,319        | \$7,137,297        |
| Time savings from dealing with NC regulators vs federal regulators              | Unquantified       | Unquantified       | Unquantified       | Unquantified       | Unquantified       |
| Ability to respond to radiation disasters at local level                        | Unquantified       | Unquantified       | Unquantified       | Unquantified       | Unquantified       |
| State Government  |                    |                    |                    |                    |                    |

| <b>Table 11c. Costs and Benefits to Parties Affected (cont.)</b> | 2024               | 2025               | 2026               | 2027               | 2028               |
|--|--------------------|--------------------|--------------------|--------------------|--------------------|
| <b>Year</b>  | <b>6</b>           | <b>7</b>           | <b>8</b>           | <b>9</b>           | <b>10</b>          |
| Increase in fees from implementing rules                         | \$576,487          | \$563,228          | \$550,273          | \$537,617          | \$525,252          |
| Increased service from available funds for X-ray                 | \$281,541          | \$287,171          | \$292,915          | \$298,773          | \$304,749          |
| Staff time savings from avoiding probation status                | Unquantified       | Unquantified       | Unquantified       | Unquantified       | Unquantified       |
|  |                    |                    |                    |                    |                    |
| <b>Total Benefits</b>  | <b>\$8,691,521</b> | <b>\$8,503,723</b> | <b>\$8,320,485</b> | <b>\$8,141,710</b> | <b>\$7,967,297</b> |
|  |                    |                    |                    |                    |                    |
| <b>NET IMPACT</b>  | <b>\$6,468,763</b> | <b>\$6,261,298</b> | <b>\$6,057,431</b> | <b>\$5,857,056</b> | <b>\$5,660,068</b> |
|  |                    |                    |                    |                    |                    |
|  |                    |                    |                    |                    |                    |
| <b>Table 11d. Net Impact by Affected Entity</b>                  |                    |                    |                    |                    |                    |
| Regulated community  | \$7,257,007        | \$7,090,096        | \$6,927,024        | \$6,767,702        | \$6,612,045        |
| Radioactive Materials Branch                                     | \$294,946          | \$276,056          | \$257,358          | \$238,844          | \$220,503          |
| X-Ray Branch   | \$281,541          | \$287,171          | \$292,915          | \$298,773          | \$304,749          |

| <b>Table 12. Regulated Community Only NPV Sensitivity Analysis - Initial Decline in Licensees vs Average Yearly Decline</b> |              |                     |              |              |              |
|---|--------------|---------------------|--------------|--------------|--------------|
| \$23,497,713  | -4%          | <b>-2.3%</b>        | 0%           | 2%           | 4%           |
| 15%   | \$22,897,001 | \$23,943,162        | \$25,407,565 | \$26,723,142 | \$28,073,346 |
| <b>12%</b>  | \$22,479,498 | <b>\$23,497,713</b> | \$24,920,338 | \$26,195,477 | \$27,500,998 |
| 10%   | \$22,201,163 | \$23,200,748        | \$24,595,519 | \$25,843,701 | \$27,119,433 |
| 5%  | \$21,505,324 | \$22,458,334        | \$23,783,474 | \$24,964,260 | \$26,165,520 |
| 0%  | \$20,809,485 | \$21,715,920        | \$22,971,429 | \$24,084,819 | \$25,211,607 |

**Table 13. NPV of Rules if NRC Revoked License Agreement in Year:**

|             |                      |
|-------------|----------------------|
| 2020        | \$ 40,036,312        |
| 2021        | \$ 33,628,068        |
| 2022        | \$ 22,560,954        |
| <b>2023</b> | <b>\$ 22,560,954</b> |
| 2024        | \$ 17,798,253        |
| 2025        | \$ 13,487,843        |

**Conclusion:**

There are considerable cost savings in fully funding the activities of the Radioactive Materials Branch by adopting the proposed fee rule. Table 13 shows that the net present value of the benefit of adopting this rule is over \$22 million if it is assumed that the baseline status continues and the NRC suspends or terminates the Agreement with North Carolina in 2023 due to insufficient funding of the Radioactive Materials Branch.

Should the Agreement be suspended or terminated in 2023, the increased cost of being regulated by the NRC would not be delayed. Prior to the loss of Agreement State status, there would be increased costs to the State to transfer the radioactive materials safety program to the NRC. For example, simply closing out and transmitting licensing actions and records, inspection records, and incident and allegation records will consume a great deal of staff time and will likely preclude conducting normal activities such as reviewing license amendment requests submitted to the Radioactive Materials Branch during this time. There would be a need for increased overtime as inspections and licensing actions are completed before the transfer, or these activities will need to be ceased so these actions can be assumed by the NRC. There are also the various severance packages to be considered for displaced staff, and hiring and re-training costs for staff taking different positions within the State. Our licensees will not be immune to the increased cost of doing business under the NRC during this period. Licensees will need to revise their radiation safety programs to reflect the new regulatory environment, and to prepare amendments to their licenses to be submitted to the NRC for issuance of NRC radioactive materials licenses. The necessary task of revising existing radiation safety programs to remove references to North Carolina regulations and substitute references to the NRC regulations will be costly for many licensees.

After the transfer of the North Carolina radioactive materials safety program to the NRC, the NRC fee structure will apply. The NRC charges application fees for license amendments, and cost recovery fees for licensing and inspection activities, on top of annual license fees. The State does not charge license amendment or cost recovery fees for licensing or inspection activities.

There are also less easily quantifiable benefits to funding the Radioactive Materials Branch: such as a local presence that is conducive to quick, timely on-site response and communication between the Branch, the regulated community and the public. In contrast, the NRC is centrally located in regions that encompass several States, which makes a quick response less likely and communication more burdensome. The NRC is also a larger agency than RPS, and this size delays communication between the various offices within the NRC, and the NRC and their regulated community and the public. The Radioactive Materials Branch offers assistance to local businesses and private citizens with the identification, and storage or disposal of radioactive material at no cost to business or the public. Conversely, under the NRC these services come with cost-recovery fees that can be substantial.

There are also negative impacts to the Radiology Compliance Branch and their registrants to consider if the baseline status is maintained and this fee rule is not adopted. Although the Radioactive Materials Branch is now fully staffed to address the performance deficiencies of the Branch that were identified in the IMPEP

performed in 2014, the Radiology Compliance Branch has lost three staff because salaries are not competitive with those found in private industry. Because monies from Radiology Compliance Branch annual registration fees are being used to fund shortcomings in Radioactive Materials Branch annual revenue, the Radiology Compliance Branch is not able to provide the level of service that its registrants pay for. This is unfair to those businesses paying for these services. If this fee rule is not adopted, the Radiology Compliance Branch will experience difficulties recruiting qualified staff for the three vacant positions and will not be able to expand the x-ray program. Compounding this problem, in October of last year a new Rule regulating computed tomography (CT) x-ray systems became effective. This Rule adds a layer of complexity, with new training and experience requirements for Radiology Compliance Branch staff that must be addressed to protect employees and the public from unnecessary radiation exposures from CT devices.

Adopting this Rule fully funding the Radioactive Materials Branch benefits the citizens of North Carolina by maintaining the Agreement with NRC and continuing regulation of the use of radioactive materials by the State. Fully funding the Radioactive Materials Branch also releases monies from Radiology Compliance Branch revenue for use by that Branch for staffing vacant positions and expanding the x-ray program to regulate the use of CT systems. The most recent increase in Radioactive Materials Branch annual license fees was in 2011. The proposed Radioactive Materials Branch annual license fees are set at one-fifth of the corresponding NRC annual license fees for each category of license type, and are designed to fund Radioactive Materials Branch activities for the next five years.

10A NCAC 15 .1106 is proposed for amendment as follows:

**10A NCAC 15 .1106 RADIOACTIVE MATERIALS AND ACCELERATOR FEE AMOUNTS**

(a) Annual fees for persons licensed pursuant to the provisions of Section .0300 of this Chapter ~~are as listed in the following table:~~ shall be:

| Type of Radioactive Material License   | Annual Fee                                |
|--|---|
| Specific license of broad scope <u>including:</u>                              |   |
| <del>Medical Broad</del> -academic or research and development (R&D)           | <del>\$ 5,250.00</del> <u>\$ 5,180.00</u> |
| <del>Academic Broad</del> -manufacture or distribution                         | <del>\$ 3,500.00</del> <u>\$ 6,100.00</u> |
| <del>Research and Development Broad</del>                                      | <del>\$ 3,000.00</del>                    |
| <del>-medical</del>  | <del>\$ 6,760.00</del>                    |
| Specific license <u>including:</u>   |   |
| <del>-educational institutions, R&amp;D laboratories</del>                     | <del>\$ 2,960.00</del>                    |
| <del>-industrial radiography (with temporary subsites)</del>                   | <del>\$ 3,500.00</del> <u>\$ 5,400.00</u> |
| <del>-industrial radiography (in plant only)</del>                             | <del>\$ 2,600.00</del>                    |
| <del>-irradiator &gt;10,000Ci</del>  | <del>\$ 19,140.00</del>                   |
| <del>-irradiator &lt;10,000Ci</del>  | <del>\$ 2,160.00</del>                    |
| <del>-manufacture or distribution</del>  | <del>\$ 2,320.00</del>                    |
| <del>-medical (human use), no written directive required</del>                 | <del>\$ 2,940.00</del>                    |
| <del>-medical (human use), written directive required</del>                    | <del>\$ 4,760.00</del>                    |
| <del>-medical institution other than teletherapy</del>                         | <del>\$ 2,900.00</del>                    |
| <del>-medical private practice</del>   | <del>\$ 950.00</del>                      |
| <del>-mobile medical practice (home office including 1 client site)</del>      | <del>\$ 1,600.00</del>                    |
| <del>-mobile medical practice (per additional client location)</del>           | <del>\$ 350.00</del>                      |
| <del>-medical teletherapy</del>  | <del>\$ 2,100.00</del>                    |
| <del>-fixed industrial gauges</del>  | <del>\$ 550.00</del>                      |
| <del>-portable gauges</del>  | <del>\$ 425.00</del>                      |
| <del>-gas chromatographs</del>   | <del>\$ 375.00</del>                      |
| <del>-manufacture or distribute</del>  | <del>\$ 2,250.00</del>                    |
| <del>-irradiator &gt;100,000Ci</del>   | <del>\$ 8,500.00</del>                    |
| <del>-irradiator ≤100,000Ci</del>  | <del>\$ 4,500.00</del>                    |
| <del>-educational institutions</del>   | <del>\$ 1,900.00</del>                    |
| <del>-water remediation activities (home office including 1 client site)</del> | <del>\$ 1,350.00</del>                    |
| <del>-water remediation activities (per additional client location)</del>      | <del>\$ 280.00</del>                      |

|  |                        |                    |
|--|------------------------|--------------------|
| <del>services/consultants</del>  | <del>\$ 400.00</del>   |                    |
| <del>other services, consultants, gauges (all types), or not specified above</del> | <del>\$ 500.00</del>   | <u>\$ 1,860.00</u> |
| <del>well logging, subsurface tracer studies</del>                                 | <del>\$ 3,200.00</del> |                    |

General licenses license including:

|  |                      |                  |
|--|----------------------|------------------|
| <del>licenses subject</del> <u>not subject</u> to annual registration requirements | <del>\$ 325.00</del> | <u>\$ 200.00</u> |
| <del>licenses not subject</del> <u>subject</u> to annual registration requirements | <del>\$ 200.00</del> | <u>\$ 325.00</u> |
| <del>possession of self-luminous devices under Rule .0309 of this Chapter</del>    | <del>no fee</del>    |                  |

(b) Annual fees for persons licensed pursuant to the provisions of Section .0900 of this Chapter ~~are as listed in the following table:~~ shall be four thousand seven hundred sixty dollars (\$4,760.00).

| Type of Accelerator License  | Annual Fee             |
|--|------------------------|
| <del>Medical (home office including 1 unit)</del>                  | <del>\$ 2,000.00</del> |
| <del>Medical (per additional unit)</del>                           | <del>\$ 200.00</del>   |
| <del>Industrial/Manufacturing (home office including 1 unit)</del> | <del>\$ 2,000.00</del> |
| <del>Industrial/Manufacturing (per additional unit)</del>          | <del>\$ 200.00</del>   |
| <del>Sales, Service, Refurbishment, Manufacture</del>              | <del>\$ 2,000.00</del> |

(c) ~~Annual fees~~ Fees for out-of-state persons granted permission to use sources of radiation in this ~~state~~ State pursuant to provisions of Rule .0345 of this Chapter are the same as that provided for in the applicable category specified in Paragraphs (a) and (b) of this Rule. ~~Such~~ The fees are ~~shall be~~ due when the application for reciprocal recognition of out-of-state license ~~or registration is made in the same manner as for a new license or registration as specified in Rule .1102:~~ is made.

(d) Each location listed on a license issued by the Agency that is not part of a contiguous property controlled by the licensee shall require an additional fee equal to the amount specified in Paragraphs (a) and (b) of this Rule. Fees for client locations listed on mobile medical licenses shall be one-half of the amount specified in Paragraphs (a) or (b) of this rule for each client site.

(e) Persons licensed to conduct activities subject to multiple categories of fees under Paragraph (a) shall be required to pay only the highest fee category.

(f) Persons possessing Sealed Source and Device Registration (SS&D) certificates shall pay an annual fee of one thousand four hundred eighty dollars (\$1,480.00) per active SS&D certificate issued by the Agency, in addition to any amounts specified in Paragraph (a) of this Rule.

*History Note: Authority G.S. 104E-9(a)(8); 104E-19(a);  
 Eff. August 1, 2007;  
 Amended Eff. July 1, 2011;  
 Transferred and Recodified from 15A NCAC 11 .1106 Eff. February 1, 2015. 2015.  
 Amended Eff. May 1, 2019.*