

DHSR Radiation Protection Section Amended Rules- Fiscal and Regulatory Impact Analysis
Security Requirements for High Level Quantities of Radioactive Sources
Approved by OSBM 12/17/15; Revised 01/05/16 (in italics and highlighted)

Agency Proposing Rule Change

North Carolina Radiation Protection Commission

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Statutory Authority

G.S. 104E-7

Impact Summary

Federal Government: Yes
State Government: Yes
Local Government: Yes
Private Sector: Yes
Substantial Economic Impact: Yes

OVERVIEW

The Radiation Protection Commission is proposing to adopt a rule in 10A NCAC 15 regarding safety requirements for licensing those possessing high quantities of radioactive materials to comply with federal requirements (see Appendices 1 and 2 for the proposed rule text and Certificate of Federal Requirement), as well as to ensure the safety of the citizens of North Carolina. The proposed adoption will have substantial economic impact.

The body of text below summarizes the cost of implementation of each of the new requirement being adopted by reference at *this time and date and not the potential impact of future amendments*. The Radiation Protection Section identified approximately 40 affected licensees, the majority of whom are industrial radiographers (21 of the 40 licensees), and the others are Academic Broad scope licensees, Medical use licensees, and Pool Irradiator licensees. Table 1 below represents a summary of the fiscal and regulatory impact as reported by this document.

Table 1. Summary of Estimated Impacts

	10-Year Present Value	First-Year Impact	Ongoing Costs
<i>COSTS</i>			
Federal Government	N/A	N/A	N/A
State Government	\$605,831	\$ 96,660	\$ 84,660
Local Government	\$39,442	\$ 19,400	\$ 3,500
Licensees	\$6,417,701	\$ 2,337,160	\$ 695,260
TOTAL COST	\$7,062,975	\$2,453,220	\$783,420
<i>BENEFITS</i>			
Licensees	\$45,554,950	\$6,486,000	\$6,486,000

BACKGROUND

Radioactive materials are necessary in today's economy, for life-saving cancer treatment, patient imaging, veterinary care, non-cancerous disease treatment, research of new pharmaceuticals, atomic physics research, bridge weld testing, pipe line testing, construction of roads, and much more. This new regulation is absolutely necessary in order to ensure the safe handling of these radioactive materials and the safety of the citizens of North Carolina. After September 11, 2001, the International Atomic Energy Association (IAEA, a cooperation of radiation protection regulatory bodies and scientists from around the world) recommended new security measures. Based on risk factors of the type of radiation emitted by different isotopes, the IAEA compiled a list of 16 isotopes that, if a terrorist were to collect in prescribed amounts, said terrorist could effect a radiological attack that would injure large populations. The licensees affected by this new regulation possess radioactive material above the threshold values for such an attack as calculated by the scientists at the IAEA.

Just as the Drug Enforcement Agency (DEA) monitors dangerous opiates, we must monitor high levels of radioactive material, as described in this proposed rule text. Adopting the proposed regulations will keep United States citizens safe and ensure that the North Carolina Radiation Protection Section is in compliance with the state's agreement with the US Nuclear Regulatory Commission (NRC), which will keep the radioactive materials program in state.

North Carolina entered into an agreement with the United States Atomic Energy Commission (now NRC) effective August 1, 1964.¹ This agreement provided for the discontinuance of United States Atomic Energy Commission regulatory authority and responsibility within the state. For the agreement to be approved, the United States Atomic Energy Commission had to determine that the North Carolina program for radiation protection was compatible with federal regulations, and that the program was adequate to protect public health and safety. North Carolina became an Agreement State as a result of the agreement signed by Governor Terry Sanford.

The agreement requires North Carolina to continue to maintain compatibility with federal (NRC) radiation protection regulations in the Code of Federal Regulations (CFR) Title 10. The North Carolina Radiation Protection Section is inspected by the NRC every four years to verify that the radiation protection program remains compatible and adequate to protect public health and safety. Part of the NRC inspection is to verify state rules compatibility with federal regulations. In most cases, the North Carolina radiation protection program rules must be identical with the matching federal regulation. Failure to maintain compatibility with appropriate federal regulation could result in North Carolina losing its Agreement State status with the NRC. The rules proposed for adoption will ensure that North Carolina rules remain compliant with changes made to the CFR in 2013.

The proposed rule adoption that references the changes to the CFR discussed in this document are aimed to reduce the burden, both regulatory and financial, on licensees in the state in North Carolina. As discussed in the alternatives section below, licensees are saving at least \$6.5 million per year in licensing fees while North Carolina remains an agreement state. This rule adoption helps maintain North Carolina's agreement state status. **If North Carolina were not an agreement state, licensees would have to comply with the same requirements as those proposed in the rule change, as well as pay higher license fees.**

Transparency to the NRC requirements is also beneficial to licensees because many licensees may start business in North Carolina, but market their products nationwide, or hope to expand to locations nationwide. The compatibility the Section is hoping to accomplish with the proposed adoption is required by all 38 agreement states. The remaining 12 states are NRC regulated states and already comply with these CFR changes. By

¹ The North Carolina Agreement with the US Atomic Energy Commission can be found at the following link: <http://nrc-stp.ornl.gov/special/regs/ncagreements.pdf>

maintaining compliance with and transparency to NRC requirements the Section is aiding businesses in North Carolina in creating a culture of uniform practices that can be easily transported across the U.S. and that would be compliant in all other states. This also helps encourage licensees when choosing to move a business to North Carolina, because radiation protection programs will not have to be rewritten to new or different requirements that are not compliant with the other 50 states and the NRC.

The Radiation Protection Commission requested participation from affected industry stakeholders in a working group to help develop this regulation text and fiscal note. A list of working group members and their affiliation is provided in Appendix 3. The working group provided information regarding affected staff members, their salary, time committed to certain tasks, cost of upgrades, and they reviewed this document. When information was provided by the working group, the document below will reference industry stakeholders or the working group.

RULE SUMMARY AND ANTICIPATED IMPACT

This rule adopts by reference the 10 CFR 37 security requirements for high level radioactive materials sources. As such, each requirement adopted by reference will be analyzed for fiscal and regulatory impact and titled with the 10 CFR 37 reference below. It is important to note that licensees have already been compliant with many of the requirements being adopted by reference in the new regulation (10 CFR 37). In 2006, the NRC and all the Agreement States issued as a license condition Increased Controls Orders (ICs) for the subset of licensees affected by this rule change (i.e. those possessing above threshold amounts of radioactive material) across the United States as an emergency measure to ensure the safety of American citizens. Federal funding programs were developed and supported by the National Nuclear Security Administration (NNSA) to support implementation of costly security upgrades, and prompt disposal of unused sources worldwide.

There are currently approximately 40 radioactive materials licensees as identified using inspection, licensing, and billing records with category one or two sources, as defined in 10 CFR 37.5 Definitions that will be affected by this rule adoption. The total number of licensees that meet this definition has been relatively constant since the Radiation Protection Section has started identifying them in 2006 for licensing purposes. For the purpose of this fiscal note, and given the low fluctuation in licensees per year, these numbers are assumed constant for the next 10 years as well.

The majority of the affected licensees are industrial radiographers (21 of the 40 licensees), and the remaining affected licensees are Academic Broad scope licensees, Medical use licensees, and Pool Irradiator licensees. Only 4 of the total 40 licensees possess category 1 sources, with the remaining 36 possessing category 2 sources only.

The cost of many of the new requirements analyzed below is calculated using a number of personnel. Inspection records were used to determine that approximately 35 of the 40 licensees are significantly smaller in personnel size than the remaining 5 institutions. Specifically, hospitals and academic institutions will most likely need to train private on-site security staff and as such, have a much larger amount of affected staff.

Many of the requirements analyzed in depth below apply specifically to licensees (licensed entities). The costs incurred by the State Government are incurred during review of documentation and compliance information during inspection and licensing, during emergency response (accepting notifications). To eliminate repetition, the overall impact for the federal and state government is analyzed here, and no additional cost is incurred unless otherwise specifically noted, as for local government (10 CFR 37.43 LLEA coordination).

Overall Impact – Local Government

State Government staff are responsible for all inspections, licensing, and for accepting notifications. Local law enforcement agencies (LLEA) will respond to 9-1-1 and other emergency calls at licensed facilities within their normal procedures. LLEA currently responds to burglary calls at commercial facilities regardless of radioactive materials license status, these regulations do not impose new requirements on how LLEA responds to burglary calls now or in the future. The only impact imposed by this additional requirement is on the coordination and education of LLEA officials, and the cost for this is evaluated under 10 CFR 37.43 LLEA coordination. There is no additional cost associated with the adoption of the rule for Local Government, unless otherwise specifically mentioned.

Overall Impact – State Government

The Radiation Protection Section currently employs a security coordinator to complete inspections, licensing, emergency response, and notification review of security requirements of the IC orders. Since the IC orders closely resemble the proposed new regulations, the Radiation Protection Section does not expect that the additional burden of this rule promulgation will create need for additional FTE to perform inspections, licensing, emergency response, or notification review.

- 1 FTE at about \$84,500 (\$55,000 average salary plus 53.5% in benefits including longevity²).

Given recent historical data on pay increases for state employees, this analysis assumes that this cost would state constant over the next few years. While the cost of the fringe benefits is likely to increase, the additional cost would be marginal, and therefore the analysis assumes benefits would stay at about 52% of salary for the next few years.

An optional week long training on these requirements is provided by the NRC free of costs to the Agreement State. Approximately half of the 15 FTE employees at the Radiation Protection Section have already completed the training as part of the IC order implementation in 2006. This training is completed once to qualifying an inspector and does not need to be repeated. On average, it may take an inspector or license writer 2-3 years of training in basic job functions before they attend this training. This is not a primary job function training and since this training is usually offered only once a year and attendance is limited and competitive among Agreement States, the inspector or license writer may need to wait for an opportunity to attend even after completing primary training. Assuming the remaining staff would be retained through 3 years and be trained the cost for the remaining employees would be:

- 40 hours of training * (\$25/hour + \$25/hour*52% for benefits) * 8 employees ≈ \$12,200³

Overall Impact – Federal Government

The NRC has provided a week long training on security requirements to NRC and Agreement State employees since the IC orders came into effect in 2006. The NRC will continue to provide the same training, with no substantial changes in cost or content. Travel costs and meals are covered for Agreement State and NRC employees that are stationed nationwide. If Agreement State (NC) employees do not attend, the training is still held for NRC employees and for other Agreement State employees. Travel costs and meal expenses for these other Agreement State staff and NRC employees are still incurred by the NRC, regardless of NC staff attendance,

² NC Office of State Human Resources. 2015 Compensation & Benefits Report.

http://s3.amazonaws.com/oshr.ncgovstaging.fayze2.com/s3fs-public/migrated_files/Guide/CompWebSite/2015%20CompBenefits%20Report%20_finalpdf.pdf

³ Ibid.

since NRC offers half the slots from any training to Agreement State staff who have to enter a lottery to be able to participate.

- No change in impact associated with the adoption of this regulation reference.

10A NCAC 15 .1701 Additional Requirements for Licensees Possessing Category 1 and Category 2 Quantities of Radioactive Material

This rule text adopts by reference the 10 CFR 37 security requirements for high level radioactive materials sources. As such, each requirement adopted by reference will be analyzed for impact and titled with the 10 CFR 37 reference below. A summary of each requirement adopted will be provided under the reference before the analysis of the impact. Many of the requirements analyzed in depth below apply specifically to licensees (licensed entities). The costs incurred by the State Government are incurred during review of documentation and compliance information during inspection and licensing, during emergency response (accepting notifications). To eliminate repetition, the overall impact for the federal, state, and local governments was analyzed above, and no additional cost is incurred unless otherwise specifically noted, as for local government (10 CFR 37.43 LLEA coordination).

The majority of the affected licensees are industrial radiographers (21 of the 40 licensees), and the remaining affected licensees are Academic Broad scope licensees, Medical use licensees, and Pool Irradiator licensees. Inspection records were used to determine that approximately 35 of the 40 licensees are significantly smaller in personnel size than the remaining 5 institutions. Specifically, hospitals and academic institutions will most likely need to train private on-site security staff and as such, have a much larger amount of affected staff. The number of licensees has ranged from 35-45 over the last 9 years, we anticipate that this trend will continue for the next 10 years, with changes in technology trending toward x-ray produced radiation. A working group of affected licensees was chartered by the Radiation Protection Commission and provided additional and specific information regarding the number of affected staff members, their salary, time committed to certain tasks, and cost of upgrades. The representative members also reviewed this document. When information was provided by the working group, the document below will reference industry stakeholders or the working group.

Part 37- Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

Subpart A- General Provisions 10 CFR 37.5 Definitions, 10 CFR 37.11 except (a) and (b) Specific Exemptions,

These regulations provide definitions and scope for the regulations in 10 CFR 37 and do not propose any new requirements. There is no impact from the adoption of definition and scope, the requirements using terms defined here are analyzed below.

Impact – Licensed Entities

- No impact associated with the adoption of this regulation reference.

Subpart B- Background Investigations and Access Control Program

10 CFR 37.21 Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material.

These regulations state that you must have a program commensurate with requirements listed later in the subpart. The cost of each program element is analyzed where it is required.

Impact – Licensed Entities

- No impact associated with the adoption of this regulation reference.

10 CFR 37.23 Access authorization program requirements

An access authorization program must be documented. This document will contain the basis of the requirements for granting and individual unescorted access to category 1 or 2 materials (as defined in 10 CFR 37.5). A reviewing official (defined in 10 CFR 37.5) must be designated by the licensee, authorized, and is responsible for implementing this procedure. Individuals requesting unescorted access must be informed of the procedure and information that will be collected. Individuals requesting unescorted access may deny any part of the investigation, but must be denied access if an investigation cannot be completed. Individuals requesting unescorted access must be allowed to review the information collected in order to determine its truthfulness before a final determination is made. A licensee shall keep the records of these determinations for 3 years.

Impact – Licensed Entities

Reviewing officials are designated by the licensee. Examples of personnel chosen usually include Human Resources, Security, or the Radiation Safety Officer. Each licensee would be required to have one reviewing official, and most licensees do currently have a person ready to take on this role. This role was formerly performed by the Trustworthy & Reliability (T&R) official under the IC order. Hourly compensation for these staff range from \$40/hr to \$65/hr (including 30% for benefits).⁴ Radiation safety professional salary information is collected and published annually by the Health Physics Society.⁵ Average Salary for all Health Physicist in the Southern region was about \$100,000.

Industry stake holders have provided information that the creation and documentation of procedures associated with this review would take approximately 40 hours (one time cost for initial creation). Licensees under the IC orders do currently have a documented basis for T&R approval, but this document must be reviewed and updated to meet new requirements.

- Implementation for an access authorization program cost per licensee: \$16,00-\$2,600 (one time cost)
 - 40 hours * (\$40/ hour) = \$1,600
 - 40 hours * (\$65/ hour) = \$2,600
- Overall impact: [35 licensees * \$1,600] + [5 licensees* \$2,600] = \$69,000 (first year, one time cost)
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This analysis assumes that the cost to licensees for maintaining records for 3 years regarding unescorted access authorizations would be small since most likely these records would be kept electronically and they are unlikely to be large files.

10 CFR 37.25 Background Investigations

Each person requesting unescorted access to Category 1 or Category 2 sources must receive a background check. Individuals declining the background investigation may access sources only if escorted by someone who has completed the background check and if it is deemed necessary by the licensee responsible. This background check must encompass at least the last 7 years or until the applicant's 18 birthday, whichever is shorter, and must be repeated every 10 years. The background check will include fingerprinting and an FBI identification and criminal history records check, a verification of true identity employment history, and education. There shall be

⁴ US Bureau of Labor Statistics. Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers, by major industry group, September 2015.

<http://www.bls.gov/news.release/ecec.t06.htm>

⁵ Health Physics Society. 2014 HPS Salary Survey. http://hps.org/documents/2014_salary_survey.pdf

independent corroboration of information provided by the individual and shall be contacted to determine character and reputation.

Impact – Licensed Entities.

Industry stakeholders have provided information that approving one new individual for unescorted access, as prescribed by this requirement, would cost approximately \$40 for FBI finger printing, and 2 hours for review of documents, reaching out to references, and documenting this review. As stated previously, in 10 CFR 37.23 reviewing officials are designated by the licensee, and hourly wages for these staff range from \$40/hr to \$65/hr (including 30% for benefits).

The individual being reviewed would spend approximately one half hour providing fingerprints on the appropriate FBI finger printing card, and could spend an additional half hour reviewing, confirming, or explaining findings on the background investigation (hourly compensation for radiation workers would range from \$40/hr to \$65/hr including 30% for benefits).

If a person cannot complete the background investigation, or the licensee deems the individual untrustworthy on the basis of the investigation, the individual may not have access to category 1 or 2 radioactive materials sources. In most cases licensees will require that the background investigation be completed as a condition of hiring, and/or they will reassign the duties of the individual in question if the background investigation deems the individual untrustworthy.

Therefore, it would cost affected North Carolina licensees between \$160 and \$235 per individual requiring access. Industry stakeholders on the working group estimate that the number of individuals requiring access can vary from 3 per year for small hospitals, to 50 students for a large university. This analysis assumes these numbers to remain stable for the years analyzed. It should be noted that it is allowed under 10 CFR 37.29 that other equivalent background checks may be substituted in place of this background check, provided that the licensee receive and document proof of the former, which can reduce the number of background checks needed.

Assuming that the same number of individuals will need to be investigated annually may be overestimating the impact, as trustworthiness evaluation is valid for 10 years. However, with many of these sources being used in medical and university settings, where there is a high turn-over and transfer rate of staff/students, it is realistic to assume a significant portion of the initial number of investigations will need to re-occur or be shared with other licensees.

- Impact per licensee of background investigations:
 - Cost to smaller licensees:
[\$40 for FBI check + 1 hour for information provided by individual* \$40/hr for individual + 2 hour review/person * \$40/hr for staff]* 3 persons/year = \$480/year
 - Cost to larger licensees:
[\$40 for FBI check + 1 hour for information provided by individual* \$65/hr for individual+ 2 hour review /person * \$65/hr for staff]* 50 persons/year = \$11,750/year

- Overall impact: [35 smaller licensees * \$480] + [5 larger licensees* \$11,750] = \$75,550 annual cost

10 CFR 37.27 Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material.

This requirement states that you must use fingerprints as a basis for criminal investigations. The cost for this requirement is evaluated under 10 CFR 37.25 above.

Impact – Licensed Entities.

- No additional impact associated with the adoption of this regulation reference.

10 CFR 37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials

This regulation does not state a new requirement, but rather defines relief from requirements being adopted and therefore licensees, state, federal and local governments will not incur additional costs from this regulation.

Impact – Licensed Entities.

- No impact associated with the adoption of this regulation reference.

10 CFR 37.31 Protection of Information

Security related information must be documented and stored in a way that it cannot become compromised.

Impact – Federal Government

- No impact associated with the adoption of this regulation reference.

Impact – State Government

The Radiation Protection Section is located inside of a secured suite at 5505 Creedmoor Road. The suite is only accessible to state employees by badge, and visitors are identified via camera, buzzed in and escorted while inside the suite. The Department of Health and Human Services has requirements for firewalls for computers, or locked file cabinets that store sensitive information. Storing information required by all the new requirements does not increase current budgetary costs to State Agencies as securing information is already a common practice. Any opportunity cost of using existing resources is likely to be small as the amount of information that the agency would have to store would not be large.

- No impact associated with the adoption of this regulation reference.

Impact – Local Government

Local law enforcement that participates in annual reviews of the security plans as they are related to high activity sources will secure this information so that it is not accessible to individuals without need-to-know. Local law enforcement has in place procedures to protect certain information from being shared during active investigations, to protect privacy of victims, and homeland security. The requirement to ensure that information regarding high level activity radioactive sources be kept protected would fall under the auspices of homeland security and this regulation would not require additional protection beyond those measures. Any opportunity cost of using existing resources is likely to be small as the amount of information that law enforcement would have to protect would not be large.

- No impact associated with the adoption of this regulation reference.

Impact – Licensed Entities

Most of the licensed facilities that need to secure documentation already have firewalls for computers, or locked file cabinets that store security or HIPPA related information. Storing information required by all the new requirements may increase costs to non-medical licensees.

- Impact per licensee: The cost to implement this regulation is nominal. \$20 dollars to install pad lock on a closet or file cabinet (one time cost), which most likely would be incurred by the smaller licensees or \$200 for a new file cabinet with cypher lock from a large chain store in 2015, which is most likely to be incurred by larger licensees. The analysis assumes these costs would be incurred in the first year the rule change becomes effective.
- Overall Impact: $[35 \text{ licensees} * \$20] + [5 \text{ licensees} * \$200] = \$1,700$ one-time cost

10 CFR 37.33 Access authentication program review.

Each licensee shall ensure that access authorization programs are reviewed at least annually to confirm compliance and that comprehensive actions are taken to correct any noncompliance that is identified, documents of this review must be maintained for at least 3 years.

Impact – Licensed Entities.

All radioactive materials licensees, including those affected by this rulemaking, are required to conduct an annual program review per 10A NCAC 15 .1603(c). Adding a subsection to review and document that review of the access authorization program would cost licensees the time of the competent individual that is conducting the review. The hourly wages for these staff range from \$40/hr to \$65/hr (including 30% for benefits) as discussed above.

Industry stake holders have provided information that the review, update and documentation of the review of procedures and their effectiveness would take 5-10 hours annually.

- Impact per licensee: \$200-\$650 dollars annually (recurring) for reviewing and updating access authorization program effectiveness and procedures.
- Overall impact: $[35 \text{ licensees} * \$200] + [5 \text{ licensees} * \$650] = \$10,250$ annual cost

Subpart C- Physical Protection Requirements During Use

10 CFR 37.41 Security program

General statement that each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this subpart, that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material. The cost of this program is evaluated with each requirement of the program below.

Impact – Licensed Entities.

- No impact associated with the adoption of this regulation reference.

10 CFR 37.43 General security program requirements

A security plan must be documented and secured. Personnel that participate in the security plan must be trained commensurate with their duties, and that training must be documented and secured.

Impact – Licensed Entities.

The security plan would be prepared, completed, and documented by competent individual(s) at an hourly rate justified above (\$40/hr to \$65/hr). Industry stakeholders estimate at least 100 man hours needed to prepare and document a security plan.

The required security plan training would be prepared, completed, and documented by competent individual(s) at an hourly rate justified above (\$40/hr to \$65/hr). Preparation for this training can be as much as 50 hours, to include preparing slides (once) then updating periodically, identifying key individual's training needs, and scheduling attendance. Training would be given on an annual basis.

Depending on the size of the licensee and whether the licensee employs their own security force (e.g. Universities, large hospitals, etc.) the size of the trainee pool can vary substantially. As little as ten individuals and as many as 200 individuals may attend these trainings that can last up to 4 hours.

There may be additional costs related to training materials, venues, etc.; however, that information has not been provided by the stakeholders and is not quantified in this analysis. Additionally, this analysis assumes that the recurring cost presented below are static for the foreseeable future.

- Impact per licensee of security plan creation
 - Cost: \$4,000-\$6,500 (one time cost)
- Impact per licensee of security plan training
 - Creation, Update and Training Scheduling Cost (annual): \$2,000-\$3,250
 - Training Attendance Cost (annual):
 - Cost to smaller licensees: 4 hour training * \$40/hr for staff * 10 persons trained/year (includes trainer attendance)= \$1,600/year
 - Cost to larger licensees: 4 hour training * \$65/hr for staff * 200 persons trained/year (includes trainer attendance) = \$52,000/year
- **Total Cost:** approximately \$7,600-\$61,750 first year and \$3,600-\$55,250 annually starting the second year per licensee.
- Overall: [35 licensees * \$7,600] + [5 licensees * \$61,750] = \$574,750 first year cost
[35 licensees * \$3,600] + [5 licensees * \$55,250] = \$402,250 annual costs starting the second year

10 CFR 37.45 LLEA Coordination

Licensees must annually reach out (or document an attempt to reach out) to local law enforcement agencies (LLEA) that may potentially respond to security threats on Category 1 and/or Category 2 sources. So that the LLEA is aware of the hazard and urgency of response needed.

Impact – Local Government

Industry stake holders estimated a competent and qualified licensee staff person would spend approximately 2 hours preparing for and making a phone call or email, and up to 8 hours on a site tour with LLEA representatives. Therefore it is reasonable to assume that one LLEA representative may spend 2 hours on the call and reviewing information from the call, and up to 8 hours on site and 1 hour on route to the site. The amount of time and money spent on fuel to travel on site will vary in each jurisdiction and will be highly variable depending on the vehicle and location of the event and patrolling officers. Assuming gas prices remain between \$2 and \$4 per gallon, this cost will be small compared to the total amount spent on the response, and it can be assumed that the cost for fuel is included in the possible variation of the estimate presented. LLEA representatives may elect to send more than one individual to the site tour but only one would be required. Hourly rates are estimated at \$44/hour by the U.S. Bureau of Labor Statistics (hourly wages reported as \$29/hour median)⁶ and the NC

⁶ US Bureau of Labor Statistics. <http://www.bls.gov/oes/current/oes333051.htm>

Office of State Human Resources (percentage of benefits estimated at 52%).⁷ Given recent historical data on pay increases for local employees, this analysis assumes that this cost would state constant over the next few years. While the cost of the fringe benefits is likely to increase, the additional cost would be marginal, and therefore the analysis assumes benefits would stay at about 52% of salary for the next few years.

LLEA response time is not reviewed here as it is assumed to be within the scope of normal work to respond to lost, missing, or stolen items or burglary or attempted burglary. This coordination will aid in speeding response time (due to familiarity with the licensee) and will ensure safety of the LLEA official from radiation exposure or contamination when responding.

- Cost: \$76- \$342 per LLEA representative.
 - 2 hours * \$44/hour salary plus benefits = \$88
 - security plan reviewed over the telephone
 - (2 + 1 + 8) hours * \$44/hour = \$484 includes call and onsite visit
- Overall: This total opportunity cost to LLEAs may range from a maximum of \$19,400 (40 licensees * \$451) assuming all licensees would require a site visit during the first year after implementation and a minimum of \$3,500 (40 licensees * \$88) annually thereafter assuming no site visit.

Impact – Licensed Entities.

A competent and qualified licensee staff person would spend approximately 2 hours preparing for and making a phone call or email, and up to 8 hours on a site tour with LLEA representatives.

- Hourly pay for the qualified licensee staff person is estimated by industry stakeholders to be \$40/hr- \$65/hr
- Cost: \$80 (minimum, no visit)-\$650 (maximum, with visit) for time.
 - 2 hours * (\$40/ hour [includes benefits])
 - (2+ 8) hours * (\$65 / hour [includes benefits])
- Overall: [35 licensees * \$80] + [5 licensees * \$650] = \$6,050 annual costs

10 CFR 37.47 Security zones

Category 1 and 2 sources must be secured in a way that only personnel determined to be trustworthy and reliable are granted access. In order to limit the amount of personnel needed to be vetted through the authorization access program licensees create security zones. These security zones are areas inside of a licensee facility that contain category 1 and 2 sources and restrict access to only those who have been deemed trustworthy and reliable. Licensees with category 1 or 2 sources may have several security zones, and will have at least one.

Examples of means of access restriction include using pin codes (cypher locks), proxy cards, biometric readers (such as retinal scanners or hand/finger print readers), or a combination of these.

Impact – Licensed Entities.

- Costs as estimated by industry stakeholders having already implemented security zones: \$2,000-\$20,000 per security zone (one time cost) plus maintenance costs approximately \$2,000 per year (electricity,

⁷ NC Office of State Human Resources. 2015 Compensation & Benefits Report.

http://s3.amazonaws.com/oshr.ncgovstaging.fayze2.com/s3fs-public/migrated_files/Guide/CompWebSite/2015%20CompBenefits%20Report%20_finalpdf.pdf

maintenance testing as required by manufacturer, repairs and batteries (\$10,000 onetime cost averaged over 5 years))

- Overall:
 - $[35 \text{ licensees} * \$2,000] + [5 \text{ licensees} * \$20,000] = \$170,000$ one-time cost, assumed to occur in the first year
 - $[40 \text{ licensees} * \$2,000] = \$80,000$ annual upkeep costs

10 CFR 37.49 Monitoring, detection and assessment.

Category 1 and 2 sources must be secured in a way that any unauthorized access, or attempt at unauthorized access is immediately detected and assessed by means of continuous monitoring, this includes weekly checks for category 2 sources. The continuous monitoring system must have back up power (if it depends on electricity), back up means of communication, and must default to failed (response required).

Examples of monitoring include cameras monitored by security personnel, motion detectors, posted security personnel, sensors, etc. Communication can be sent through electrical wiring (telephone or internet), satellite, radio, or cell phone signal. Batteries or generators are generally required as when choosing two options for monitoring access and two options for communicating unauthorized access or attempt of, it is impossible to avoid using electricity.

Impact – Licensed Entities.

Medical use licensees have remote monitoring systems installed by the National Nuclear Security Agency (NNSA) through the Global Threat Reduction Initiative (GTRI) program. This program actively sought out radioactive materials licensees in North Carolina starting in 2004 and systems were installed at no cost to the licensee. It is estimated that the NNSA spent approximately \$200,000 per system upgrade for each licensee. The systems came with a warranty that licensees could extend for \$1,400 per zone per year. One zone is assumed for all licensees. Licensees may elect to have additional zones for ease of use, but the design of the facility is discretionary. The regulation only requires that sources be stored and used in a security zone, not that individual sources be used inside of separate security zones.

Current regulation requires physical inventory of sources at least every 6 months and a daily use log be completed. This new regulation additionally requires that weekly checks or inventory be completed only for category 2 sources (36 of 40 affected licensees). If it can be assumed that the individual using the device can also verify its presence, the cost of documenting this additional step will be nominal, taking less than 5 minutes per week.

Other industry stake holders that were not able to participate in the GTRI program were able to create other types of monitoring, detection, and assessment systems that meet the 10 CFR 37.49 requirements. The estimates provided by representatives of licensees ranged from \$10,000- \$168,000.

- Overall:
 - $[35 \text{ licensees} * \$10,000 \text{ (one time cost)}] + [5 \text{ licensees} * \$200,000] = \$1,350,000$ one-time cost
 - $[40 \text{ licensees} * \$1,400] = \$56,000$ per year

10 CFR 37.51 Maintenance and testing

Licensees implement maintenance and testing programs that ensure intrusion alarms, associated communication systems, and other systems are functioning appropriately at least annually (or longer if allowed according to manufacturer's instructions).

Impact – Licensed Entities

Industry stakeholders estimated that it would take at least 2 competent qualified individuals (\$40/hr-\$65/hr) approximately 8 hours to complete and document this testing.

- Overall: [35 licensees * \$640] + [5 licensees * \$1,040] = \$27,600 annually

10 CFR 37.53 Requirements for mobile devices

There are currently approximately 40 radioactive materials licensees with category one or two sources. A small subset of these licensees (21 licensees of the total 40) possess mobile category 1 or 2 sources, as defined in 10 CFR 37.5 Definitions.

The two barrier regulation has been enforced by license condition since 2005. Mobile devices are stored inside of a transport container that is provided to the licensee by the manufacturer. These storage containers can vary in size, depending on the model, and are typically approximately 2 ft. x 2 ft. x 3 ft. Under the proposed rule, these containers would need to be secured using a minimum of two independent tangible barriers while the gauge is being transported and also while it is in storage (a discussion of this requirement can be found in NRC Issue Summary 2007-28⁸). Mobile device licensees usually possess an average of 5 devices, ranging from owning one gauge for occasional use, to larger corporations that maintain an inventory to be shared among several licensees. To comply with this new requirement, licensees would use chains and pad locks. During transport, a mobile device would have to be chained down in a truck bed, using four eye-bolts, two separate chains and two separate pad locks. Once the mobile device is returned to storage, it is usually chained down again using four eye-bolts and a pad lock, inside of a locked closet to satisfy the new requirement.

Based on current market data average costs were assumed to be:

- \$13 for 10 ft. of chain
- \$10 for a pad lock
- \$20 for a keyed door knob
- \$8 for an eye-bolt

Assuming 5 mobile devices per each licensee and preparing a truck to transport each mobile device, a licensee from the effected group would spend approximately \$700 each, as a one-time cost. This group of 21 licensees can be expected to spend \$14,700 altogether, as a one-time cost because of the introduction of this new requirement. Though, because this requirement was introduced by license condition in 2005, most licensees are already compliant.

- Overall: [21 licensees * \$700 for varied combinations of chain, padlocks, keyed door knobs, and eyebolts] = \$14,700 one-time cost.

10 CFR 37.55 Security program review

Licensees must ensure that the security program continues to remain compliant by reviewing the program annually, if not on a more frequent basis. The licensees must take comprehensive corrective actions to address any noncompliance. Also, they must retain documentation relating to the review for 3 years.

Impact – Licensed Entities

All radioactive materials licensees, including those affected by this rulemaking, are required to conduct an annual program review per 10A NCAC 15 .1603(c). Adding a subsection to review and document the review of the

⁸ Nuclear Regulatory Commission, Issue Summary 2007-28: Security Requirements for Portable Gauges, published December 7, 2007. http://www.apnga.com/security_summary.pdf

security program would cost licensees the time of the competent individual that is conducting the review. The hourly wages for these staff range from \$40/hr to \$65/hr (including 30% for benefits) as discussed above. Industry stake holders have provided information that the review, update and documentation of the review of procedures and their effectiveness would take 10-20 hours annually.

- Overall: [35 licensees * \$400] + [5 licensees * \$1,300] = \$20,500 annually (recurring) for reviewing and updating access security program effectiveness and procedures.

10 CFR 35.57 Reporting of events

In the event of an attempt at unauthorized access or if an unauthorized individual gains access to category 1 and/or 2 sources licensees must report this event to the radiation protection section as soon as required by this regulation and in the form required by this regulation (phone call or written (email, fax, mail)). This is only a requirement for reporting the event and does not outline requirements for the subsequent investigations.

Impact – Licensed Entities

This requirement would cost licensees the time (approximately 1-2 hours) of the competent individual who is qualified to correspond on behalf of the licensee to the regulatory body. One hour for preparing for the phone call and one additional hour on the phone with the regulator. These event are infrequent (less than annually) and it would be conservative to estimate this cost as annual, the Radiation Protection Section has received no actual reports of attempt at unauthorized access or if an unauthorized individual gains access to category 1 and/or category two sources in the last 5 years, and approximately 1 false alarm or potential event notification per year.

- Overall: \$80-\$130 dollars in time per event (annual estimate)

Subpart D- Physical Protection in Transit

There are currently approximately 40 radioactive materials licensees with category 1 or 2 sources. A small subset of these licensees possess mobile devices, as defined in 10 CFR 37.5 Definitions, category 1 or 2 sources (21 licensees of 40 total licensees affected by this rulemaking). These licensees incur the majority of transportation costs. If a licensee possesses a non-mobile radioactive materials source, this source is installed and serviced by the vendor or manufacturer (vendors) to ensure proper function of the device into which it is installed. These vendors will transport the sources under their radioactive materials licenses and incur the costs associated with complying with the requirements in these proposed regulations. We currently do not have any vendors of category 1 or 2 radioactive material sources licensed in the state of North Carolina. Vendors in other states will have to comply with these regulations, regardless of if they are promulgated in North Carolina, as the state in which the vendor is licensed will be either an agreement state or an NRC regulated state (as discussed in the background section above).

10 CFR 37.73 Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit.

This regulation is not a requirement. This regulation outlines which of the regulation requirements are applicable to Category 1 or Category 2 source transfers. The cost of implementing these requirements are analyzed individually below.

Impact – Licensed Entities

- No impact

10 CFR 37.75 Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material

This regulation has specific requirements for Category 1 and Category 2 sources separately (as defined in 10 CFR 37.5). There are 4 licensees possessing Category 1 level radioactive material in North Carolina. Category 1 radioactive sources are non-mobile, meaning these sources are installed and serviced by a vendor or manufacturer (vendors) to ensure proper function of the device into which it is installed. These vendors will transport the sources under their radioactive materials licenses and incur the costs associated with complying with the requirements in these proposed regulations. We currently do not have any vendors of category 1 or 2 radioactive material sources licensed in the state of North Carolina. Vendors in other states will have to comply with these regulations, regardless of if they are promulgated in North Carolina, as the state in which the vendor is licensed will be either an agreement state or an NRC regulated state (as discussed in the background section above). For category 2 sources the regulations require that licensees coordinate a delivery time and verify receipt of the radioactive source, no notifications are made to regulators at the time of shipment unless there is an emergency (costs are covered under 10 CFR 37.81).

Impact – State Government

There are approximately 4 licensees that possess category 1 radioactive materials sources. These sources are serviced very infrequently. Inspection records indicate that a re-sourcing event might occur once every year in the state of North Carolina. During this re-sourcing, the sources will be shipped by the vendor, but this regulation introduces a requirement to coordinate with a governor's designee, so that government officials and agencies are ready to respond in the event of an accident. It is reasonable to assume that coordination of shipment may take up to 4 hours of the governor's designee's time. He/she will inform other agencies and communicate during the transport.

- Overall: [1 licensees * 1 shipments * 4 hours * \$40/hr] = \$160 annually

Impact – Licensed Entities

There are approximately 21 licensees that possess category 2 sources that are shipped frequently based on half-life of the radioactive material and the licensed use, the number of licensees is confirmed by inspection records at the Radiation Protection Section. It is reasonable to assume that coordination of shipment and verification of receipt may take up to 2 hours.

- Overall: [21 licensees * 10 shipments * 2 hours * \$40/hr] = \$16,800 annually.

10 CFR 37.77 Advance notification of shipment of category 1 quantities of radioactive material

Category 1 radioactive sources are non-mobile, meaning these sources are installed and serviced by a vendor or manufacturer (vendors) to ensure proper function of the device into which it is installed. These vendors will transport the sources under their radioactive materials licenses and incur the costs associated with complying with the requirements in these proposed regulations. Vendors must submit plans of shipment to the Agency at least 7 days prior to shipment for Category 1 radioactive sources.

Impact – State Government

As stated previously, one shipment of this type can be expected per year, and the vendors beholden to this requirement are not North Carolina Licensees. The cost of receipt and review of this information is adsorbed in the annual salary of the security coordinator. This is within the scope and job description and does not require additional time or personnel.

Impact – Licensed Entities

- No impact.

10 CFR 37.79 Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment

This regulation requires that licensees shipping category 1 or 2 sources use carriers that have established package tracking systems, that maintain constant control and/or surveillance during transit, have the capability for immediate communication to summon appropriate response or assistance, and that require an authorized signature prior to releasing the package for delivery or return. There are additional requirements for shipping category 1 sources that are not discussed under the impact section, since category 1 sources are shipped by out of state vendors and the costs are adsorbed there.

Impact – Licensed Entities

Large carriers such as USPS, FedEx, DHL, and UPS all have tracking and verification systems in place for parcels being shipped. Drivers/shipments are monitored using GPS and radio, and have cell phones available to make any communication necessary regarding shipments. Additionally, due to shipper variances not related to this rule making, only FedEx will accept radioactive packages for shipment. Therefore licensees must use FedEx, and FedEx does have the systems, monitoring, and checks in place for shipments required by this regulation. Licensee shipment preparation and carrier choice is not affected by this rule-making.

- No impact.

10 CFR 37.81 Reporting of events

In the event of an attempt at unauthorized access, loss of shipment, loss of communication with a shipment, or if an unauthorized individual gains access to category 1 and/or 2 sources licensees must report this event to the radiation protection section as soon as required by this regulation and in the form required by this regulation (phone call or written (email, fax, mail)). This is only a requirement for reporting the event and does not outline requirements for the subsequent investigations.

Impact – Licensed Entities

This requirement would cost licensees the time (approximately 1-2 hours) of the competent individual who is qualified to correspond on behalf of the licensee to the regulatory body. One hour for preparing for the phone call and one additional hour on the phone with the regulator. These event are infrequent (less than annually) and it would be conservative to estimate this cost as annual. The Radiation Protection Section has received no actual, potential, or false alarm reports of at unauthorized access, loss of shipment, loss of communication with a shipment, or if an unauthorized individual gains access to category 1 and/or 2 sources in the last 5 years.

- Overall: \$80-\$130 dollars in time per event (annual estimate)

Subpart F-Records

10 CFR 37.101 Form of records

This regulation is a description o allowed forms for records. There are no new or different requirements. Records may be hard copy or electronic copy, as long as records are legible for their required retention period.

Impact – Licensed Entities

- No impact.

10 CFR 37.103 Record retention

The cost of record retention is addressed under 10 CFR 37.31 above.

Impact – Licensed Entities

- No impact.

BENEFITS

Aside from ensuring the security of high quantities of radioactive materials as discussed in the NRC analysis of the federal regulations,⁹ one benefit from the proposed regulation that the agency is required to adopt is that NC would maintain its Agreement State status. As a result, the licensees would save about \$6.5 million annually from not having to pay higher license fees to the NRC.

The avoided cost estimate was computed in Table 2 using current NRC license categories, license fees and inspection fees, as published in 10 CFR 170.21 and 170.32, and current NC license fees and categories, as published in 10A NCAC 15 .1106. The NRC has not proposed any fee changes and therefore it is reasonable to assume that fees will not increase within the next 5 years. The total annual savings per licensee in each category was calculated by adding the NRC license fee and an adjusted NRC inspection fee and subtracting the North Carolina license fees. Note, North Carolina does not charge licensees an inspection fee. The adjusted inspection fee was calculated by dividing the inspection fee by the priority code, which is assigned to each license type. If a licensee is to be inspected every year, the priority code assigned to that licensee is 1. The simplifying assumption was made that if a licensee is inspected once every 5 years, they would incur one fifth of the inspection fee every year. The calculations for savings per type of licensee used the number of licensees in the state tracked in the North Carolina Radiation Protection license databases. Table 2 below reflects the impact of doing nothing, i.e. reverting back to Federal control.

⁹ Nuclear Regulatory Commission. Rulemaking Issue. Final rule: Physical Protection of Byproduct Material (RIN 3150-A112). <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0170scy.pdf>

Table 2. Annual License Cost Savings from Maintaining the NC Agreement State Status with the NRC

Type	# Licen- sees	NRC License Fee	NRC Inspec- tion Fee	NC License Fee	Priority Code	Annual Savings
Medical Broad A	5	\$46,100	\$5,500	\$5,250	2	\$218,000
Academic Broad B	5	\$46,100	\$5,500	\$3,500	2	\$226,750
R&D Broad C	5	\$14,700	\$5,400	\$3,000	3	\$67,500
Industrial Radiology (Booth & Field)	18	\$25,900	\$4,000	\$3,500	1	\$475,200
Industrial Radiology (Booth Only)	3	\$25,900	\$4,000	\$2,600	1	\$81,900
Diagnostic Hospital Nuclear Medicine	57	\$8,600	\$2,700	\$2,900	3	\$376,200
Therapeutic Hospital Nuclear Med.	58	\$8,600	\$2,700	\$2,900	2	\$408,900
Sealed Source Hospital Nuclear Med.	8	\$17,900	\$8,800	\$2,900	3	\$143,467
Diagnostic Private Practice Nuclear Med. (.100, .200, .500)	158	\$8,600	\$2,700	\$950	3	\$1,350,900
Therapeutic Private Practice (.300, .392, 394, .396, .1000)	5	\$8,600	\$2,700	\$950	2	\$45,000
Private Practice Nuclear Med. (.400, .600)	0	\$17,900	\$8,800	\$950	3	\$0
Mobile Nuclear Medicine	8	\$8,600	\$2,700	\$1,600	3	\$63,200
Additional client site	0					-
Teletherapy	0	\$17,900	\$8,800	\$2,100		-
Fixed Nuclear Gauges	52	\$4,900	\$1,500	\$550	5	\$241,800
Portable Nuclear Gauges	134	\$4,900	\$1,500	\$425	4	\$649,900
Gas Chromatograph only	4	\$4,900	\$1,500	\$375	5	\$19,300
Distribution (radiopharmacy)	23	\$16,900	\$6,500	\$2,250	2	\$411,700
>100kCi irradiator (panoramic)	4	\$140,900	\$61,200	\$8,500	2	\$652,000
'= or <100kCi irradiator	4	\$9,100	\$3,200	\$4,500	5	\$20,960
Educational R&D Lab	13	\$8,700	\$3,500	\$1,900	5	\$97,500
*Water Remediation	3	\$4,900	\$1,500	\$1,350	5	\$11,550
Additional water remediation sites	4	n/a	n/a	\$280		-
Service and or Repair	30	\$14,900	\$6,400	\$400	5	\$473,400
Industrial/Lab "Other"	96	\$4,900	\$1,500	\$500	5	\$451,200
General License Gauge (annual registration)	96	\$400	n/a	\$350	5	-
General License Gauge (not annual registration)	147	\$400	n/a	\$200	5	-
Hospital Accelerator - one unit	92	n/a	n/a	\$2,000	5	-
Hospital Accelerator each additional unit	42	n/a	n/a	\$200	5	-
Industrial Accelerator - one unit	10	n/a	n/a	\$2,000	5	-
Industrial Accelerator each additional unit	3	n/a	n/a	\$200	5	-
Accelerator - Sales, refurbishment and distribution	2	n/a	n/a	\$2,000	5	-
New and Renewal Application - processing fee	141					-
Sealed Source & Device (SS&D) New Application Review (per SS&D application)	0	\$16,200	\$7,700	\$10,000		-
SS&D Review (per SS&D application) Revisions or Amendments	0	\$16,200	\$7,700	\$10,000		-
Total	1,230					\$6,486,327

An additional impact from failure to maintain the Agreement State status would be the state losing the ability to regulate. This would result in a decrease in state revenue, which based on the information provided in Table 2 would be about \$1.2 million annually, since it would no longer collect license fees from licensees. The state, however, would also experience savings in terms of the staff time that is currently required to carry out the state's regulatory role. It is assumed that the revenue loss would completely offset the savings in staff time since currently the Division does not receive any appropriations from the General Fund to carry out its regulatory tasks.

Additionally, the security of high level radiation sources is imperative. While there has not yet been a source lost or stolen in the United States, an example of the havoc that can ensue after one of these sources is lost can be demonstrated with an example from Brazil. In 1987 in Goiania, Brazil, a category 2 source (category 1 sources are 10 times the quantity of category 2) was abandoned.¹⁰ The source was subsequently stolen by untrained and unauthorized individuals. These individuals sold the metal shielding to a scrap yard, where the new owner opened the shielding and gave pieces of the source as gifts to friends and relatives, thinking it was valuable. Eventually the entire town became contaminated and people started dying from internal bleeding and other radiation effects. As a result, 4 people died (including a 6 year old girl), 249 people were internally contaminated, and areas of the town are still contaminated to this day. The promulgation of these regulations will add many levels of security, checks and balances so that once of these sources can never be abandoned and lost like the source in Brazil was and lead to the horrific tragedy.

ALTERNATIVES TO RULE ADOPTION

Two alternatives to the proposed rule adoption will be discussed:

1) Impact from Failure to Adopt New Rules that Comply with NRC Regulations:

In the unlikely event that NC would fail to maintain its Agreement State status, the NRC would then resume regulatory authority over radioactive materials use and licensee regulation in North Carolina. Reverting back to federal control would result in substantial radioactive materials license fee increases for North Carolina business entities that require radioactive materials licenses for use of radioactive materials. In most cases, the NRC radioactive materials license fees are at least double the current North Carolina fees, so failure to maintain the Agreement State status could result in fee increases of up to \$6.5 million annually (see Table 1 above).

Federal Government – Costs incurred by NRC taking over the NC radiation protection section duties would be reflected in the costs charged the licensees, \$6.5 million dollars annually.

State Government – If the radiation protection section is eliminated, the Department of Health and Human Services would lose all income from the licensee fees of approximately \$1.2 million annually. The radiation protection section is self-supporting from licensing fees and does not draw money from the general fund.

Local Government – Same impact since the same rules would be applied, i.e. about \$19,400 in the first year and \$3,500 per year thereafter.

Private Sector – increased fees from NRC of \$6.5 million dollars annually, as well as the costs estimated in this fiscal note of about \$2.3 million the first year and about \$695,000 thereafter, because the same rules would be applied.

2) Implement via license condition

The Radiation Protection Section has implemented these requirements by license condition. This is the less preferred option of the Radiation Protection Commission (RPC). The RPC has been granted the authority to promulgate rules in North Carolina and is made up of industry stakeholders. The RPC has elected to intimate

¹⁰ http://www-pub.iaea.org/mtcd/publications/pdf/pub815_web.pdf

rulemaking in order to avoid licensee confusion and transboundary issues for reciprocity licensees and licensee transporting through the state.

The cost of implementation is the same if the rules are promulgated or if they are issued via license condition but there is more opportunity for human error, such as the license condition not being issued or not being noticed. The turn-around time for licensing actions issued by the radiation protection section may go up as review for these specific conditions will be necessary.

Federal Government - No change in fiscal impact associated with the adoption of this regulation reference.

State Government – Regardless of whether the requirements are implemented by rule or license condition, the Division would incur the same costs, i.e. about \$97,000 in the first year and \$85,000 annually thereafter.

Local Government - Regardless of whether the requirements are implemented by rule or license condition, the Division would incur the same costs, i.e. about \$19,400 in the first year and \$3,500 per year thereafter.

Licensed Entities - fiscal note of about \$2.3 million the first year and about \$695,000 thereafter, because the same rules would be applied.

Impact Summary

The aggregate impact of the proposed rule adoption is reflected in the tables and discussion below:

Federal Government:

- No change in impact associated with the adoption of this regulation reference.

State Government:

- 1 FTE at \$84,500 average salary.
- Training = \$12,000
- Shipping Coordination: \$160
- Overall: \$96,660 first year and \$84,660 annually thereafter.

Local Government:

- First year and on-going costs are estimated to be approximately \$19,400 in the first year assuming a site visit to each licensee at least once, and \$3,500 annually thereafter.

Licensed Entities:

- The table below summarizes the impact on the licensees by federal regulation the NC rule proposed to adopt.

Table 3. Estimated Impact of Rule Change on Licensed Entities

Code of Federal Regulations Citation	First Year	On-Going Costs
10 CFR 37.23	\$ 69,000	
10 CFR 37.25	\$ 75,550	\$ 75,550
10 CFR 37.31	\$ 1,700	
10 CFR 37.33	\$ 10,250	\$ 10,250
10 CFR 37.43	\$ 574,750	\$ 402,250
10 CFR 37.45	\$ 6,050	\$ 6,050
10 CFR 37.47	\$ 170,000	\$ 80,000
10 CFR 37.49	\$ 1,350,000	\$ 56,000
10 CFR 37.51	\$ 27,600	\$ 27,600
10 CFR 37.53	\$ 14,700	
10 CFR 37.55	\$ 20,500	\$ 20,500
10 CFR 37.57	\$ 130	\$ 130
10 CFR 37.75	\$ 16,800	\$ 16,800
10 CFR 37.81	\$ 130	\$ 130
Total Estimated Impact on Licensees	\$ 2,337,160	\$ 695,260

APPENDIX 1: Proposed Rule Text

10A NCAC 15 .1701 is proposed for adoption as follows:

SECTION .1700 – PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

10A NCAC 15 .1701 ADDITIONAL REQUIREMENTS FOR LICENSEES POSSESSING CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

(a) Licensees possessing an aggregate category 1 or category 2 quantity of radioactive material, as defined in 10 CFR 37.5, shall comply with the requirements for the physical protection program listed in 10 CFR Part 37, including any subsequent amendments and editions, except as follows:

- (1) 10 CFR 37.1;
- (2) 10 CFR 37.3;
- (3) 10 CFR 37.7;
- (4) 10 CFR 37.9;
- (5) 10 CFR 37.11(a) and (b);
- (6) 10 CFR 37.13;
- (7) 10 CFR 37.71;
- (8) 10 CFR 37.77(f);
- (9) 10 CFR 37.105;
- (10) 10 CFR 37.107; and
- (11) 10 CFR 37.109.

(b) In lieu of the address given in 10 CFR 37.27(c), licensees shall submit fingerprint cards or records to Director, Division of Facilities and Security, U.S. NRC, 11545 Rockville Pike, Rockville, Maryland 20852-2738, ATTN: Criminal History Program, Mail Stop T-03B46M.

(c) Licensee required reports of events or notifications in 10 CFR 37.41, 37.45, 37.57, 37.77(a) through (d), 37.81, shall use the Agency contact information in Rule .0111 of this Chapter.

(d) A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the U.S. Nuclear Regulatory Commission (NRC) or to an Agreement State of the NRC shall meet the license verification provisions listed in Rule .0343 of this Chapter.

(e) The Code of Federal Regulations parts 1-50 may be obtained from the U.S. Government Publishing Office, P.O. Box 979050 St. Louis, MO 63197-9000 for sixty-four dollars (\$64.00), and are available free of charge at <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>.

History Note: Authority G.S. 104E-7;

*Eff. **June** 1, 2016.*

APPENDIX 2: Certification of Federal Requirement



**North Carolina Department of Health and Human Services
Division of Health Service Regulation**

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Drexdal Pratt
Division of Health Service Regulation

MEMORANDUM

TO: Office of State Budget & Management
FROM: Nadine Pfeiffer, DHSR Rule-making Coordinator
DATE: November 2, 2015
RE: Federal Certification for Radiation Protection Rule Amendments

Rule-making Coordinator's Certificate

As Required by GS 150B-19.1(g)
For Proposed Permanent and Temporary Rules Adopted to
Implement a Federal Law or which upon Receipt of Federal Funds is Conditioned

Regulation by the State of North Carolina of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended" under provisions of Public Law 86-373, as amended, and 10 CFR Part 150. The "United States Atomic Energy Commission" is now called the "United States Nuclear Regulatory Commission (USNRC).

Rule 10A NCAC 15 .1701 is proposed for adoption to be compatible with federal regulations 10 CFR 37 in its entirety except as follows (i.e. the following are omitted from the adoption): 10 CFR 37.1; 10 CFR 37.3; 10 CFR 37.7; 10 CFR 37.9; 10 CFR 37.11(a) and (b); 10 CFR 37.13; 10 CFR 37.71; 10 CFR 37.77(f); 10 CFR 37.105; 10 CFR 13.107; and 10 CFR 37.109 in compliance with North Carolina's agreement with the U.S. Nuclear Regulatory Commission. This rule applies to the required security practices of radioactive materials licensees in North Carolina that use radioactive materials of category 1 or category 2 level activity, as defined in 10 CFR 37.5. These are high activity sources that can cause harm if accessed by unauthorized individuals or lost.

The adoption of the above-named rule is necessary to comply with the Agreement and federal regulations, as the state is inspected regularly by the USNRC to ensure the compatibility of its regulations.



Office of the Director

<http://www.ncdhhs.gov/dhsr/>

Phone: 919-855-3750 / Fax: 919-733-2757

Location: 809 Ruggles Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603

Mailing Address: 2701 Mail Service Center • Raleigh, North Carolina 27699-2701

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APPENDIX 3: 10CFR37 Working Group Member Affiliations

Last Name	Title	Company
Larry Haynes, CHP	WORKING GROUP CHAIR RAM Control Advisory Committee Emergency Response Advisory Committee Chair NC RP Commission	Duke Energy
Jerry Hightower, DABMP	RAM Control Advisory Committee NC RP Commission	Vidant Medical Center
Allen Mabry, CHP	LLRW Management Advisory Committee Chair NC RP Commission	GE
Carmine Plott, PhD, CHP	RAM Control Advisory Committee Chair NC RP Commission Chair	Novant Health Forsyth Medical Center
Wayne Thomann, DrPH	Non-Ionizing Advisory Committee NC RP Commission Vice Chair	Duke University Medical Center
Diana Thompson	Section Liaison	NC Radiation Protection Section
Mark Brueckner	Associate RSO	UNC Chapel Hill
William (Bill) Byrum, CHP	RSO	Duke Energy EnRad Laboratories
Brian Cripe, CHP	RSO	Novant Health Presbyterian Medical Center
David Howell	RSO	Wake Forest Baptist Health
Grant Mills	Health Physicist	NC Radiation Protection Section
Chris Puckett	RSO	Carolinas Medical Center North East
David Rushing	Medical Physicist	Vidant Medical Center
Frieda Sehat	Assistant RSO	Carolinas Medical Center
Michael (Mike) Thouin	RSO and Supervisor Nuclear Quality Inspection-Radiography	Duke Energy