State of Board of Health
Agenda
September 7, 2017 – 9:00 a.m.
Perimeter Center – Boardroom 2

Call to Order and Welcome	Faye Prichard, Chair
Pledge of Allegiance	Benita Miller, DDS
Introductions	Ms. Prichard
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of June 1, 2017 Minutes	Ms. Prichard
Commissioner's Report	Marissa Levine, MD, MPH, FAAFP State Health Commissioner
Regulatory Action Update	Mr. Hilbert
Break	
Public Comment Period	

Board Action Item

Board of Health Annual Report – Virginia's Plan for Well-Being	Mr. Hilbert Leslie Hoglund, PhD, Director, Division of Population Health Data

Regulatory Action Items

Radiation Protection Regulations: Fee Schedule 12VAC5-490 (Final amendments – private inspector fees)	Steve Harrison, Director Office of Radiological Health
Radiation Protection Regulations: Fee Schedule 12VAC5-490 (Proposed amendments – fees for X-ray program and radioactive materials program)	Mr. Harrison
Working Lunch Overview of the Lenowisco Health District	Dr. Sue Cantrell, District Director

Regulatory Action Item

Regulations for Disease Reporting and Control 12VAC5-90 (Fast Track Amendments)	Laurie Forlano, DO, Director Office of Epidemiology
2018 Board Meeting Schedule	Ms. Prichard
Member Reports	
Other Business	
Adjourn	

COMMONWEALTH of VIRGINIA

Department of Health

Marissa J. Levine, MD, MPH, FAAFP
State Health Commissioner

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RICHMOND, VA 23218

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August 22, 2017

MEMORANDUM

TO: State Board of Health Members

FROM: Joseph Hilbert
Director of Governmental and Regulatory Affairs

SUBJECT: Virginia Plan for Well Being/Board of Health Annual Report

Attached for your review please find a draft copy of "Virginia's Plan for Well Being – Annual Report 2017." The draft report provides a status update concerning the 28 metrics across the Plan's four aims:

- Healthy, Connected Communities
- Strong Start for Children
- Preventive Actions, and
- System of Health Care

Please note the enclosed draft is missing updated 2017 data for three of the metrics. That updated information will be provided to you at the September 7th Board meeting. VDH will recommend that the Board approve the annual report for submission to the Governor and General Assembly, in compliance with the Board's annual reporting requirement pursuant to § 32.1-14 of the Code of Virginia.

Virginia's Plan for Well-Being

2016-2020

Annual Report, 2017

Virginia Department of Health
109 Governor Street
Richmond, VA 23219
www.vdh.virginia.gov

Background

This document serves as an annual report to *Virginia's Plan for Well-Being*, the Commonwealth of Virginia's state health improvement plan for 2016-2020. The plan has four aims:

1. Healthy, Connected Communities
2. Strong Start for Children
3. Preventive Actions
4. System of Health Care

Within this framework, the plan lays out 13 goals and 29 measures of success. This document describes the first year measures and status of indicators for review.

Vision: Well-Being for All Virginians

Well-Being

Measure Percent of adults in Virginia who report positive well-being; Baseline: N/A.

2017 Update ____% (2016*) – to be provided by Elizabeth Ferree by BOH meeting

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The four-item Satisfaction with Life Scale (SWLS) asks respondents to indicate how much they agree with the four following statements on a scale from 1 (strongly agree) to 5 (strongly disagree): (1) "In most ways my life is close to ideal," (2) "The conditions of my life are excellent," (3) "I am satisfied with my life," and (4) "So far I have gotten the important things I want in life." Responses to the four SWLS questions are dichotomized into those indicating positive well-being (e.g., agree/strongly agree) and those indicating negative well-being (e.g., disagree/ strongly disagree). For overall SWLS, adults responding agree or strongly agree to all four questions (score = 4), are considered positive. Data collection for the SWLS scale began in 2016 as part of Virginia's Behavioral Risk Factor Surveillance System.

The Behavioral Risk Factor Surveillance System is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. Responses of don't know/not sure, refused, or missing are removed from the numerator and denominator in all estimates.

* *Data collection for this measure began in January 2016. The percentage above serves as the baseline.*

AIM 1 — Healthy, Connected Communities

Goal 1.1 Virginia's Families Maintain Economic Stability

1.1 A High School Graduates Enrolled in Higher Education

Measure Percent of Virginia high school graduates enrolled in an institute of higher education within 16 months after graduation; Baseline: 70.9% (2013).

2017 Update 72.0% (2014)

2020 Goal 75%

Data Source Virginia Postsecondary Enrollment Reports. Virginia Department of Education.

Description The percent of Virginia high school graduates who:

1. Graduated within five years of entering high school,
2. Earned a standard or advanced studies diploma, and
3. Were enrolled in an institute of higher education within 16 months of graduation.

This measure follows a cohort of students who entered ninth grade in the same year.

1.1 B Cost-Burdened Households

Measure **P**ercent of cost-burdened households in Virginia (more than 30% of monthly income spent on housing costs); Baseline: 31.4% (2013).

2017 Update 31.6% (2014)

2020 Goal 29.0%

Data Source American Community Survey. U.S. Census Bureau.

Description This measure is calculated by dividing the number of Virginians that spent more than 30% of their monthly income on rent, mortgage, or housing without a mortgage* by the number of occupied housing units in Virginia. The numerator* is housing cost as a proportion of total income in a given year. The data are from the American Community Survey 1-Year Estimates. This is a point-in-time annual survey.

1.1 C Consumer Opportunity Index Score

Measure Consumer Opportunity Index score in Virginia; Baseline: 81.8 (2009-2013).

2017 Update 86.1* (2011-2015)

2020 Goal 83.7

Data Source The Virginia Department of Health created the Consumer Opportunity Index utilizing the following data sources: Affordability, Education, Townsend Profile from the U.S. Census American Consumer Survey and 5-Year Food Accessibility Index from the U.S. Department of Agriculture.

Description The Consumer Opportunity Index is an indicator of consumer access to resources that support long and healthy lives, with 100% representing perfect access and 0% representing no access. The metric is a multivariate index comprised of four indicators:

1. Affordability (housing and transportation cost as a percent of income),
2. Education (average years of schooling),
3. Food Accessibility (percent of population that is both low income and has low access to food), and
4. Townsend Material Deprivation Profile (unemployment, home ownership, overcrowded homes and homes without an automobile).

The Consumer Opportunity Index is one of four multivariate profiles that make up the Health Opportunity Index (HOI). The Virginia Department of Health convened stakeholders to identify 13 indicators to include in the HOI. From these indicators, four separate profiles were created using principal component analysis. Data for the indicators are taken from different sources using different methodologies, and are updated on differing schedules. Indicators in each

profile are combined using the geometric mean. Each indicator is given equal weight in the profile. The Consumer Opportunity Index indicators are established at the census-tract level. County-level profiles are determined for each indicator using a population-weighted average of each tract in the county. The state score represents the median county score.

** The HOI is a new measure and it is unclear how it will fluctuate with conditions over time. For that reason, our choice of a goal was somewhat arbitrary. The HOI is based in large part on ACS 5-year estimates for the ranges listed above. The new ACS data dropped 2009-2010, two years at the worst of the Great Recession, and added 2014-2015, two years at the end of a long period of economic growth. Our ability to sustain upward trends, or minimize reductions, over economic downturns will be key for these measures.*

1.1 D Economic Opportunity Index Score

Measure Economic Opportunity Index score in Virginia; Baseline: 70.7 (2009-2013).

2017 Update 75.0* (2011-2015)

2020 Goal 73.7

Data Source The Virginia Department of Health created the Economic Opportunity Index utilizing the following data sources**:** U.S. Census, American Economic Survey, and 5-Year Estimates.

Description The Economic Opportunity Index is an indicator of access to the economic resources that support long and healthy lives, with 100% representing perfect access and 0% representing no access. The metric is a multivariate profile comprised of three indicators:

1. Employment (jobs per worker weighted by distance to job),
2. Income Inequality (Gini Coefficient), and
3. Job Participation (percent of working age population in the labor force).

The Economic Opportunity Index is one of four multivariate profiles that make up the Health Opportunity Index (HOI). The Virginia Department of Health convened stakeholders to identify 13 indicators to include in the HOI. From these indicators, four separate profiles were created using principal component analysis. Indicators in each profile are combined using the geometric mean. Data for the indicators are taken from different sources using different methodologies, and are updated on differing schedules. Each indicator is given equal weight in the profile. The Economic Opportunity Index indicators are established at the census-tract level. County-level profiles are determined for each indicator using a population-weighted average of each tract in the county. The state score represents the median county score.

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Goal 1.2 **Virginia's Communities Collaborate to Improve the Population's Health**

1.2 Districts with Collaborative Community Health Improvement Processes

Measure Percent of Virginia health planning districts that have established an on-going collaborative community health improvement process; Baseline: 43.0% (2015).

2017 Update 82.8% (2016)

2020 Goal 100%

Data Source Virginia Department of Health.

Description The measure is calculated by dividing the number of health districts in Virginia that report that a collaborative community health improvement process is established in their health planning district divided by 35 (total number of health planning districts).

AIM 2 — Strong Start for Children

Goal 2.1 Virginians Plan Their Pregnancies

2.1 Teen Pregnancy Rate

Measure Teen pregnancy rate per 1,000 females, ages 15 to 19 years, in Virginia; Baseline: 27.9 (2013).

2017 Update 24.9 (2014)

2020 Goal 25.1*

Data Source Virginia Vital Records and Health Statistics Electronic Birth Certificates, Fetal Death Certificates, Induced Termination of Pregnancy Certificates. Virginia Department of Health.

Description This metric is created using live birth data from the electronic birth certificate as reported by birth facilities, Induced Termination of Pregnancy (ITOP) data as reported by ITOP facilities, fetal death data as reported by medical providers and the number of female teens (15-19 years of age) from the National Center for Health Statistics population estimates.

* *The 2020 goal metric has been met.*

Goal 2.2 Virginia's Children Are Prepared to Succeed in Kindergarten

2.2 A Kindergartens Not Meeting Phonological Awareness Literacy (PALS-K) Benchmark

Measure Percent of children in Virginia who do not meet the PALS-K benchmarks in the fall of kindergarten and require literacy intervention; Baseline: 12.7% (2014-2015).

2017 Update 13.8%* (2015-2016)

2020 Goal 12.2%

Data Source Phonological Awareness Literacy Screening – Kindergarten Results. Virginia Department of Education.

Description The Phonological Awareness Literacy Screening – Kindergarten (PALS-K) is conducted in the fall of each school year and identifies kindergarten students who are at risk for reading difficulties. The tool measures children's knowledge of several literacy fundamentals: phonological awareness, alphabet recognition, concept of word, knowledge of letter sounds, and spelling. The PALS-K is an assessment of literacy readiness and is not a comprehensive measure of school readiness. PALS-K is the state-provided screening tool for Virginia's Early Intervention Reading Initiative (EIRI) and is used by 99% of school divisions in the state on a voluntary basis.

** The PALS-K test was revised between 2014-2015 to 2015-2016, so the increase was due to test differences from needing to know four syllables to five per the Virginia Department of Education.*

2.2 B Third Graders Passing Reading Standards of Learning (SOL) Assessment

Measure Percent of third graders in Virginia who pass the Standards of Learning third grade reading assessment; Baseline: 69.0% (2014-2015).

2017 Update 75.4% (2015-2016)

2020 Goal 80.%

Data Source Virginia Standards of Learning Results. Virginia Department of Education.

Description The Standards of Learning (SOL) for Virginia Public Schools establish minimum expectations for what students should know and be able to do at the end of each grade. All items on SOL tests are reviewed by Virginia classroom teachers for accuracy and fairness, and teachers also assist the state Board of Education in setting proficiency standards for the tests.

Goal 2.3 The Racial Disparity in Virginia's Infant Mortality Rate is Eliminated

2.3 Infant Mortality Rate by Race

Measure **I**nfant mortality rate in Virginia per 1,000 live births by race; Baseline: 12.2 (2013).

2017 Update 11.2 (2014)

2020 Goal 5.2

Data Source Virginia Vital Records and Health Statistics Electronic Birth Certificates and Electronic Death Certificates. Virginia Department of Health.

Description Virginia's infant mortality rate is calculated by dividing the number of deaths of children under one year of age by the number of live births to mothers living in the state. The resulting number is multiplied by 1,000 to compute the rate.

AIM 3 — Preventive Actions

Goal 3.1 Virginians Follow a Healthy Diet and Live Actively

3.1 A Adults Not Participating in Physical Activity

Measure Percent of Virginia adults 18 years and older who do not participate in any physical activity during the past 30 days; Baseline: 23.5% (2014)

2017 Update 25.1% (2015)

2020 Goal 20.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The percent of Virginia adults 18 years and older who reported that they did not participate in any physical activity other than their regular job during the past 30 days. The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control

and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

3.1 B Adults Who Are Overweight or Obese

Measure Percent of Virginia adults 18 years and older who are overweight or obese; Baseline: 64.7% (2014)

2017 Update 64.1% (2015)

2020 Goal 63.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The percent of Virginia adults 18 years and older who reported a body mass index (BMI) greater than 25. The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey asks respondents what their height and weight are. BMI is then calculated based on reported height and weight. The survey is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

3.1 C Households That Are Food Insecure

Measure Percent of Virginia households that are food insecure for some part of the year. Baseline: 11.9% (2013)

2017 Update 11.8% (2014)

2020 Goal 10.0%

Data Source *Map the Meal Gap* utilized the Current Population Survey, and American Community Survey from the U.S. Census Bureau.

Description Feeding America's *Map the Meal Gap* analyzes the relationship between food insecurity and indicators of food insecurity, and child food insecurity (poverty, unemployment, median income, etc.) at the state level.

Goal 3.2 Virginia Prevents Nicotine Dependency

3.2 Adults Using Tobacco

Measure Percent of Virginia adults aged 18 years and older who report using tobacco. Baseline: 21.9% (2014)

2017 Update 19.4% (2015)

2020 Goal 12.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The percent of Virginia adults 18 years and older who report that they have smoked at least 100 cigarettes in their lifetime and currently smoke tobacco on at least some days, use chewing tobacco, use snuff and/or use snus. The Behavioral Risk Factor Surveillance System (BRFSS) is an

ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

Goal 3.3 Virginians Are Protected Against Vaccine-Preventable Diseases

3.3 A Adults Vaccinated Against Influenza

Measure Percent of Virginia adults 18 years and older who received an annual influenza vaccine. Baseline: 48.2% (2014-2015)

2017 Update 46.0% (2015-2016)

2020 Goal 70%

Data Source Behavioral Risk Factor Surveillance System, and the National Immunization Survey. Centers for Disease Control and Prevention.

Description The percent of Virginians 18 years of age and older who received an annual influenza vaccine. The Centers for Disease Control and Prevention analyzed the National Immunization Survey-Flu and the Behavioral Risk Factor Surveillance System to estimate national and state level flu vaccination coverage. Influenza vaccination status is based on self-report and not validated with medical records.

3.3 B Adolescents Vaccinated Against HPV

Measure Percent of girls aged 13-17 in Virginia who receives three doses of HPV vaccine and percent of boys aged 13-17 in Virginia who receive three doses of HPV vaccine. Girls Baseline: 35.9% (2014), Boys Baseline: 22.5% (2014)

2017 Update Girls: 38.5% (2015), Boys: 25.7% (2015)

2020 Goal Girls and Boys: 80.0%

Data Source National Immunization Survey-Teen. Centers for Disease Control and Prevention.

Description The percent of Virginia adolescents aged 13-17 (girls and boys reported separately) who received three doses of human papillomavirus (HPV) vaccine. The National Immunization Survey-Teen (NIS-Teen) is an ongoing, annual survey of children, whose parents/guardians are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention and conducted in all 50 states. Doses of vaccines administered are verified by providers through a mailed survey to the girls' immunization providers.

Goal 3.4 Cancers Are Prevented or Diagnosed at the Earliest Stage Possible

3.4 Adults Screened for Colorectal Cancer

Measure Percent of Virginia adults aged 50 to 75 years who receive colorectal cancer screening. Baseline: 69.1% (2014)

2017 Update 70.3%* (2016)

2020 Goal 85.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description	The percent of Virginia adults, ages 50 to 75 years, who report receiving a colorectal cancer screening test based on the most recent guidelines (fecal occult blood test, proctoscopy, colonoscopy, or sigmoidoscopy). The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

***** *Colorectal screening was not collected in 2015, but it was added to the state questions for odd years going forward.*

Goal 3.5 Virginians Have Life-Long Wellness

3.5 A Disability-Free Life Expectancy

Measure	Average years of disability-free life expectancy for Virginians; Baseline: 66.1 (2013)
2017 Update	66.0 (2014)
2020 Goal	67.3
Data Source	U.S. Census Intercensal Population File Vintage 2014, Virginia Vital Records and Health Statistics Electronic Death Certificates, and the American Community Survey. Virginia Department of Health.
Description	Disability-free life expectancy (DFLE) was calculated for Virginia census tracts by adding the estimates of the proportion of individuals with disabilities by tract and age group to the abridged life table estimates of mortality and population used for creating life expectancy (LE) estimates. The life table with the proportion of disabled individuals was the input for the analysis using the Chiang II methodology with Silcock's adjustment for calculation of LE and Sullivan's methods for DFLE. The disabled population proportion was defined for this study as answering yes to any one of the six disability questions (2009-2013 aggregate) in the American Community Survey. Significant consideration was given to disability chosen, small area analysis problems, and how to share the analysis for best impact. At the tract level, data censorship was considered when unusual population distributions were encountered. Minimum population size requirements were met to reduce large standard errors. DFLE estimates were added to a multiple linear regression model with social determinants of health as the explanatory variables.

3.5 B Adults with Adverse Childhood Experiences

Measure	Percent of adults in Virginia who report adverse childhood experiences; Baseline: N/A.
2017 Update	____% (2016*) – to be provided by Elizabeth Ferree by BOH meeting
Data Source	Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.
Description	Adverse childhood experiences (ACEs) include verbal, physical, or sexual abuse, as well as family dysfunction (e.g., an incarcerated, mentally ill, or substance-abusing family member; domestic violence; or absence of a parent because of divorce or separation). The ACE score is a measure of cumulative exposure to particular adverse childhood conditions. Exposure to any single ACE condition is counted as one point. If an adult experienced none of the conditions in childhood,

the ACE score is zero. Points are totaled for a final ACE score. The Behavioral Risk Factor Surveillance System is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

* *Data collection for this measure began in January 2016. The percentage above serves as the baseline.*

AIM 4 — System of Health Care

Goal 4.1 Virginia Has a Strong Primary Care System Linked to Behavioral Health Care, Oral Health Care, and Community Support Systems

4.1 A Adults with a Regular Health Care Provider

Measure Percent of adults 18 years and older who have a regular health care provider; Baseline: 69.3% (2014)

2017 Update 71.1% (2015)

2020 Goal 85.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The percent of Virginia adults who report that they have at least one personal healthcare provider for ongoing care. The Behavioral Risk Factor Surveillance System is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

4.1 B Avoidable Hospital Stays

Measure Rate of avoidable hospital stays for ambulatory care sensitive conditions in Virginia per 100,000 persons; Baseline: 1,294 (2013)

2017 Update ____ (2014) – to be provided by VHI, pending response from Kyle Russell

2020 Goal 1,100

Data Source Virginia Inpatient Hospitalization. Virginia Health Information.

Description The measure is the Agency for Healthcare Research and Quality's Prevention Quality Overall Composite (PQI #90) in Virginia. It includes hospitalizations that could have been prevented through high quality outpatient care, including uncontrolled diabetes, short-term diabetes complications, long-term diabetes complications (including amputated limbs), chronic obstructive pulmonary disease, high blood pressure, heart failure, chest pain, adult asthma, dehydration, pneumonia, and urinary tract infections. The number of hospital stays is provided for every 100,000 people who reside in that area.

4.1 C Avoidable Cardiovascular Disease Deaths

Measure Rate of avoidable deaths from heart disease, stroke, or hypertensive disease in Virginia per 100,000 persons; Baseline: 49.9 (2013)

2017 Update 49.1 (2014)

2020 Goal 40.0

Data Source Virginia Vital Records and Health Statistics Electronic Death Certificates. Virginia Department of Health.

Description Deaths included were those caused by cardiovascular disease, including chronic rheumatic heart disease (ICD 10 codes I05-I09), hypertension (ICD codes I10, I12, I15), ischemic heart disease (ICD 10 codes I20-I25), and cerebrovascular disease (ICD 10 codes I60-I69). An age-adjusted formula for population was used, truncating the years over 75, and then reformatting to the new million population for those age ranges.

4.1 D Adult Mental Health and Substance Abuse Hospitalizations

Measure Rate of adult mental health and substance abuse hospitalizations in Virginia per 100,000 adults; Baseline: 668.50 (2013).

2017 Update 687.0 (2014)

2020 Goal 635.1

Data Source Virginia Inpatient Hospitalization. Virginia Health Information.

Description Diagnosis codes to include for mental health and substance abuse hospitalizations were selected based on criteria developed by the Healthcare Cost and Utilization Project. The case definition used excluded discharges related to maternity stays and individuals under the age of 18. Population denominators were derived from midyear Census estimates provided by the National Center for Health Statistics.

4.1 E Adults Whose Poor Health Kept Them from Usual Activities

Measure Percent of adults 18 years and older in Virginia who reported having one or more days of poor health that kept them from doing their usual activities; Baseline: 19.5% (2014).

2017 Update 19.0% (2015)

2020 Goal 18.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description Percent of Virginia adults who reported having one or more days of poor health (physical health or mental health) and reported that poor health kept them from doing usual activities. The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, annual survey of adults, who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

Goal 4.2 Virginia's Health IT System Connects People, Services and Information to Support Optimal Health Outcomes

4.2 A Providers with Electronic Health Records

Measure Percent of health care providers in Virginia who have implemented a certified electronic health record; Baseline: 70.6% (2014)

2017 Update 73.4% (2015)

2020 Goal 90.0%

Data Source National Electronic Health Records Survey. Centers for Disease Control and Prevention.

Description Data are from the 2015 National Electronic Health Records Survey (NEHRS). NEHRS, which is conducted by the National Center for Health Statistics and sponsored by the Office of the National Coordinator for Health Information Technology, is a nationally representative mixed mode survey of office-based physicians that collects information on physician and practice characteristics, including the adoption and use of EHR systems. NEHRS sampling design allows for both national and state-based estimates of EHR adoption. NEHRS is conducted annually as a sample survey of nonfederal office-based patient care physicians, excluding anesthesiologists, radiologists, and pathologists. The 2015 NEHRS sample consisted of 10,302 office-based physicians. Non-respondents to the mail survey received follow-up telephone calls. The 2015 NEHRS data collection took place from August through December 2015, and used a sequential mixed mode design to collect data through web, mail, and phone. Using a physician database, email addresses of sampled physicians were identified. Sampled physicians that did not have an email match were asked to complete the survey by mail or phone. Among those with email addresses, respondents were randomly assigned to one of four groups: an invitation to take the web survey through email, US mail, both, or no web survey option. Nonresponse to the web survey resulted in 3 mailings of the questionnaire followed by phone contacts.

4.2 B Entities Connected to Health Information Exchange

Measure Number of entities in Virginia connected through Connect Virginia HIE Inc., the electronic health information exchange, and the national e-Health Exchange; Baseline: 3,800 (2015).

2017 Update 4,832 (2016)

2020 Goal 7,600

Data Source Connect Virginia HIE, Inc.

Description Connect Virginia HIE, Inc. is the statewide health information exchange (HIE) for the Commonwealth of Virginia. The HIE uses secure, electronic, internet-based technology to allow medical information to be exchanged by participating entities. Connect Virginia reports the number of entities in Virginia connected on a quarterly basis.

4.2 C Health Districts with Electronic Health Records

Measure Number of Virginia's local public health districts that have electronic health records and connect to Connect Virginia, Virginia's Health Information Exchange; Baseline: 0 (2015).

2017 Update 0 (2016)

2020 Update 35

Data Source Virginia Department of Health.

Description Count of Virginia's local public health districts (total of 35) that have electronic health records and connect to Connect Virginia, Virginia's Health Information Exchange.

Goal 4.3 Health Care-Associated Infections Are Prevented and Controlled in Virginia

4.3 Hospitals Meeting State Goal for Prevention of *C. difficile* Infections

Measure Percent of hospitals in Virginia meeting the state goal for prevention of hospital-onset *Clostridium difficile* infections; Baseline: 38.5% (2013).

2017 Update 38.3% (2014)

2020 Goal 100.0%

Data Source National Healthcare Safety Network. Centers for Disease Control and Prevention.

Description The percent of Virginia hospitals that meet the state goal for prevention of hospital-onset *C. difficile* laboratory-identified events. The state goal is a standardized infection ratio ≤ 0.7, which aligns with the goal of the Department of Health and Human Services National Healthcare-Associated Infections Action Plan.

The standardized infection ratio (SIR) is calculated by dividing the number of observed events by the number of predicted events (based on national data from a historical baseline time period). An SIR of 0.7 means that 30% fewer events were observed than were predicted. This measure is risk-adjusted and takes into account the type of laboratory testing, facility bed size, facility affiliation with a medical school, and the number of patients admitted to the hospital that already have *C. difficile* ("community-onset" cases).

COMMONWEALTH of VIRGINIA

Department of Health

MARISSA J. LEVINE, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

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MEMORANDUM

DATE: July 17, 2017

TO: Virginia State Board of Health

FROM: Steven A. Harrison, MA, MEP
Director, Office of Radiological Health

SUBJECT: Virginia Radiation Protection Regulations: Fee Schedule (12VAC5-490)
(Fees for registration of individuals)

Enclosed for your review are the final amendments for the Virginia Radiation Protection Regulation: Fee Schedule (12VAC5-490). The final amendments will establish fees for the registration of individuals that inspect X-ray devices in the Commonwealth. Proposed amendments were published in the Virginia Register on May 15, 2017 (Vol. 33, Issue 19), which was followed by a 60-day public comment period that ended on July 14, 2017. No comments were received during the public comment period. No substantive changes were made to the proposed amendments that were presented to the Board on November 1, 2016, but two minor changes were subsequently incorporated at the recommendation of the Office of Attorney General. Subsections A and A.1 were combined into one sentence; and, the phrase "Pursuant to subsection A of this section" was added to Subsection B.3 to add clarity.

The purpose of the X-ray program is to protect the public from unnecessary radiation due to faulty X-ray equipment or substandard practices. The regulations require the registration of individuals that inspect X-ray producing devices in the Commonwealth. The regulations, though, do not require fees for their initial registration or annual renewal.

The regulations currently require the registration of individuals that inspect X-ray producing devices in the Commonwealth. The regulations, though, do not establish fees for their initial registration or annual renewal. Registration fees for X-ray device Private Inspectors are charged in other states to help offset administrative costs associated with document collection, review, approval, the issuance of certificates and the maintenance of an up-to-date Private Inspector directory. A fee of $150 per year is proposed, which will help offset administrative costs that were once supported using general funds allocated to ORH but which have since been abolished.

The Board of Health is requested to approve the final amendments. Should the Board of Health approve the final amendments, they will be submitted to the Office of the Attorney General to begin the executive branch review process, as specified by the Administrative Process Act. Following executive branch review and approval, the final amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website, and a 30 day final adoption period will begin.

townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-490-50
Regulation title(s)	Virginia Radiation Protection Regulations: Fee Schedule
Action title	Establish X-ray Device Private Inspector Fees.
Date this document prepared	07/27/2017

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Virginia Department of Health's Office of Radiological Health (ORH) proposes to amend the Virginia Radiation Protection Regulations Fee Schedule (12VAC5-490) in order to establish fees for the initial registration and subsequent annual renewal of individuals that inspect X-ray devices in the Commonwealth.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

ORH - Office of Radiological Health
VDH – Virginia Department of Health

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken;2) the name of the agency taking the action; and 3) the title of the regulation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

These regulations are authorized by the Code of Virginia § 32.1-229.1, Inspections of X-ray machines required; Radiation Inspection Reports; fees; qualification of inspectors (effective July 1, 2016).

Section 32.1-229.1 authorizes the Board of Health to set annual registration fees for X-ray device Private Inspectors, not to exceed $150.00 for such registration. Upon approval of the application, the Private Inspector will be included on the Commonwealth's list of qualified X-ray machine inspector published pursuant to § 32.1-228.1.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The Virginia Department of Health (VDH), ORH proposes to amend 12VAC5-490, Radiation Protection Fee Schedule, by establishing a new section 12VAC5-490-50, Private Inspector fees. Radiological Control Program regulations, which already require the registration of individuals that inspect X-ray producing devices in the Commonwealth, do not establish fees for their initial registration or annual renewal. Revenue recovery, as is the practice in other states using X-ray device Private Inspectors, will help offset administrative costs associated with document collection, review, approval, the issuance of certificates and the maintenance of an up-to-date Private Inspector directory. This regulatory amendment is essential to protect health and safety by ensuring the safe operation of X-ray equipment through

inspections by qualified X-ray device Private Inspectors who will be registered and certified by the Office of Radiological Health's X-ray Program. Fees are necessary to accommodate registration and certification in order to offset administrative costs that were once supported using General Funds.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

The Virginia Department of Health's Office of Radiological Health (ORH) proposes to amend the Virginia Radiation Protection Regulations Fee Schedule (12VAC5-490) in order to establish fees for the registration of individuals that inspect X-ray devices in the Commonwealth. Radiological Control Program regulations currently require the registration of individuals that inspect X-ray producing devices in the Commonwealth. The regulations, though, do not establish fees for their initial registration or annual renewal. Registration fees for X-ray device Private Inspectors are charged in other states to help offset administrative costs associated with document collection, review, approval, the issuance of certificates and the maintenance of an up-to-date Private Inspector directory. These fees will help offset such administrative costs that were once supported using General Funds allocated to ORH but which have since been abolished.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

1. Primary advantages and disadvantages to the public:
   The primary advantage to the public is to ensure the safe operation of X-ray equipment through inspections by qualified X-ray device Private Inspectors who will be registered and certified through the establishment of fees that will help offset administrative costs that were once supported using General Funds but which have since been abolished. Registering and certifying Private Inspectors of X-ray machines allows ORH to maintain an accurate database of trained, certified inspectors that are available to ensure the machines are functioning properly so as to minimize the risk of equipment malfunction and accidental overexposures.

   There are no disadvantages to the public in promulgating the proposed fee schedule.

2. Primary advantages and disadvantages to the agency and Commonwealth:
   Approving the proposed fee structure will allow the Commonwealth to recover more of the costs associated with carrying out the legislative mandate.

   There are no disadvantages to the agency and Commonwealth in promulgating the proposed fee schedule.

3. Other pertinent matters of interest to the regulated community:

Private inspectors of X-ray machines have an interest in ensuring that inspection fees by agency inspectors do not hurt their business by undercutting the private sector pricing, and Virginia Code § 32.1-229.2 requires the agency to establish inspection fees in such a manner so as to minimize competition with the private inspector while recovering costs.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements or no requirements that exceed applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities that would be disproportionately affected by this action.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed changes would not have a direct impact on the institution of the family and family stability.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

No changes were made to the proposed amendments as published in the Virginia Register dated May 15, 2017 (Vol. 33, Issue 19).

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

No comments were received during the public comment period (5/15/17 – 7/14/17) following the publication of the proposed stage.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Radiological Control Program regulations currently require the registration of individuals that inspect X-ray producing devices in the Commonwealth. The regulations, though, do not establish fees for their initial registration or annual renewal. Registration fees for X-ray device Private Inspectors are charged in other states to help offset administrative costs associated with document collection, review, approval; the issuance of certificates; and the maintenance of an up-to-date Private Inspector directory. A fee of $150 per year is proposed, which will help offset administrative costs that were once supported using General Funds allocated to ORH but which have since been abolished. The proposed new regulation follows:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
None.	12VAC5-490-50	None.	12VAC5-490-50. Private Inspector registration fees. A. Individuals included on the Commonwealth's list of qualified inspectors of x-ray machines pursuant to § 32.1-229.1 D 5 of the Code of Virginia as of November 1, 2016, shall pay annually a registration renewal fee of $150 to the Virginia Department of Health X-ray Program to remain on the list as a qualified inspector of x-ray machines pursuant to 12VAC5-481-340. B. Individuals requesting to be placed on the Commonwealth's list of qualified inspectors of x-ray machines pursuant to § 32.1-229.1 D 5 of the Code of Virginia shall: 1. Request approval by the Office of Radiological Health to become a qualified inspector of x-ray machines pursuant to 12VAC5-481-340; 2. Pay an initial registration fee of $150 to the Virginia Department of Health X-ray Program, once approved; and 3. Pursuant to subsection A of this section, pay annually a registration renewal fee of

			$150 to remain on the list as a qualified inspector of x-ray machines pursuant to 12VAC5-481-340. **Intent/Rationale/Impact**: This new regulation would establish annual registration and application change fees for individuals certified to inspect x-ray producing devices in the Commonwealth. Private X-ray device inspectors are already required to register with ORH, but ORH has not, in the past, been authorized to collect a fee to recover administrative costs. Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in 2009, and the use of general funds to support the X-ray program was eliminated in SFY16. Instituting these fees will help to sustain the X-ray program. The impact to Private Inspectors operating in the Commonwealth will be the registration and/or any applicable inspection category change fees, and any costs associated with preparing and submitting that fee to ORH.

Project 4856 - Proposed

DEPARTMENT OF HEALTH
Establish X Ray Device Private Inspector Fees

12VAC5-490-50. Private inspector registration fees.

A. Individuals included on the Commonwealth's list of qualified inspectors of x-ray machines pursuant to § 32.1-229.1 D 5 of the Code of Virginia as of November 1, 2016, shall pay annually a registration renewal fee of $150 to the Virginia Department of Health X-Ray Program to remain on the list as a qualified inspector of x-ray machines pursuant to 12VAC5-481-340.

B. Individuals requesting to be placed on the Commonwealth's list of qualified inspectors of x-ray machines pursuant to § 32.1-229.1 D 5 of the Code of Virginia shall:

1. Request approval by the Office of Radiological Health to become a qualified inspector of x-ray machines pursuant to 12VAC5-481-340;

2. Pay an initial registration fee of $150 to the Virginia Department of Health X-Ray Program, once approved; and

3. Pursuant to subsection A of this section, pay annually a registration renewal fee of $150 to remain on the list as a qualified inspector of x-ray machines pursuant to 12VAC5-481-340.

FORMS (12VAC5-490)

Application to be Listed as a Private Inspector of X-ray Machines, RH-F-27 (eff. 9/2014)

COMMONWEALTH of VIRGINIA

Department of Health

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

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TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 16, 2017

TO: Virginia State Board of Health

FROM: Steven A. Harrison, MA, MEP
Director, Office of Radiological Health

SUBJECT: Virginia Radiation Protection Regulations: Fee Schedule (12VAC5-490) – fees for X-ray program and radioactive materials program

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The Virginia Department of Health's Office of Radiological Health (ORH) proposes to amend the existing Virginia Radiation Protection Regulations: Fee Schedule (12VAC5-490) in order to update fees for X-ray Program (XRP) device registrations and inspections, and to amend the fee schedule used by the Radioactive Materials Program (RMP) for charging annual licensing fees. The fee increase is necessary to maintain program solvency so as to provide services and adequate regulatory controls necessary to protect public and worker health, safety and welfare. A Notice of Intended Regulatory Action was published in the Virginia Register on May 29, 2017 notifying the public of our intent to propose changes to this regulation, and no public comments were received.

The purpose of the regulations is to provide the monetary means for supporting the XRP and RMP by setting fees for the registration, inspection and licensing fees of regulated entities among the respective programs.

The proposed amendments are necessary to maintain XRP and RMP program solvency given the elimination of general fund support and the subsequent spend down of surplus fee revenue. With one exception, fees for these programs have not increased since 2009 when X-ray fees were adjusted and the RMP was established along with commensurate fees necessary for program operations. At that time, fees were sufficient to accommodate program and ancillary business functions as they were supplemented by general funds which were allocated to ORH (then Division of Radiological Health). General funds that were used to support ORH were abolished effective July 1, 2016. Since that time, ORH's surplus has been used to cover the balance and is projected to be depleted in 2018. The proposed fee increases were derived based on Office of Financial Management revenue and expenditure projections through the year 2021.

The Board is requested to approve the proposed amendments. Should the Board approve the proposed amendments, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website and a 60-day public comment period will begin.

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-490
Regulation title(s)	Virginia Radiation Protection Regulations: Fee Schedule
Action title	X-ray and Radioactive Materials Fee Schedule Revisions
Date this document prepared	August 9, 2017

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Virginia Department of Health's (VDH) Office of Radiological Health (ORH) is requesting a revision to 12VAC5-490 in order to amend the fee schedule used by the X-ray Program (XRP) for device registrations and inspections, and to amend the fee schedule used by the Radioactive Materials Program (RMP) for charging annual licensing fees. The fee increase is necessary to maintain program solvency so as to provide services and adequate regulatory controls necessary to protect public and worker health, safety and welfare.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CAT – Category
CRCPD - Conference of Radiation Control Program Directors
FDA – United States Food and Drug Administration
FY – Fiscal Year
KY - Kentucky
MQSA - Mammography Quality Standards Act
NC – North Carolina
NRC – Nuclear Regulatory Commission
OFM - Office of Financial Management
ORH - Office of Radiological Health
PA - Pennsylvania
RMP – Radioactive Materials Program
IN - Tennessee
VDH – Virginia Department of Health
VITA – Virginia Information Technology Agency
XRP – X-ray Program

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

These regulations are authorized by the Code of Virginia §§ 32.1-229 et seq.

- Section 32.1-229 authorizes the Board of Health to establish fee schedules, which shall not exceed comparable U.S. Nuclear Regulatory Commission (NRC) fees, for the licensure and inspection of radioactive materials.
- Section 32.1-232.1 establishes a special trust fund for Radioactive Materials Facility Licensure and Inspection fees.
- Section 32.1-229.1 requires the Board of Health to establish fee schedules for registration of machines, for inspections of X-ray machines by VDH personnel; however, no fee shall be charged for inspections initiated by VDH.
- Section 32.1-229.2 requires the Board of Health to set inspection fees to minimize competition with the private sector and include all reasonable costs.

Refer to the following websites for viewing the statutory authority cited in §§ 32.1-229, 32.1-229.1, 32.1-229.2 and 32.1-232.1of the Code of Virginia:
http://law.lis.virginia.gov/vacode/title32.1/chapter6/section32.1-229/
http://law.lis.virginia.gov/vacode/title32.1/chapter6/section32.1-229.1/
http://law.lis.virginia.gov/vacode/title32.1/chapter6/section32.1-229.2/
http://law.lis.virginia.gov/vacode/title32.1/chapter6/section32.1-232.1/

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The proposed regulatory action addresses fees for two program areas, XRP and RMP, and is necessary to maintain program solvency, so as to provide services and adequate regulatory controls necessary to protect public and worker health, safety, and will fix the elimination of general fund support for the programs and the subsequent spend down of surplus fee revenue since 2015. With one exception, fees for these programs have not increased since 2009 when X-ray fees were adjusted and the RMP was established along with commensurate fees necessary for program operations. At that time, fees were sufficient to cover program and ancillary business expenditures since they were supplemented by general funds that were allocated to ORH (then Division of Radiological Health). In fact, the fees generated a surplus. As a result, a 20% decrease in RMP fees went into effect in 2012, due in part to the overage, the anticipated continuation of general funds, and a petition for small business relief. On 7/12/2017, a change in non-medical X-ray device registration and inspection fees was adopted. This regulatory action was initiated in early 2015, prior to the loss of general fund support, to help offset the cost of administrative activities involved in the registration, inspection, and certification of non-medical X-ray equipment – equipment which had not been assessed a registration fee prior to that time.

As mentioned earlier, general funds that were used to support ORH were abolished effective July 1, 2016. The 2015 general fund amount, having been reduced from about $466,000 to $361,000 over several years, constituted 19.3% of ORH's then budgeted resources (revenues) of $1,871,476 and 13.4% of ORH's budgeted expenditures of about $2,700,000. Since that time, the surplus has been used to balance the budget but is projected to be depleted in 2018.

The proposed fee increases were derived based on OFM revenue and expenditure projections through the year 2021 that have been deemed necessary to maintain the programs solvent, as follows:

Program	2017 Revenue	2021 Expenditure Forecast
X-ray	$713,000	$1,064,729
Radioactive Materials	$750,000	$1,248,278

X-ray Program

The XRP is responsible for the registration and inspection of x-ray producing devices in the Commonwealth, in which there are approximately 7,000 registrants with approximately 22,300 x-ray tubes. The XRP is also responsible for FDA Mammography Quality Standards Act (MQSA) facility inspections; performs inspection reviews, correspondence, enforcement and other associated activities; employs staff that maintain specialized training and certifications necessary to conduct XRP activities; reviews the academic and occupational credentials of and certifies private inspectors authorized to conduct business in the Commonwealth, reviews their inspection reports for accuracy; and responds to incidents and emergencies requiring radiological technical expertise and dose characterization. Staff members are emergency response trained, maintain training to perform exposure assessment and participate in radiological drills and exercises with federal, state and local stakeholders and responders.

Current XRP staffing includes six (6) Compliance/Safety Officers in addition to supervisory and office services personnel who perform registrations, certifications and billing, process and track payments, and provide client contact services. This staff complement, according to the Conference of Radiation Control Program Directors (CRCPD), is performing the workload of a minimum of eight (8) XRP FTEs for an equivalent program (CRCPD, Criteria for and Adequate Radiation Control Program, Appendix C, May 2014).

The proposed regulatory action will address two sets of fees levied by the XRP: X-ray machine registration fees and X-ray machine inspection fees. With respect to the X-ray machine registration fees, the existing regulation is proposed to be amended due to the increased costs of maintaining a registration program for X-ray producing devices since publication of the overall fee schedule effective March 4, 2009.

The registration fees need to be adjusted to reflect the elimination of general funds. The X-ray machine inspection fees also need to be modified to accommodate increased personnel, overhead and travel costs to the agency since 2009 and which are projected to continue to increase in the coming years. Virginia's current and proposed X-ray registration fees, in comparison to those charged by other nearby states, appears below.

X-ray Facility	Virginia Current Registration	Virginia Proposed Registration Fee	Virginia Current Inspection Fee	Virginia Proposed Inspection Fee	Virginia Frequency
Chiropractors	$50	$100	$230	$250	Annual
Dentists	$50	$100	$90	$100	3 year
Medical Offices	$50	$100	$230	$250	Annual
Hospitals	$50	$100	Private Inspectors Only	Private Inspectors Only	Annual
Veterinary Offices	$50	$100	$160	$175	3 year
Podiatric Offices	$50	$100	$90	$125	3 year
Therapy <0.9MeV	$50	$100	Private Inspectors Only	Private Inspectors Only	Annual
Therapy > 0.9 MeV	$50	$100	Private Inspectors Only	Private Inspectors Only	Annual
Educational	$50	$100	Instrument Dependent	Instrument Dependent	Annual
Government (Academic)	$50	$100	Instrument Dependent	Instrument Dependent	Annual
Baggage	$20	$40	100	100	5 year
Cabinet/Analytical	$25	$50	150	150	3 year
Industrial	$50	$100	200	200	Annual
Bone Density	$50	$100	$90	90	3 year

X-ray Facility	Tennessee*	Tennessee Frequency	Maryland*	Maryland Frequency	North Carolina* (Initial + $24 to $50/tube)	North Carolina Frequency
Chiropractors	$195	2 years	$222	2 years (Private)	$180	3 year
Dentists	$85	4 years	$80	3 years (State)	$180	5 year
Medical Offices	$286	Annual	$222	2 years (Private)	$180	3 year
Hospitals	$286	Annual	$222	2 years (Private)	$390	3 year
Veterinary Offices	$195	2 years	$222	2 years (State)	$130	4 year
Podiatric Offices	$195	2 years	$222	2 years (Private)	$180	3 year
Therapy <0.9MeV	$390	Annual	$882	Annual (Private)	$400	3 year
Therapy > 0.9 MeV	$2,600	Annual	$882	Annual (Private)	$400	3 year
Educational	$780	2 years	$222	3 years (Private)	$130	4 year

Government (Academic)	$780	2 years	$222	3 years (Private)	$130	4 year
Baggage/Cabinet/ Industrial	$780	2 years	$222	3 Years (Private)	$180	3 year
Bone Density	$195	2 years	$222	2 years (Private)	$180	3 year

*Inspection fees included in registration fee, where conducted by state inspectors.

Radioactive Materials Program

Virginia entered into an agreement with the NRC on March 31, 2009 to assume the responsibilities of regulating the use of radioactive materials in Virginia. 12VAC5-490 was promulgated at that time to supply the monetary means for supporting the RMP by charging application and annual licensing fees.

The RMP is tasked with performing detailed technical reviews of license applications submitted for possession, use, manufacture, and distribution of radioactive materials, as well as any other associated activities requiring licensing by regulations (e.g., decontamination services) prior to approval for possession and/or operation. Contacts with applicants during the review process are documented through review letters and memoranda. For major operations, facilities subject to increased controls or applicants with no previous history with the RMP, pre-licensing visits to examine facilities and equipment may be in order. Procedures are in place to promote thoroughness, technical quality and uniformity. The RMP requires license amendments for any significant change in authorized radioactive materials, uses and operations and an amendment review is equivalent to the license application review. A complete technical review and reauthorization of active licenses comparable to the original licensing process are also conducted at a frequency based on the type of facility, materials and/or activities authorized. The program requires the registration of certain devices containing large quantity or otherwise hazardous sealed sources of radioactive material that are generally licensed under its regulations and also requires evidence of financial assurance/surety for large quantity licensees with substantial potential for contamination of facilities, equipment, and the environment, or which possess large quantities of radioactive material requiring disposal. Inspections are conducted to evaluate compliance with regulatory standards, and inspection reports are generated that follow a uniform format and allow for timely (no later than 30 days after inspection) communication of results to the licensee. These reports summarize the inspection scope, include measurement data with appropriate interpretation, clearly list and categorize as to the severity each item of noncompliance, set a reasonable date for correction of each item, and require a plan for corrective action that includes submission of evidence that corrections have been performed and are effective.

The RMP licenses and inspects approximately 400 specific licensees. The RMP also tracks over 2,900 general licensees which possess over 34,000 general licensed devices; however, general licensees are not subject to inspection. RMP staffing consists of one (1) supervisor who conducts inspections, five (5) program support inspectors, and two (2) Administrative Program Specialists. These personnel maintain the RMP's databases on licensure and inspections; prepare and distribute statistical and informational reports, including monthly reports on the number of inspections (due, past due and conducted), license applications, amendments, license actions overdue, violations, denials, etc.; receive and process the daily mail including license applications, amendments and renewals, inspection letters and licensing fees; mail out licensing bills, inspection letters, renewal applications and general information to licensees; contact licensees by phone regarding licensing fees and renewals; and maintain the licensing file system including file numbers, licenses, inspection reports, billing notices and other materials.

According to the CRCPD, RMP professional/technical personnel requirements should consist of eight (8) to twelve (12) inspectors plus management and administrative support (CRCPD, Criteria for and Adequate Radiation Control Program, Appendix C, May 2014).

This proposal seeks to continue to assess RMP fees equitably across all license categories by using the fee structure adopted in 2009 upon Virginia's becoming an Agreement State, while also incorporating the regulatory changes adopted on November 22, 2012 to accommodate small business relief. Using this approach, revenue generation is estimated to be about $1,248,500 which will approximate OFM's

projected expenditures of about $1,248,300. It is also important to note that this proposal does not suggest establishing an hourly rate for initial license application and amendment reviews as does the NRC, which is currently $263 per hour for such reviews. A comparison of the NRC's existing fees to VDH's proposed fees, as well as a sampling of other Agreement State fees, appears below:

Cat	Specific License Type	NRC FY17 Fee*	VDH Proposed Fee	PA Fee**	TN Fee	KY Fee	NC Fee
1	Special Nuclear Material						
A.	Possession and use of SNM in sealed sources contained in devices used in measuring systems	$8,000	$1,700	$3,150			
B.	SNM to be used as calibration and reference sources	$3,000	$900	$8,700			
C.	SNM - all other, except license authorizing special nuclear material in unsealed form that would constitute a critical mass [Fee waived if facility holds additional license category]	$8,600	$3,400	$8,700	$7,800		
2	Source Material						
A.	Source material processing and distribution	$8,000	$5,100	$45,100			
B.	Source material in shielding [Fee waived if facility holds additional license category]	$3,300	$300	$1,125	$425		
C.	Source material - all other, excluding depleted uranium used as shielding or counterweights	$9,400	$3,400	$20,100			
3	Byproduct, NARM						
A.	Broad scope for processing or manufacturing of items for commercial distribution	$30,500	$17,000	$12,450	$7,800	$5,200	$2,250
B.	Processing or manufacturing and commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$12,900	$9,000	$17,850	$7,800	$5,200	
C.	Commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$12,900	$6,800	$10,200	$7,800	$5,200	
D.	Processing or manufacturing of items for commercial distribution	$11,600	$3,400	$12,450		$3,600	$2,250
E.	Industrial radiography operations performed only in a shielded radiography installation	$27,000	$5,100	$21,150	$7,800	$4,000	$2,600
F.	Industrial radiography performed only at the address indicated on the license, and at temporary job sites	$27,000	$6,000	$21,150	$7,800	$4,000	$3,500
G.	Possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is not removed from the shield [Fee waived if facility holds additional irradiator license category]	$10,800	$3,400	$6,300	$1,950	$1,750	$4,500
H.	Possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes. The category also includes underwater irradiators for irradiation	$11,800	$5,100	$11,700	$36,000	$4,200	$4,500
I.	Possession and use of at least 370 TBq (10,000 curies) and less than 3.7 PBq (100,000 curies)of radioactive material in sealed sources for irradiation of materials	$95,700	$5,100	NRC Fee + 10% Application or Renewal	$36,000	$4,200	$8,500

J.	Possession and use of 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources for irradiation of materials	$95,700	$8,500	$46,800	$36,000	$4,200	$8,500
K.	Distribute items containing radioactive materials to persons under a general license	$4,600	$1,700	$3,750	$36,000		
L.	Possess radioactive materials intended for distribution to persons exempt from licensing	$11,600	$1,700	$16,050	$2,730		
M.	Broad scope for research and development that does not authorize commercial distribution	$16,300	$10,200	$22,600	The sum of all applicable categories	$3,500	$3,000
N.	Research and development that does not authorize commercial distribution	$14,800	$1,700	$8,400	$1,170	$1,250	
O.	Installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services	$22,100	$1,700	$12,750		$1,200	
P.	Portable gauges	$9,300	$1,300	$4,050	$2,730	$1,300	$425
Q.	Portable x-ray fluorescence analyzer, dewpointer or gas chromatograph	$9,300	$400	$4,050	$850		
R.	Leak testing services	$9,300	$900	$4,050	$850	$1,200	$400
S.	Instrument calibration services	$9,300	$1,700	$4,050	$850	$1,200	$400
T.	Fixed gauges	$9,300	$1,300	$3,150	$1,950	$1,100	$550
U.	All other byproduct, naturally-occurring or accelerator-produced material licenses, except as otherwise noted	$9,300	$2,600	$4,050	Case-by-case basis		$500
4	Waste Processing						
A.	Commercial waste treatment facilities, including incineration		$170,000	Full Cost	$450,000		
B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	$20,800	$12,800	$18,000	$14,625	$10,000	
C.	Waste processing - all other, including decontamination service		$8,500	Full Cost	Case-by-case basis	$25,000	
5	Well Logging						
A.	Well logging using sealed sources or sub-surface tracer studies	$16,000	$5,100	$6,600	$5,200	$2,500	
B.	Well logging using sealed sources and sub-surface tracer studies	$16,000	$5,100	Full Cost	$5,200	$2,500	
6	Nuclear Laundry						
A.	Commercial collection and laundry of items contaminated with radioactive material	$38,500	$17,000	$43,200	$14,625	$7,500	
7	Medical/Veterinary						
A.	Human use of sealed sources contained in teletherapy-or stereotactic radiosurgery devices, including mobile therapy	$23,800	$10,200	$7,350	$2,730	$4,000	
B.	Broad scope for human use in medical diagnosis, treatment, research and development (excluding teletherapy or stereotactic radiosurgery devices)	$33,800	$20,400	$43,500	The sum of all applicable categories	$7,500	$5,250
C.	Mobile nuclear medicine	$14,700	$3,400	$7,350	$7,800	$2,500	$1,600
D.	Medical Institutions providing imaging,diagnostic or radionuclide therapy	$14,700	$4,000	$7,350	$1,170	$2,100	$2,900

E.	HDR, Emerging Technologies	$14,700	$6,400	$7,350	$2,730	$4,000	$2,100
F.	Veterinary use of radioactive materials	$9,300	$1,700	NRC Fee + 10% Application or Renewal	$2,730	$2,100	
G.	In-Vitro	$9,300	$1,700	NRC Fee + 10% Application or Renewal		$1,250	
8	Academic						
A.	Possession and use of byproduct,naturally-occurring or accelerator produced radioactive material for educational use or academic research and development that does not authorize commercial distribution, excluding broad scope or human use license	$14,800	$1,300	$1,300	$7,800	$1,250	
9	Accelerator						
A.	Accelerator production of radioisotopes with commercial distribution	$32,000	$3,400	NRC Fee + 10% Application or Renewal			
B.	Accelerator isotope production - all other [Fee waived if facility holds medical broad scope license with no commercial distribution]	$32,000	$3,400	NRC Fee + 10% Application or Renewal			
10	Reciprocity						
A.	Reciprocal recognition of an out-of-state specific license		50% of annual fee of applicable category	$2,250			
	* The NRC also charges an initial application fee. Fees for permits, licenses, amendments, renewals, special projects, 10 CFR part 55 re-qualification and replacement examinations and tests, other required reviews, approvals, and inspections will be calculated using the professional staff-hour rate of $263 per hour.			**Small Business Fee: $3,450			

The fee schedule continues to be designed on the premise that all licensees will pay a fair share of the program costs. One fee is set per category of licensee based on time and effort. When the Commonwealth's program was developed, the NRC fee schedule was referenced and then adjusted for expected time and effort involved in RMP staff managing each license category. Unlike the NRC program, the RMP did not include a reduced rate for small business licensees as the size of the business (i.e., licensee) did not correlate with the time and effort involved. However, a Petition for Rulemaking was submitted to the Virginia Regulatory Town Hall on August 17, 2009 requesting the radioactive material licensing fees be lowered to accommodate this provision to the extent possible. That change took effect on November 22, 2012 and as a result, 19 of 54 licensees were assessed a higher licensing fee by VDH than they paid to the NRC while 35 were lower than the NRC fee. The same category and fee structure applied at that time was followed for this proposal. Using the 2017 NRC small business fees in comparison to the VDH proposed fees, 14 businesses would be charged a fee higher than the NRC small business fee, while 48 would be charged less, as shown below:

#	Name	TYPE	CAT	2017 NRC Small Business Fee	Proposed VA Fee	Difference VA Proposed to NRC
1	Blue Ridge Isotopes, LLC	Nuclear Pharmacy	3B	$ 4,100	$ 9,000	$ 4,900
2	Radiology Services of Northern VA	Nuclear Pharmacy	3B	$ 4,100	$ 9,000	$ 4,900
3	Martin Industrial Testing, Inc.	Industrial Radiography	3F	$ 850	$ 6,000	$ 5,150
4	Hampton Roads Cardiology, PLLC	Medical	7D	$ 850	$ 4,000	$ 3,150
5	Precision Nuclear Diagnostics	Mobile Medical	7C	$ 850	$ 3,400	$ 2,550
6	Advex Corporation	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
7	J Core Drilling, Inc.	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
8	Pole Brothers Imaging Co	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
9	Scientific Technical, Inc.	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
10	Testing Technologies, Inc	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
11	Well Data Services, Inc.	Well Logger	5B	$ 4,100	$ 5,100	$ 1,000
12	General Health Physics	Calibration	3S	$ 850	$ 1,700	$ 850
13	Wise County Coals, Inc.	Portable Gauge	3P	$ 850	$ 1,300	$ 450
14	Geo Design & Engineering, Inc.	Portable Gauge	3P	$ 850	$ 1,300	$ 450
15	Ajay A. Acharya, M.D., P.C.	Medical	7D	$ 4,100	$ 4,000	$ (100)
16	Blue Ridge Cardiovascular Associates	Medical	7D	$ 4,100	$ 4,000	$ (100)
17	Cardiac & Vascular Care of Virginia, P.C.	Medical	7D	$ 4,100	$ 4,000	$ (100)
18	Cardiology Associated, PC	Medical	7D	$ 4,100	$ 4,000	$ (100)
19	Cardiology of Virginia, Inc.	Medical	7D	$ 4,100	$ 4,000	$ (100)
20	Cardiology Specialists of Virginia, PC	Medical	7D	$ 4,100	$ 4,000	$ (100)
21	Cardiovascular Associates of Charlottesville, PLC	Medical	7D	$ 4,100	$ 4,000	$ (100)
22	Heart Care Associates, P.C.	Medical	7D	$ 4,100	$ 4,000	$ (100)

23	Henrico Cardiology Associates	Medical	7D	$ 4,100	$ 4,000	$ (100)
24	Javed Cardiac Center, PLLC	Medical	7D	$ 4,100	$ 4,000	$ (100)
25	M. Rafiq Zaheer, M.D., F.A.C.C.	Medical	7D	$ 4,100	$ 4,000	$ (100)
26	Medical Associates of Northern VA	Medical	7D	$ 4,100	$ 4,000	$ (100)
27	Northern Virginia Endocrinologists	Medical	7D	$ 4,100	$ 4,000	$ (100)
28	Odyssey Imaging, LLC	Medical	7D	$ 4,100	$ 4,000	$ (100)
29	Prince William Nuclear Cardiology	Medical	7D	$ 4,100	$ 4,000	$ (100)
30	Richmond Cardiology Associates	Medical	7D	$ 4,100	$ 4,000	$ (100)
31	Roanoke Heart Institute, PLC	Medical	7D	$ 4,100	$ 4,000	$ (100)
32	Tidewater Heart Institute	Medical	7D	$ 4,100	$ 4,000	$ (100)
33	Best Medical International, Inc.	Mfg./Dist.	3D	$ 4,100	$ 3,400	$ (700)
34	Blue Ridge Equine Clinic, Inc	Veterinary	7F	$ 4,100	$ 1,700	$(2,400)
35	Wm. G. Brewer, DVM	Veterinary	7F	$ 4,100	$ 1,700	$(2,400)
36	Health Physics Consultation	Other - Consult	3U	$ 4,100	$ 2,600	$(1,500)
37	Physics Associates	Other - Consult	3U	$ 4,100	$ 2,600	$(1,500)
38	Dilon Technologies, LLC	R&D	3N	$ 4,100	$ 1,700	$(2,400)
39	EPL Pathology, Inc.	Other - Consult	3U	$ 4,100	$ 2,600	$(1,500)
40	Spurlock Equine Associates	Veterinary	7F	$ 4,100	$ 1,700	$(2,400)
41	Veterinary Emergency Center, Inc.	Veterinary	7F	$ 4,100	$ 1,700	$(2,400)
42	AlexCom & Associates, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
43	ATCS, P.L.C.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
44	Branscome, Inc	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
45	Commonwealth Environmental Associates, Inc	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
46	Consulting Engineers Corporation	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
47	Dominion Engineering Associates, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
48	Dominion Inspection Co., Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
49	ECS Mid-Atlantic, LLC (Winchester)	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
50	EnCon Consulting Services, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
51	Engineering & Materials Technology, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
52	Engineering and Testing Consultants, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
53	GeoConcepts Engineering, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
54	Geotechnics, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
55	HDH Associates, PC	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
56	Lee Hy Paving Corporation	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
57	NXL Construction Serivces, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)

58	Roofing Consulting Service, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
59	Seal Engineering, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
60	Terra Tech Engineering Service, P.C.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
61	Viola Engineering, PLC	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
62	Zannino Engineering, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)

Other Actual and Anticipated Cost Increases:

It is important to note that VDH's Office of Financial Management's (OFM) expenditure budget forecast assumes no reductions in staff/operating costs and the following future cost impact assumptions through 2021:

a) Health Insurance: Likely 8% increase in FY18 (based on statewide central appropriation planning in Appropriation Act).
b) Health Insurance: Additional conservative individual FY19 - FY21 increases of 5%, 2% and 2%.
c) VITA: Annual conservative 1% increase in each FY.
d) State Compensation: Conservative 3% annual salary cost impact factored in FY18 and beyond (FY18 and future FYs speculative).
e) OFM forecasts X-ray Program expenditures of about $1,065,000 by the year 2021, while revenue is expected to remain constant at about $713,000 unless fees are raised.
f) OFM forecasts RMP expenditures of about $1,250,000 by the year 2021, while revenue is expected to remain constant at about $750,000 unless fees are raised.

OFM also provided information on various cost increases since the RMP fee reduction of 2012 went into effect. Specifically:

a) FY18: 3% legislated raise in staff compensation.
b) FY14: 2% legislated raise in staff compensation.
c) FY13 and FY14: Health insurance employer premium increases each year (individual plan increases vary; average increased in 3-8% range annually).
d) FY11 and FY12: Modest health insurance employer premium increase
e) There were additional net contributions required of agency non-general funds/cash balances that were used to support the Virginia Retirement System's pension liability.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

Section 10 of the Regulations is proposed to be amended to increase the X-ray machine registration fee for operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation as well as operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts that are capable of producing radiation, and for non-medical X-ray devices.

Section 20 of the Regulations is proposed to be amended to increase fees charged for surveys (inspections) requested by a registrant and performed by a VDH inspector.

Section 40 of the Regulations is proposed to revise the annual fees for entities issued a radioactive materials license pursuant to 12VAC5-481, as necessary, to support the licensing and inspection program under the Commonwealth's authority as a NRC Agreement State. Since the 2012 revision, fee collection by the RMP has averaged about $750,000 while expenses have averaged about $950,000. This action is

expected to increase the RMP revenue generation to be in line with current and anticipated future expenditures.

The Atomic Energy Act of 1954, as amended, provides the statutory basis by which the NRC relinquishes portions of its regulatory authority to license and regulate radioactive material to a state that agrees to accept that responsibility. Through the Agreement State program, 37 states, including Virginia, have signed formal agreements for inspection and enforcement authority with the NRC. The NRC retains an oversight role and periodically reviews Agreement State programs for continued adequacy to protect public health and safety through their Integrated Materials Performance Evaluation Program (IMPEP). All IMPEP reviews use common performance indicators in the assessment. For most IMPEP reviews, no action other than issuance of the final report is needed. In cases where additional action is needed, the NRC may consider monitoring, heightened oversight, probation, suspension or termination. Suspension and termination are considered when a program is deemed inadequate to protect public health and safety. In these situations, the state's authority is revoked and reverts back to the NRC, and the state's revenue stream normally generated by program fees would be eliminated.

In November 2014, the NRC's IMPEP review team evaluated Virginia's RMP and found "the Program experienced a backlog in inspections due, in part, to having a shortage of qualified staff to complete inspections within the required timeframe." Since that time, the RMP has hired and trained two new inspectors and completed the overdue inspection backlog, thus avoiding monitoring, probation or forfeiture. The NRC warned, however, that a loss of even one inspector could create an environment for recurrence due to the absence of staffing depth. The NRC also noted that the administrative assistant responsible for maintaining the database had been filled three times since 2010 and was vacant again at the time of the review. ORH explained that efforts would be undertaken to request the conversion of that position to a Full-Time Equivalent, which was granted in 2015 and subsequently filled.

The RMP, through its registration fees, currently provides for about 30% of ORH's overall revenue and supports Administration, the RMP Supervisor, RMP Inspectors and Business staff salaries, as well as some office-wide equipment purchases and emergency response capabilities. A loss of the RMP and the revenue it generates, even temporarily, would challenge the viability of the office-at-large.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage of this change to the public and the regulated community is that registering all X-ray machines allows ORH to maintain an accurate database of the devices, track inspections and ensure that the machines are functioning properly so as to minimize the risk of equipment malfunction and accidental overexposures.

1. Primary advantages and disadvantages to the public:
   The primary advantage to the public is that the X-ray machine registration and inspection fees rely on owners/operators of the X-ray equipment. Similarly, radioactive materials licensing fees rely on the owners/operators of radioactive materials sources and devices.

   There are no disadvantages to the public in promulgating the proposed fee schedule.

2. Primary advantages and disadvantages to the agency and Commonwealth:

Approving the proposed fee structure will allow the Commonwealth to recover more of the costs associated with carrying out the legislative mandate.

There are no disadvantages to the agency and Commonwealth in promulgating the proposed fee schedule.

3. Other pertinent matters of interest to the regulated community:

X-ray machine registrants and Radioactive Materials licensees have an interest in keeping inspection fees as low as possible. Potential concerns may be expressed by private X-ray device inspectors whose fees are independent of VDH's inspection fees and are negotiated between individual private inspectors and the registrants. Virginia Code § 32.1-229.2 requires the agency to establish inspection fees to minimize competition with the private inspector and recover its costs. X-ray machine registrants may also express concerns that the proposed inspection fees are excessive.

Similarly, VDH may anticipate objection from the radioactive materials licensees due to a proposed increase, even though the proposed fee schedule for radioactive materials will remain below the NRC's fees for equivalent (non-Agreement State) services.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements or no requirements that exceed applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities that would be disproportionately affected by this action.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal; the costs and benefits of the alternatives stated in this background document or other alternatives; and, the potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**) or by mail, email, or fax to **Steve Harrison, Virginia Department of Health, Office of Radiological Health, 109 Governor Street, Room 736, Richmond, VA 23219; Office Phone: (804) 864-8151; Fax: (804) 864-8175; email: steve.harrison@vdh.virginia.gov**. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	a) Fund Source: X-ray Machines, 02601 and Radioactive Materials Program, 09312. The two programs are not supported by state general funds, but rather by fees collected from X-ray registrations and inspections and RMP licensing fees, respectively. b) Ongoing: Program expenditures are primarily on-going and sometimes increase with salary adjustments such as cost of living raises. OFM forecasts X-ray Program expenditures of about $1,065,000 by the year 2021, while revenue is expected to remain constant at about $713,000. OFM forecasts RMP expenditures of about $1,250,000 by the year 2021, while revenue is expected to remain constant at about $750,000 if unchanged.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no direct charges to the localities for X-ray devices, which are exempt from registration fees for X-ray machines. Nevertheless these facilities are required to register their X-ray machines. For those localities that have radioactive materials licenses, the VDH fee will remain below the NRC's scheduled fee for the equivalent service.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	a) This amendment affects any entity that owns/operates an X-ray device in the Commonwealth. Entities affected by the regulation include: health care facilities ranging from single practitioner to major medical centers; engineering and industrial firms; and security screening. b) This amendment affects any entity that owns/operates/possesses licensed radioactive material/devices regulated by the Commonwealth. Any person required to possess a license for the use of radioactive material must pay an annual licensing fee to the Department of Health. The licensing fees are based upon the type of material use. Diversity of uses of radioactive material covers medicine, academia, industry, and other applications.
Agency's best estimate of the number of such entities that will be affected. Please include an	a) X-ray: Currently about 7,000 registrants with approximately 21,000 x-ray tubes; staff inspects

estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	about 1,000 facilities and 2,100 machines per year. The majority of registrants (dental facilities, chiropractic facilities, podiatry offices, medical facilities/offices, veterinary facilities) are assumed to be small businesses while hospitals, of which there are about 100, generally are not. b) Radioactive Materials: Currently there are about 400 specific licensees. The NRC's definition of a small entity is found in 10 CFR 171.16. The Department of Health will not be offering a small business exemption for the licensing of radioactive material; however, accommodations for small businesses were made based upon the amount of work needed for licensing/inspecting a specific type of radioactive material as described on pages 9 – 11 of this proposal.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	a) X-ray Registration Fees: Direct Costs for implementing this regulation will be $100 per X-ray tube annually for those facilities on a one year machine inspection cycle (medical, hospitals, and chiropractic), and every three years for those facilities on a three-year inspection cycle (dental, podiatry, and veterinary). Indirect cost includes the facility staff time to update the database, prepare and submit a registration form, cost of generating a check to VDH in response to a VDH invoice, and postage (approximately $40). b) X-ray Inspection Fees: Direct Costs for implementing this regulation will be dependent on the type of X-ray machine and will range from $100 for a simple dental intra-oral machine to $250 for a moderately complex general purpose machine, to $250 for a complex fluoroscopic X-ray machine The direct cost may be an annual expense or incurred every three years depending on the facility's inspection cycle. X-ray machine facilities may choose to obtain the services of an approve Private Inspector rather than use a VDH inspector. Private inspector fees for services are independently negotiated with each facility, and may be higher or lower than VDH's proposed inspection fees. Indirect costs for the inspection requirement include staff time to schedule either a Private Inspector or a VDH inspector, to submit an Inspector's report to VDH, to keep record of inspection reports and correspondences, and, if a VDH inspector is used, to prepare a check in response to a VDH invoice. RMP: Costs for implementing this regulation for an annual license fee would include the cost of registration depending on the radioactive material category, generating a check to VDH and postage in response to a VDH invoice. In addition to the previous cost estimate for preparing payment,

	there would be additional staff time ranging from an hour to several hours to review applications, prepare, print and approve licenses, etc. These costs are included in the VDH application or renewal fee. It is important to note that this action does not propose establishing an hourly rate for license application and amendment reviews, as does the NRC (NRC 2017 fee is $263 per hour for such reviews). b) There are no costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes.
Beneficial impact the regulation is designed to produce.	Ensure Virginia's X-ray and Radioactive Materials programs meet current standards and practices by generating revenue necessary to maintain an adequately trained and competent workforce to administer and enforce Virginia Radiation Protection Regulations.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

Failure to update the existing regulation would be inconsistent with the agency's mission and the need to provide adequate regulatory programs that protect public health and safety with regard to the maintenance and operation of X-ray devices and Radioactive Material devices.

The VDH considered the alternative of not participating in the NRC's Agreement State program; however, significantly higher NRC fees would result in commensurate higher fees to Virginia's licensees.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

1. The regulations for licensing and inspecting of radioactive material must at a minimum be equal to the regulations of the NRC as listed in 10 CFR. The NRC uses a compatibility program that delineates the flexibility of each 10 CFR regulation. The Commonwealth's regulations (12 VAC 5-481) have been reviewed and approved by the NRC.

2. The establishment of schedules or deadlines for compliance with registration or inspection requirements is consistent with other states. Less stringent X-ray registration and inspection requirements may result in undetected non-compliances that may adversely affect patient care and safety, while less stringent Radioactive Materials registrations may adversely impact the inventory of radioactive materials devices and sources throughout the Commonwealth, and consequently the staff's ability to track users and perform inspections intended to ensure the protection of public health and safety.
3. The fee schedules were kept as simple as possible.
4. Establishment of performance standards in place of operational standards does not appear to be applicable to implementing a fee schedule.
5. Many of the entities this regulation applies to are small businesses. The Code of Virginia does not provide exemptions for the requirements of this regulation.

Periodic review and small business impact review report of findings

If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Not applicable.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

No comments were received following the publication of the NOIRA.

Commenter	Comment	Agency response

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed changes would not have a direct impact on the institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-490-10		All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee: $50 for each machine and additional tube(s) that have a required annual inspection, collected annually; $60 for each machine and additional tube(s) that have a required inspection every three years, collected every three years. All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee: $50 for each machine with a maximum beam energy of less than 500 KVp; $50 for each machine with a maximum beam energy of 500 KVp or greater. All operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation shall pay	All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee: ~~$50~~ $100 for each machine and additional tube(s) that have a required annual inspection, collected annually; ~~$60~~ $100 for each machine and additional tube(s) that have a required inspection every three years, collected every three years. All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee: ~~$50~~ $100 for each machine with a maximum beam energy of less than 500 KVp; ~~$50~~ $100 for each machine with a maximum beam energy of 500 KVp or greater. All operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation shall pay the following annual registration fee: ~~$20~~ $40 for each machine used for baggage inspection;

<table>
<tr>
<td></td>
<td></td>
<td>the following annual registration fee:

$20 for each machine used for baggage inspection;

$25 for each machine identified as cabinet or analytical; and

$50 for each machine used for industrial radiography.

Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.</td>
<td>~~$25~~ $50 for each machine identified as cabinet or analytical; and

~~$50~~ $100 for each machine used for industrial radiography.

Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.

Intent/Rationale/Impact: This change would increase registration fees for all x-ray producing devices. Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in totality (in 2009), and the use of general funds to support the X-ray program was eliminated in SFY16. Instituting these fees will help to sustain the X-ray program.</td>
</tr>
<tr>
<td>12VAC5-490-20</td>
<td></td>
<td>The following table lists the fees that shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, as well as the required inspection frequencies for each type of X-ray machine:

<table>
<tr><th>Type</th><th>Cost Per Tube</th><th>Inspection Frequency</th></tr>
<tr><td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td><td>$230</td><td>Annually</td></tr>
<tr><td>Fluoroscopic, C-arm Fluoroscopic</td><td>$230</td><td>Annually</td></tr>
<tr><td>Combination (General Purpose-Fluoroscopic)</td><td>$460</td><td>Annually</td></tr>
<tr><td>Dental Intraoral and Panographic</td><td>$90</td><td>Every 3 years</td></tr>
<tr><td>Veterinary</td><td>$160</td><td>Every 3 years</td></tr>
<tr><td>Podiatric</td><td>$90</td><td>Every 3 years</td></tr>
<tr><td>Cephalometric</td><td>$120</td><td>Every 3 years</td></tr>
<tr><td>Bone Densitometry</td><td>$90</td><td>Every 3 years</td></tr>
<tr><td>Combination (Dental</td><td>$210</td><td>Every 3 years</td></tr>
</table>
</td>
<td>The following table lists the fees that shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, as well as the required inspection frequencies for each type of X-ray machine:

<table>
<tr><th>Type</th><th>Cost Per Tube</th><th>Inspection Frequency</th></tr>
<tr><td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td><td>~~$230~~ $250</td><td>Annually</td></tr>
<tr><td>Fluoroscopic, C-arm Fluoroscopic</td><td>~~$230~~ $250</td><td>Annually</td></tr>
<tr><td>Combination (General Purpose-Fluoroscopic)</td><td>~~$460~~ $500</td><td>Annually</td></tr>
<tr><td>Dental Intraoral and Panographic</td><td>~~$90~~ $100</td><td>Every 3 years</td></tr>
<tr><td>Veterinary</td><td>~~$160~~ $175</td><td>Every 3 years</td></tr>
<tr><td>Podiatric</td><td>~~$90~~ $125</td><td>Every 3 years</td></tr>
<tr><td>Cephalometric</td><td>~~$120~~ $130</td><td>Every 3 years</td></tr>
<tr><td>Bone Densitometry</td><td>~~$90~~ $100</td><td>Every 3 years</td></tr>
<tr><td>Combination (Dental Panographic and Cephalometric)</td><td>~~$210~~ $230</td><td>Every 3 years</td></tr>
<tr><td>Shielding Review for Dental Facilities</td><td>~~$250~~ $300</td><td>Initial/Prior to use</td></tr>
<tr><td>Shielding Review for Radiographic, Chiropractic, Veterinary,</td><td>~~$450~~ $500</td><td>Initial/prior to use</td></tr>
</table>
</td>
</tr>
</table>

Panographic and Cephalometric)		
Shielding Review for Dental Facilities	$250	Initial/Prior to use
Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities	$450	Initial/prior to use
Baggage X-Ray Unit	$100	Every 5 years
Cabinet/Analytical X-ray Unit	$150	Every 3 years
Industrial Radiography X-Ray Unit	$200	Annually

Fluoroscopic, or Podiatric Facilities		
Baggage X-Ray Unit	$100	Every 5 years
Cabinet/Analytical X-ray Unit	$150	Every 3 years
Industrial Radiography X-Ray Unit	$200	Annually

Intent/Rationale/Impact: This change increases x-ray device inspection fees except for non-medical devices (Baggage, Cabinet, Industrial), which were adjusted effective July 2017. Administrative, personnel, travel and other expenses have increased since the overall inspection fee schedule was last revised in 2009 (with the exception of the aforementioned non-medical devices), and the use of general funds to support the X-ray program was eliminated in SFY16.

12VAC5-490-40. Application and licensing fees for radioactive materials licenses.

Application for a radioactive materials license and annual fees for persons issued a radioactive materials license pursuant to 12VAC5-481 are listed in the following table:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-490-40			

Category		Specific License Type	Application & Annual Fee
1		Special Nuclear Material (SNM)	
	A.	Possession and use of SNM in sealed sources contained in devices used in measuring systems	$1,000
	B.	SNM to be used as calibration and reference sources	$500
	C.	SNM - all other, except license authorizing special nuclear material in unsealed form that would constitute a critical mass (fee waived if facility holds additional license	$2,000

Category		Specific License Type	Application & Annual Fee
1		Special Nuclear Material (SNM)	
	A.	Possession and use of SNM in sealed sources contained in devices used in measuring systems	~~$1,000~~ $1,700
	B.	SNM to be used as calibration and reference sources	~~$500~~ $900
	C.	SNM - all other, except license authorizing special nuclear material in unsealed form that would constitute a critical mass (fee waived if facility holds additional license category)	~~$2,000~~ $3,400
2		Source Material	

				category)	
	2			Source Material	
		A.		Source material processing and distribution	$3,000
		B.		Source material in shielding (fee waived if facility holds additional license category)	$200
		C.		Source material - all other, excluding depleted uranium used as shielding or counterweights	$2,000
	3			Byproduct, NARM	
		A.		Broad scope for processing or manufacturing of items for commercial distribution	$10,000
		B.		Processing or manufacturing and commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$6,000
		C.		Commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$4,000
		D.		Processing or manufacturing of items for commercial distribution	$2,000
		E.		Industrial radiography operations performed only in a shielded radiography installation	$3,000
		F.		Industrial radiography performed only at the address indicated on the license, and at temporary job sites	$3,500

	A.	Source material processing and distribution	~~$3,000~~ $5,100
	B.	Source material in shielding (fee waived if facility holds additional license category)	~~$200~~ $300
	C.	Source material - all other, excluding depleted uranium used as shielding or counterweights	~~$2,000~~ $3400
3		Byproduct, NARM	
	A.	Broad scope for processing or manufacturing of items for commercial distribution	~~$10,000~~ $17,000
	B.	Processing or manufacturing and commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	~~$6,000~~ $9,000
	C.	Commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	~~$4,000~~ $6,800
	D.	Processing or manufacturing of items for commercial distribution	~~$2,000~~ $3,400
	E.	Industrial radiography operations performed only in a shielded radiography installation	~~$3,000~~ $5,100
	F.	Industrial radiography performed only at the address indicated on the license, and at temporary job sites	~~$3,500~~ $6,000

				G.	Possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is not removed from the shield (fee waived if facility holds additional irradiator license category)	$2,000			G.	Possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is not removed from the shield (fee waived if facility holds additional irradiator license category)	~~$2,000~~ $3,400
				H.	Possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes. The category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation	$3,000			H.	Possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes. The category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation	~~$3,000~~ $5,100
				I.	Possession and use of at least 370 TBq (10,000 curies) and less than 3.7 PBq (100,000 curies) of radioactive material in sealed sources for irradiation of materials)	$3,000			I.	Possession and use of at least 370 TBq (10,000 curies) and less than 3.7 PBq (100,000 curies) of radioactive material in sealed sources for irradiation of materials)	~~$3,000~~ $5,100
				J.	Possession and use of 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources for irradiation of materials	$5,000			J.	Possession and use of 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources for irradiation of materials	~~$5,000~~ $8,500
				K.	Distribute items containing radioactive materials to persons under a general license	$1,000			K.	Distribute items containing radioactive materials to persons under a general license	~~$1,000~~ $1,700

				L.	Possess radioactive materials intended for distribution to persons exempt from licensing	$1,000			L.	Possess radioactive materials intended for distribution to persons exempt from licensing	~~$1,000~~ $1,700
				M.	Broad scope for research and development that does not authorize commercial distribution	$6,000			M.	Broad scope for research and development that does not authorize commercial distribution	~~$6,000~~ $10,200
				N.	Research and development that do not authorize commercial distribution	$1,000			N.	Research and development that do not authorize commercial distribution	~~$1,000~~ $1,700
				O.	Installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services	$1,000			O.	Installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services	~~$1,000~~ $1,700
				P.	Portable gauges	$750			P.	Portable gauges	~~$750~~ $1,300
				Q.	Portable X-ray fluorescence analyzer (XRF), dewpointer or gas chromatograph	$250			Q.	Portable X-ray fluorescence analyzer (XRF), dewpointer or gas chromatograph	~~$250~~ $400
				R.	Leak testing services	$500			R.	Leak testing services	~~$500~~ $900
				S.	Instrument calibration services	$1,000			S.	Instrument calibration services	~~$1,000~~ $1,700
				T.	Fixed gauges	$750			T.	Fixed gauges	~~$750~~ $1,300
				U.	All other radioactive material licenses, except as otherwise noted	$1,500			U.	All other radioactive material licenses, except as otherwise noted	~~$1,500~~ $2,600
			4		Waste Processing			4		Waste Processing	
				A.	Commercial waste treatment facilities, including incineration	$100,000			A.	Commercial waste treatment facilities, including incineration	~~$100,000~~ $170,000
									B.	All other commercial	~~$7,500~~

	B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	$7,500		facilities involving waste compaction, repackaging, storage or transfer	$12,800
	C.	Waste processing - all other, including decontamination service	$5,000	C.	Waste processing - all other, including decontamination service	~~$5,000~~ $8,500
5		Well Logging		5		Well Logging	
	A.	Sealed sources or subsurface tracer studies	$3,000	A.	Sealed sources or subsurface tracer studies	~~$3,000~~ $5,100
	B.	Sealed sources and subsurface tracer studies	$3,000	B.	Sealed sources and subsurface tracer studies	~~$3,000~~ $5,100
6		Nuclear Laundry		6		Nuclear Laundry	
	A.	Commercial collection and laundry of items contaminated with radioactive material	$10,000	A.	Commercial collection and laundry of items contaminated with radioactive material	~~$10,000~~ $17,000
7		Medical/Veterinary		7		Medical/Veterinary	
	A.	Human use of sealed sources contained in teletherapy or stereotactic radiosurgery devices, including mobile therapy	$6,000	A.	Human use of sealed sources contained in teletherapy or stereotactic radiosurgery devices, including mobile therapy	~~$6,000~~ $10,200
	B.	Broad scope for human use of byproduct, source, special nuclear or NARM materials used in medical diagnosis, treatment, research and development (excluding	$12,000	B.	Broad scope for human use of byproduct, source, special nuclear or NARM materials used in medical diagnosis, treatment, research and development (excluding teletherapy or stereotactic radiosurgery devices)	~~$12,000~~ $20,400
				C.	Mobile nuclear medicine	~~$2,000~~

			teletherapy or stereotactic radiosurgery devices)	
	C.	Mobile nuclear medicine	$2,000	
	D.	Medical Institutions providing imaging, diagnostic or radionuclide therapy.	$2,300	
	E.	Medical institutions using High Dose Remote Afterloaders or Emerging Technologies	$3,750	
	F.	Veterinary use of radioactive materials	$1,000	
	G.	In-Vitro	$1,000	
8		Academic		
	A.	Possession and use of radioactive material for educational use or academic research and development that does not authorize commercial distribution, excluding broad scope or human use licenses	$750	
9		Accelerator		
	A.	Production of radioisotopes with commercial distribution	$2,000	
	B.	Production - all other (fee waived if facility holds medical broad scope license with no commercial distribution)	$2,000	
10		Reciprocity		
	A.	Reciprocity recognition of an out-of-state specific license	50% of annual fee of applicable category	

			~~$3,400~~
	D.	Medical Institutions providing imaging, diagnostic or radionuclide therapy.	~~$2,300~~ $4,000
	E.	Medical institutions using High Dose Remote Afterloaders or Emerging Technologies	~~$3,750~~ $6,400
	F.	Veterinary use of radioactive materials	~~$1,000~~ $1,700
	G.	In-Vitro	~~$1,000~~ $1,700
8		Academic	
	A.	Possession and use of radioactive material for educational use or academic research and development that does not authorize commercial distribution, excluding broad scope or human use licenses	~~$750~~ $1,300
9		Accelerator	
	A.	Production of radioisotopes with commercial distribution	~~$2,000~~ $3,400
	B.	Production - all other (fee waived if facility holds medical broad scope license with no commercial distribution)	~~$2,000~~ $3,400
10		Reciprocity	
	A.	Reciprocity recognition of an out-of-state specific license	50% of annual fee of applicable category

Rationale: RMP: VDH staff applied an increase of about 70% to the current fee structure which was originally instituted in 2009 and amended in 2012 and based on workload and device type for the various categories of licenses. Revenue generated will approximate projected expenditures for the activity. Proposed fees will remain less than NRC fees in all categories.

Project 5089 - none

DEPARTMENT OF HEALTH

CH 490 X-ray and Radioactive Material Fees

12VAC5-490-10. Registration fees.

A. All operators or owners of diagnostic x-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee:

1. ~~$50~~ $100 for each machine and additional tube(s) that have a required annual inspection, collected annually; and

2. ~~$60~~ $100 for each machine and additional tube(s) that have a required inspection every three years, collected every three years.

B. All operators or owners of therapeutic x-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee:

1. ~~$50~~ $100 for each machine with a maximum beam energy of less than 500 KVp;

2. ~~$50~~ $100 for each machine with a maximum beam energy of 500 KVp or greater.

C. All operators or owners of baggage, cabinet or analytical, or industrial x-ray machines capable of producing radiation shall pay the following annual registration fee:

1. ~~$20~~ $40 for each machine used for baggage inspection;

2. ~~$25~~ $50 for each machine identified as cabinet or analytical; and

3. ~~$50~~ $100 for each machine used for industrial radiography.

D. Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.

12VAC5-490-20. Inspection fees and inspection frequencies for x-ray machines.

The following table lists the fees that shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, as well as the required inspection frequencies for each type of x-ray machine:

Type	Cost Per Tube	Inspection Frequency
General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)	~~$230~~ $250	Annually
Fluoroscopic, C-arm Fluoroscopic	~~$230~~ $250	Annually
Combination (General Purpose-Fluoroscopic)	~~$460~~ $500	Annually
Dental Intraoral and Panographic	~~$90~~ $100	Every 3 years
Veterinary	~~$160~~ $175	Every 3 years
Podiatric	~~$90~~ $125	Every 3 years

Cephalometric	~~$120~~ $130	Every 3 years
Bone Densitometry	~~$90~~ $100	Every 3 years
Combination (Dental Panographic and Cephalometric)	~~$210~~ $230	Every 3 years
Shielding Review for Dental Facilities	~~$250~~ $300	Initial/Prior to use
Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities	~~$450~~ $500	Initial/Prior to use
Baggage X-ray Unit	$100	Every 5 years
Cabinet or Analytical X-ray Unit	$150	Every 3 years
Industrial Radiography X-ray Unit	$200	Annually

12VAC5-490-40. Application and licensing fees for radioactive materials licenses.

The application fee for a radioactive materials license and annual fees for persons issued a radioactive materials license pursuant to 12VAC5-481 are listed in the following table:

Category		Specific License Type	Application & Annual Fee
1		Special Nuclear Material (SNM)	
	A.	Possession and use of SNM in sealed sources contained in devices used in measuring systems	~~$1,000~~ $1,700
	B.	SNM to be used as calibration and reference sources	~~$500~~ $900
	C.	SNM - all other, except license authorizing SNM in unsealed form that would constitute a critical mass (fee waived if facility holds additional license category)	~~$2,000~~ $3,400
2		Source Material	
	A.	Source material processing and distribution	~~$3,000~~ $5,100
	B.	Source material in shielding (fee waived if facility holds additional license category)	~~$200~~ $300
	C.	Source material - all other, excluding depleted uranium used as shielding or counterweights	~~$2,000~~ $3,400
3		Byproduct, NARM	
	A.	Broad scope for processing or manufacturing of items	~~$10,000~~

		for commercial distribution	$17,000
	B.	Processing or manufacturing and commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	~~$6,000~~ $9,000
	C.	Commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	~~$4,000~~ $6,800
	D.	Processing or manufacturing of items for commercial distribution	~~$2,000~~ $3,400
	E.	Industrial radiography operations performed only in a shielded radiography installation	~~$3,000~~ $5,100
	F.	Industrial radiography performed only at the address indicated on the license, and at temporary job sites	~~$3,500~~ $6,000
	G.	Possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is not removed from the shield (fee waived if facility holds additional irradiator license category)	~~$2,000~~ $3,400
	H.	Possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes. The category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation	~~$3,000~~ $5,100
	I.	Possession and use of at least 370 TBq (10,000 curies) and less than 3.7 PBq (100,000 curies) of radioactive material in sealed sources for irradiation of materials)	~~$3,000~~ $5,100
	J.	Possession and use of 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources for irradiation of materials	~~$5,000~~ $8,500
	K.	Distribute items containing radioactive materials to persons under a general license	~~$1,000~~ $1,700
	L.	Possess radioactive materials intended for distribution to persons exempt from licensing	~~$1,000~~ $1,700

	M.	Broad scope for research and development that does not authorize commercial distribution	~~$6,000~~ $10,200
	N.	Research and development that does not authorize commercial distribution	~~$1,000~~ $1,700
	O.	Installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services	~~$1,000~~ $1,700
	P.	Portable gauges	~~$750~~ $1,300
	Q.	Portable X-ray fluorescence analyzer (XRF), dewpointer or gas chromatograph	~~$250~~ $400
	R.	Leak testing services	~~$500~~ $900
	S.	Instrument calibration services	~~$1,000~~ $1,700
	T.	Fixed gauges	~~$750~~ $1,300
	U.	All other radioactive material licenses, except as otherwise noted	~~$1,500~~ $2,600
4		Waste Processing	
	A.	Commercial waste treatment facilities, including incineration	~~$100,000~~ $170,000
	B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	~~$7,500~~ $12,800
	C.	Waste processing - all other, including decontamination service	~~$5,000~~ $8,500
5		Well Logging	
	A.	Well logging using sealed sources or subsurface tracer studies	~~$3,000~~ $5,100
	B.	Well logging using sealed sources and subsurface tracer studies	~~$3,000~~ $5,100
6		Nuclear Laundry	
	A.	Commercial collection and laundry of items contaminated with radioactive material	~~$10,000~~ $17,000
7		Medical/Veterinary	

	A.	Human use of sealed sources contained in teletherapy or stereotactic radiosurgery devices, including mobile therapy	~~$6,000~~ $10,200
	B.	Broad scope for human use in medical diagnosis, treatment, research and development (excluding teletherapy or stereotactic radiosurgery devices)	~~$12,000~~ $20,400
	C.	Mobile nuclear medicine	~~$2,000~~ $3,400
	D.	Medical institutions providing imaging, diagnostic or radionuclide therapy	~~$2,300~~ $4,000
	E.	Medical institutions using a High Dose Remote Afterloader (HDR) or emerging technologies	~~$3,750~~ $6,400
	F.	Veterinary use of radioactive materials	~~$1,000~~ $1,700
	G.	In-vitro	~~$1,000~~ $1,700
8		Academic	
	A.	Educational use or academic research and development that does not authorize commercial distribution, excluding broad scope or human use licenses	~~$750~~ $1,300
9		Accelerator	
	A.	Production of radioisotopes with commercial distribution	~~$2,000~~ $3,400
	B.	Production - all other (fee waived if facility holds medical broad scope license with no commercial distribution)	~~$2,000~~ $3,400
10		Reciprocity	
	A.	Reciprocity recognition of an out-of-state specific license	50% of annual fee of applicable category

COMMONWEALTH of VIRGINIA
Department of Health
Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 3, 2017

TO: Virginia State Board of Health

FROM: Laurie Forlano, DO, MPH
State Epidemiologist & Director, Office of Epidemiology

SUBJECT: Fast Track Amendment to the *Regulations for Disease Reporting and Control*

The agency is proposing to amend the *Regulations for Disease Reporting and Control* (12VAC5-90-230 through 270, HIV Testing of Gamete Donors). This regulatory action is necessary to comply with a change in the *Code of Virginia*, and no agency discretion is involved.

The law that formerly charged the Board of Health with promulgating regulations to establish a testing protocol for gamete donors (§32.1-45.3) was repealed in 2015. Thus, the related regulations that are currently contained in 12VAC5-90-230, 12VAC5-90-240, 12VAC5-90-250, 12VAC5-90-260, and 12VAC5-90-270 are no longer necessary and are being repealed in this regulatory action.

The Board of Health is requested to approve the fast track amendments. Should the Board of Health approve the amendments, they will be submitted to the Office of the Attorney General to begin the executive branch review process, as specified by the Administrative Process Act. Following executive branch review and approval, the amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. The amendments will become effective 45-days following publication in the Virginia Register of Regulations.

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12 VAC 5-90-230 through 12 VAC 5-90-270
Regulation title(s)	Regulations for Disease Reporting and Control
Action title	Repeal Sections Pertaining to HIV Testing of Gamete Donors
Date this document prepared	6/30/2017

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This regulatory action is necessary to comply with a change in the Code of Virginia, and no agency discretion is involved. The law that formerly charged the Board of Health with promulgating regulations to establish a testing protocol for gamete donors (§ 32.1-45.3) was repealed in 2015. Thus, the related regulations, which are currently contained in 12VAC5-90-230, 12VAC5-90-240, 12VAC5-90-250, 12VAC5-90-260, and 12VAC5-90-270, are no longer necessary and are being repealed in this regulatory action.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

No acronyms have been used in this Agency Background Document.

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

§§ 32.1-12 and 32.1-35 of the Code of Virginia authorizes the Board of Health to promulgate regulations and empowers the Board of Health to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the Commissioner of the Department of Health.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The section of the Code of Virginia that promulgated the regulations in this action has been repealed. Therefore, the sections of regulations contained in this regulatory action are no longer authorized, necessary, or applicable.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

As the section of the Code of Virginia has already been repealed, the repeal of the regulation is noncontroversial. This regulatory action aligns regulations with the Code, and no agency discretion is involved.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

Not applicable; regulatory language is being repealed, in compliance with Code, and no new provisions are being proposed.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage to the public is the removal of potentially confusing regulatory language that no longer applies. This is also the primary advantage to the agency. No disadvantages or other pertinent matters have been identified as this action simply removes these sections of the regulations because they are no longer authorized by the Code of Virginia.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

Not applicable; the section of the Code of Virginia has been repealed and this action repeals the corresponding sections of the Regulations for Disease Reporting and Control.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality is disproportionately affected by this action.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

Not applicable; the section of the Code of Virginia has been repealed and thus corresponding sections of the regulations also need to be repealed.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	None.
Projected cost of the new regulations or changes to existing regulations on localities.	None.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	None.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	None.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	None.
Beneficial impact the regulation is designed to produce.	None.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

No viable alternatives exist.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Any public comments may be submitted to Diane Woolard, Director, Division of Surveillance and Investigation, Virginia Department of Health at diane.woolard@vdh.virginia.gov or via the regulatory Town Hall.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response

Not applicable.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

This action is not anticipated to have an impact on the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-90-230 through 12VAC5-90-270	N/A		These sections are to be repealed in order to comply with changes to the Code of Virginia.

If an existing regulation or regulations (or parts thereof) are being repealed and replaced by one or more new regulations, please use the following chart:

Current chapter-section number	Proposed new chapter-section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements

If a new regulation is being promulgated, that is not replacing an existing regulation, please use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements

If the proposed regulation is intended to replace an emergency regulation, and the proposed regulation is identical to the emergency regulation, please choose and fill out the appropriate chart template from the choices above. In this case "current section number" or "current chapter-section number" would refer to the **pre**-emergency regulation.

If the proposed regulation is intended to replace an emergency regulation, and the proposed regulation includes changes since the emergency regulation, please create two charts: 1) a chart describing changes from the **pre-emergency** regulation to the proposed regulation as described in the paragraph above, and 2) a chart describing changes from the **emergency** regulation to the proposed regulation. For the second chart please use the following title: "Changes from the Emergency Regulation." In this case "current section number" or "current chapter-section number" would refer to the **emergency** regulation.

Project 5211 - none

DEPARTMENT OF HEALTH

Gamete Donor Repeal 12VAC5-90

Part XII

Human Immunodeficiency Virus (HIV) Testing of Gamete Donors

12VAC5-90-230. ~~Definitions.~~ (Repealed.)

~~The following words and terms, when used in this part, shall have the following meanings unless the context clearly indicates otherwise:~~

~~"Artificial insemination" means instrumental placement of semen into the vagina, cervical canal, or uterus of a recipient.~~

~~"Donor" means an individual who is unrelated by marriage to the recipient and who contributes sperm or ova used in the following procedures: treatment of infertility by artificial insemination; in vitro fertilization; gamete intrafallopian tube transfer; zygote intrafallopian tube transfer or any other gamete, zygote, or embryo transfer; or other intervening medical technology using sperm or ova.~~

~~"Embryo" means the product of a fertilized ovum prior to the eighth week of development inside a uterus.~~

~~"Gamete" means either sperm or ova.~~

~~"Gamete intrafallopian tube transfer" means placement of harvested ova and sperm into the fallopian tube or tubes of a recipient.~~

~~"HIV-1" means the retrovirus causing the human immunodeficiency virus infection, type 1.~~

~~"HIV-2" means the retrovirus causing the human immunodeficiency virus infection, type 2.~~

~~"In vitro fertilization" means placement of a zygote or embryo that has been fertilized outside the body into the uterus of a recipient.~~

~~"Zygote" means a fertilized ovum prior to cell cleavage.~~

~~"Zygote intrafallopian tube transfer" means placement of a zygote or zygotes into the fallopian tube or tubes of a recipient.~~

12VAC5-90-240. ~~Excluding donors with high risk factors.~~ (Repealed.)

~~A. Practitioners using gametes for the treatment of infertility by transfer of such gametes to a recipient shall interview all gamete donors at the time of donation in order to screen for high risk behavior indicating potential exposure to HIV-1 and HIV-2.~~

~~B. Any gamete donor reporting infection with HIV-1 or HIV-2 or any of the following risk factors shall be excluded from donating:~~

~~1. Men who have had sex with another man within the preceding five years.~~

~~2. Persons who have injected drugs for a nonmedical reason in the preceding five years, including intravenous, intramuscular, and subcutaneous injections of recreational or illegal drugs.~~

~~3. Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates.~~

~~4. Persons who have had sex in exchange for money or drugs in the preceding five years.~~

~~5. Persons who have had sex in the preceding 12 months with any person described in subdivisions 1 through 4 of this subsection or with any person suspected of being infected with HIV-1 or HIV-2.~~

6. Persons who have been exposed within the last 12 months to known or suspected HIV-1 or HIV-2 infected blood through percutaneous inoculation (e.g., needle stick) or through contact with an open wound, nonintact skin, or mucous membrane.

7. Current inmates of correctional systems, including jails and prisons, and individuals who have been confined in jail or incarcerated in prison for more than 72 consecutive hours during the previous 12 months.

8. Persons who have had or have been treated for syphilis or gonorrhea during the preceding 12 months.

9. Persons who within 12 months of donation have undergone acupuncture, ear or body piercing or tattooing in which sterile procedures were not used or where it is unknown if sterile procedures were used.

10. Persons who choose to defer from donation whether or not they report any of the above potential exposures to HIV-1 or HIV-2.

12VAC5-90-250. Storage of semen pending negative HIV tests. (Repealed.)

Semen specimens from donors shall be stored and withheld from use for at least 180 days following donation and used only if the donor tests negative for serum antibodies for HIV-1 and HIV-2 on enzyme-linked immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at least 180 days after donation.

12VAC5-90-260. Use of ova after negative HIV tests. (Repealed.)

Ova shall be used only if the donor tests negative for serum antibodies to HIV-1 and HIV-2 on enzyme-linked immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at the initiation of the cycle during which the ova are harvested.

12VAC5-90-270. Notifying recipients of option to delay transfer. (Repealed.)

Practitioners using ova, embryos, or zygotes for the treatment of infertility or other medical technology involving the transfer of ova, embryos, or zygotes to a recipient shall notify these recipients of the option for having donor ova fertilized and the resultant zygotes frozen and then transferred to the recipient only if the ova donor is negative for serum antibodies for HIV-1 and HIV-2 on enzyme-linked immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at least 180 days after donation.