Chapter 6 – Environmental Health
Subchapter 5

Radiological Health Rule

Table of Contents

Part A: Radiation-Producing Machines 2

1.0 Authority 2

2.0 Purpose and Scope 2

3.0 Definitions 2

4.0 Exemptions 11

5.0 Registration 12

6.0 Inspections 19

7.0 Standards for Protection Against Radiation 19

8.0 X-Ray Imaging in the Healing Arts and Veterinary Medicine 34

9.0 Particle Accelerators and Therapeutic Radiation Machines in the Healing Arts 70

10.0 Radiation Safety Requirements for Radiation Generating Machines Not Used in the Healing Arts 124

11.0 Radiation Safety Requirements for Industrial Radiographic Machines 132

12.0 Radiation Safety Requirements for Particle Accelerators Not Used in the Healing Arts 137

13.0 Record Keeping Requirements 144

14.0 Notice, Corrective Actions, and Enforcement 144

Part B: Radioactive Materials 145

Section I. Overview 145

Section II. Radioactive Material 158

Part C: Vermont Yankee Nuclear Power Station (VYNPS) 169

DRAFT

Part A: Radiation-Producing Machines

1.0 Authority

This rule is adopted pursuant to 18 V.S.A. Chapter 32.

2.0 Purpose and Scope

2.1. Part A of this Rule establishes standards for the control of ionizing radiation-producing machines for the protection of occupational and public health and safety.

2.2. Part A of this rule regulates x-ray and other ionizing radiographic diagnostic and/or therapeutic equipment used by physicians, dentists, and other health professionals, as well as veterinary, industrial and other non-medical x-ray equipment, and occupational sources of radiation.

2.3. Part A of this Rule applies to all persons who receive, possess, use, or transfer machine-based sources of radiation, except that nothing in this Rule shall be construed to limit the kind or amount of radiation that may be applied intentionally to a patient for diagnostic or therapeutic purposes by or under the direction of a practitioner of the healing arts licensed by the State of Vermont.

3.0 Definitions

3.1. "AAPM" means the American Association of Physicists in Medicine.

3.2. "Absorbed dose" means the energy imparted by ionizing radiation per unit of mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

3.3. "Accredited Dosimetry Calibration Laboratory (ADCL)" means a laboratory, accredited by AAPM, which provides calibration services for most radiation measurement instrumentation available in the medical or health physics community. Every piece of equipment used in this laboratory has its calibration directly traceable to the National Institute of Standards and Technology (NIST)."

3.4. "Adult" means and individual 18 years or more in age.

3.5. "Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

3.6. "Air kerma (exposure) rate" means the kinetic energy released in the mass of a small volume of air by ionizing radiation, per unit time. Air kerma is measured in joules per kilogram (J/kg). For diagnostic x-rays, air kerma is the same as the absorbed

DRAFT

dose in gray (Gy) delivered to the volume of air in the absence of scatter. (1 Gy = 100 rem)

3.7. "Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition, examine the microstructure, and/or ascertain certain characteristics of materials.

3.8. "Annual" means twelve consecutive months.

3.9. "As low as is reasonably achievable (ALARA)" means the principle of making every reasonable effort to maintain exposures to radiation as far below the dose limit in this Rule as is practical, consistent with the purpose for which the regulated activity is undertaken, taking into account the state of technology, and the economics of improvements in relation to the benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and regulated materials in the public interest.

3.10. "Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product or source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the regulated entity. It does not include radiation from source, byproduct, or special nuclear materials regulated by this Rule.

3.11. "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure called a cabinet that is independent of existing architectural structures except the floor. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. This definition includes x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

3.12. "Commissioner" means the Commissioner of the Vermont Department of Health, or designee.

3.13. "Declared pregnant person" means a person who has voluntarily informed the regulated entity, in writing, of their pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant person withdraws the declaration in writing or is no longer pregnant.

3.14. "Department" means the Vermont Department of Health.

DRAFT

3.15. "Diagnostic x-ray system" means an assemblage of components for the generation, emission, and reception of x-rays and the transformation, storage, and visual display of the resultant x-ray image, with the assembled system designed and used for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

3.16. "Direct supervision" means that the person being supervised remains in the physical presence of the supervisor at all times.

3.17. "Dose-area product (DAP)" means the product of the air kerma and the area of the irradiated field and is typically expressed in Gy-cm2, so it does not change with distance from the x-ray tube.

3.18. "Dose equivalent" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv). Other necessary modifying factors include the specific energy or spectrum of energies of radiation; the specific size and shape of the source of radiation and radiation detector; the specific radiation scattering characteristics in the environment; differences in temperature, humidity, and atmospheric pressure of the radiation detector and radiation environment; limitations of the radiation detector; characteristics of the specific tissues absorbing the radiation; and differences in physiological responses in specific persons absorbing the radiation.

3.19. "Effective dose equivalent" means the sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated.

3.20. "Electronic brachytherapy system" means a therapeutic radiation machine in which an x-ray source is used to irradiate tissue by intracavitary, intraluminal, interstitial, or similar application with the source in contact with, very close to, or at a distance usually less than five centimeters from the target volume.

3.21. "Embryo/fetus" means the developing human organism from conception until the time of birth.

3.22. "Exposure" means being exposed to ionizing radiation or to radioactive material. The unit of measurement of external exposure is the roentgen (R).

3.23. "Exposure value" means the numerical value of the measured exposure in units of milliroentgen or roentgen where 1 roentgen equals exactly 2.58×10^{-4} coulombs per kilogram of air at standard temperature and pressure.

3.24. "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

DRAFT

3.25. "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

3.26. "Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more radiation machines are installed, located and/or used.

3.27. "Gray" means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads).

3.28. "General supervision" means that the supervisor is readily available for consultation or intervention on the premises where radiologic technology services are being provided.

3.29. "Healing arts" means medicine, surgery, dentistry, osteopathy, podiatry and chiropractic."

3.30. "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in one hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that radiation penetrates.

3.31. "Individual" means any human being.

3.32. "Individual monitoring" means:

3.32.1. The assessment of dose equivalent by the use of devices designed to be worn by an individual; or

3.32.2. The assessment of dose equivalent by the use of survey data.

3.33. "Industrial radiographic machine" means an instrument designed for the examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images. This does not include machines containing radioactive materials.

3.34. "Interventional x-ray" means imaging used for guidance of procedures. Imaging includes, but is not limited to, fluoroscopy and CT scan.

3.35. "Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

3.36. "Limits" (dose limits) means the permissible upper bounds of radiation doses.

3.37. "Member of the public" means any individual except when that individual is receiving an occupational dose.

DRAFT

3.38. "Mini c-arm x-ray system" means a system that meets the following criteria:

3.38.1. Source-image receptor distance less than or equal to 45 cm (18 inches)

3.38.2. Field of view less than or equal to 15 cm (6 inches)

3.38.3. Maximum kVp less than or equal to 80 kVp; and

3.38.4. Maximum mA less than or equal to 0.25 mA

3.39. "Minor" means an individual less than 18 years of age.

3.40. "Monitoring" (radiation monitoring, radiation protection monitoring) means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

3.41. "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from regulated and unregulated sources of radiation, whether in the possession of the regulated entity or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, from voluntary participation in medical research programs, or as a member of the public.

3.42. "Personal Supervision" means a Qualified Medical Physicist must exercise General supervision and be present in the room during the performance of the procedure.

3.43. "Position Indicator Device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance, without regard to whether the device incorporates or serves as a beam-limiting device.

3.44. "Public dose" means the dose received by a member of the public from exposure to radiation or to radioactive material released by a regulated entity, or to any other source of radiation under the control of a regulated entity. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, or from voluntary participation in medical research programs.

3.45. "Qualified Expert" means a person who designs or evaluates shielding for a radiation machine. A Qualified Expert shall have current certification in health physics or a subfield of medical physics by:

3.45.1. The American Board of Medical Physics; or

3.45.2. The American Board of Health Physics; or

3.45.3. The Canadian College of Medical Physics; or

3.45.4. The American Board of Radiology in a radiological physics category; or

3.45.5. The American Board of Science in Nuclear Medicine in: radiation protection or nuclear medicine physics and instrumentation; and

3.45.5.1. Holds a master or doctorate degree from an accredited college or university in physics, biophysics, radiological physics, health physics, or medical physics; and

3.45.5.2. Has satisfactorily completed 2 years of training and work experience acceptable to the Department that includes one year of documented, full-time training in the appropriate field under the supervision of a qualified expert.

3.46. "Qualified Health Physicist" and "Health Physicist" means an individual who specializes in radiation biology, applying scientific understanding of the physical interaction of radiation with the body and environment to maintain protection from the potential hazards of ionizing and nonionizing radiation. The combination of education and experience for health physicists depends on the specific field in which the health physicist is engaged.

3.47. "Qualified Medical Physicist" means an individual who is competent to independently provide clinical professional services in one or more of the subfields of medical physics. A Qualified Medical Physicist is qualified to practice only in the subfield(s) in which they are certified by a national certifying body. A list of the subfields and the recognized national certifying bodies can be found on the Department's website.

3.48. "Quarter" means a period of time equal to one-fourth of the year observed by the regulated entity (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

3.49. "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 Joule/kilogram (0.01 gray). A subunit of the rad is the millirad. One millirad = 0.001 rad.

3.50. "Radiation" and "ionizing radiation" mean gamma rays and X-rays, alpha and beta particles, high speed electrons, neutrons, protons, and other nuclear particles. Radiation, as used in this Rule, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

3.51. "Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation. Radiation machine includes any accelerator and/or x-ray system, subsystem, or equipment.

3.52. "Radiation Protection Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or

presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation.

3.53. "Radiation Safety Officer" means, for Part A of this rule, an individual who, under the authorization of the licensee or registrant of a radiation installation, administers a radiation protection program in accordance with Part A of this rule and is qualified by training and experience in radiological health to evaluate the radiation hazards of such installation and administer such radiation protection program. Additionally, for healing-arts purposes, the radiation safety officer shall be:

3.53.1. A practitioner of the healing arts or veterinary medicine, licensed in accordance with State of Vermont regulations to engage in the healing arts or veterinary medicine, and practicing within the scope of their professional practice; or

3.53.2. A physicist certified by the American Board of Health Physics, the American Board of Radiology in a branch of physics related to the type of use of radiation sources in the installation, or, an individual with equivalent training and experience."

3.54. "Radiation Therapist" means an individual who possesses a current State of Vermont Radiation Therapist professional license in accordance with State licensing requirements.

3.55. "Radiation Therapy Physician" means an individual who possesses a current State of Vermont professional license to practice medicine in accordance with State licensing requirements, and who is trained to use therapeutic radiation machines on humans. A Radiation Oncologist is one type of radiation therapy physician.

3.56. "Radiation Therapy Physicist" means an individual who is currently registered with the Department as a Qualified Medical Physicist. A Radiation Therapy Physicist must also meet the applicable requirements of Section 9.3, including a certification in the applicable subfield.

3.57. "Radiation Therapy Veterinarian" means a veterinarian trained to use therapeutic radiation machines on animals.

3.58. "Radiographer" means for the purposes of Part A, any individual who performs or who, in attendance at the site where the industrial radiographic machine(s) are being used, personally supervises industrial radiographic operations and who is responsible to the registrant for assuring compliance with the requirements of the Department's regulations

DRAFT

3.59. "Radiographer's assistant" means, for the purposes of Part A, any individual who under the direct supervision of a radiographer, uses radiographic exposure devices or radiation survey instruments in industrial radiography.

3.60. "Registrant" means any person who is registered with the Department and is legally obligated to register with the Department pursuant to these regulations.

3.61. "Regulated entity" means all persons who receive, possess, use, or transfer sources of ionizing radiation in the State of Vermont.

3.62. "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). A subunit of the rem is the millirem (mrem). One mrem = 0.001 rem.

3.62.1. As used in this Rule, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

Table I. Quality Factors and Absorbed Dose Equivalencies

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent
X-, gamma, or beta	1	1
Alpha particles, multiple-charged particles, fission fragments, and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

3.63. "Restricted area" means an area, access to which is limited by the registrant for the purpose of protecting individuals against undue risks from exposure to radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

3.64. "Roentgen" means a measure of exposure and is equivalent to 2.58×10^{-4} coulombs per kilogram in air at standard temperature and pressure. A subunit of the roentgen is the milliroentgen (mR). One mR = 0.001 R.

3.65. "Scan" or "patient scanning" means the process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms

DRAFT

3.66. “Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

3.67. "Security screening system" means radiation-generating equipment used for the sole purpose of screening an individual who is in custody of a law enforcement agency to identify contraband items that would present a security threat within a secured facility perimeter.

3.68. “Sievert” means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor. One Sv = 100 rems.

3.69. “Site boundary” means the line beyond which the land or property is not owned, leased, or otherwise controlled by the regulated entity.

3.70. “Source-image receptor distance (SID)” means the distance from the source to the center of the input surface of the image receptor.

3.71. “Source-skin distance (SSD)” means the distance between the source and the skin of the patient.

3.72. “Stochastic effects” means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

3.73. “Storage” means a condition in which a device or source is not being used for an extended period of time and has been made inoperable.

3.74. “Survey” means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radiation-producing machines and measurements or calculations of levels of radiation.

3.75. “Target-to-Skin Distance (TSD)” means the distance measured along the beam axis from the center of the front surface of the x-ray target, or electron virtual source, or the nominal position of the electron source to the surface of the irradiated object or patient.

3.76. "Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for radiation therapy, including external beam and electronic brachytherapy systems.

3.77. “Unrestricted area” means any space not meeting the definition of restricted area.

DRAFT

3.78. "Useful beam" and "Primary beam" means the radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

3.79. "Weighting factor" for an organ or tissue means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the weighting factors can be found in Table II.

Table II. Organ Dose Weighting Factors

Tissue	Tissue weighting factor wT	ΣwT
Bone-marrow (red), colon, lung, stomach, breast, remaining tissues(*)	0.12	0.72
Gonads	0.08	0.08
Bladder, esophagus, liver, thyroid	0.04	0.16
Bone surface, brain, salivary glands, skin	0.01	0.04
	Total	**1.00**

**Remaining tissues: Adrenals, extrathoracic region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate, small intestine, spleen, thymus, uterus/cervix.*

3.80. "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

4.0 Exemptions

4.1. The following materials, machines, and conditions are exempt from Part A of this Rule:

4.1.1. Radioactive materials of an equivalent specific radioactivity not exceeding that of natural potassium (10^{-9} curies per gram of potassium).

4.1.2. Quantities of byproduct, source, accelerator produced, and special nuclear materials exempt from licensing requirements of the U.S. Nuclear Regulatory Commission (NRC).

4.1.3. Domestic television receivers and video display terminals, provided the effective dose rate at 5 centimeters from any outer surface is less than 0.5 mrem per hour.

4.1.4. Other electrical equipment that produces radiation incidental to its operation for other purposes, provided that the dose equivalent rate averaged over an area of 10 cm^2 does not exceed 5 μSv (0.5 mrem) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

4.1.5. Radiation machines in transit or in storage incident to transit. This exemption does not apply to the providers of radiation machines for mobile services. Facilities that have placed all radiation machines in storage, including on-site storage, and have notified the Department in writing, are exempt from the requirements of this Rule. This exemption is void if any radiation machine is energized resulting in the production of radiation.

4.1.6. A radiation machine that is out of service yet kept at a facility is exempt from the registration requirements provided the radiation machine has been made physically inoperable by inactivating or dismantling the electrical circuitry such that the radiation machine is not capable of producing radiation.

4.1.7. Financial institutions that take possession of radiation machines as the result of foreclosure, bankruptcy, or other default of payment are exempt from the requirements in this Part to the extent that they demonstrate that the unit is operable for the sole purpose of selling, leasing, or transferring. However, written notification to the Department shall be required.

4.1.8. Other sources of radiation that have been granted a waiver by the Department.

5.0 Registration

5.1. Purpose and Scope

5.1.1. This Section provides for the registration with the Department of ionizing radiation machine facilities and persons providing radiation machine installation, servicing and/or services.

5.1.2. In addition to the requirements of this Section, all registrants are subject to the applicable provisions of the Section 7.0 of this Rule. In addition, some registrants are subject to provisions of Sections 8.0, 9.0, 10.0, 11.0, or 12.0 of this Rule.

5.2. Prohibitions

5.2.1. All registrants shall prohibit any person from providing radiation machine servicing or services as described in 5.7.4 to their radiation machine facility until such person provides evidence of registration with the Department as a provider of services in accordance with Section 5.7.

5.3. **Shielding Plan Review**

5.3.1. Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations utilizing ionizing radiation machines shall be submitted by the applicant to the Department for review and approval. The required information is denoted in the Department's Shielding Plan Review Guidance document, which can be found on the Department's website.

5.3.2. Prior to the plan review and approval, the Department may require the applicant to utilize a shielding design service provider that is registered with the Department in order to determine the shielding requirements.

5.3.3. The Department may require additional conditions as necessary, including modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Sections 7.2 through 7.6 of this Rule.

5.3.4. After installation of a radiation machine, the registrant shall maintain for inspection by the Department:

5.3.4.1. The maximum rated technique factors of each machine;

5.3.4.2. A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

5.3.4.2.1. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

5.3.4.2.2. The type and thickness of materials, or lead equivalency, of each protective barrier, and the results of a visual inspection of shielding installed.

5.3.5. A facility area is exempt from the requirements of Section 5.3 if:

5.3.5.1. Only dental intraoral, dental panoramic, mini-c-arm, podiatric, or bone densitometry equipment is used in the area;

5.3.5.2. Only mobile or portable x-ray equipment is used infrequently and not regularly in the same location;

5.3.5.3. Only cabinet x-ray equipment is used in the area; or

5.3.5.4. Exemption for a specific area or location has been applied for in writing and granted by the Department.

5.4. **Registration of Radiation Machine Facilities**

5.4.1. Each regulated entity having a radiation machine facility, except those exempted in Section 4.0, shall apply for registration of such facility with the Department prior to the operation of a radiation machine facility. Application for registration shall be completed on forms published by the Department and shall contain all the information required by the form and accompanying instructions.

5.4.2. A practitioner, licensed by the respective state licensing board, responsible for directing the operation of radiation machines, shall be designated on each healing arts application. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility has more than one licensed practitioner (for example, hospitals, large clinics, or multi-practitioner practices).

5.4.3. Registered facilities shall register each source of ionizing radiation with the Department within 30 days after the acquisition of such source.

5.4.4. The owner or person having possession of any source of ionizing radiation not exempted in Section 4.0 shall re-register such source every calendar year.

5.5. **Registration of Mobile Machine Operations**

5.5.1. In addition to the requirements of Section 5.4, the applicant shall submit the following information:

5.5.1.1. An established main location where the machine(s), records, etc. will be maintained for inspection. This shall be a street address, not a post office box number.

5.5.1.2. If a mobile van is used with a fixed unit inside, provide the floor plan indicating protective shielding and the operator's location.

5.6. **Registration of Healing Arts Screening and Medical Research**

5.6.1. Authorization for healing arts screening may be granted by the Department provided the registrant demonstrates that such healing arts screening will not result in undue risk.

5.6.2. Each healing arts screening program shall obtain prior written approval by the Department.

5.6.3. In addition to the requirements of Section 5.4, each applicant shall apply for and receive authorization for healing arts screening before initiating a screening program, using a separate application provided by the Department.

5.6.4. Persons requesting that the Department approve a healing arts screening program, except for mammography, shall submit the Department's applications, which includes but is not limited to questions and documentation covering the following information and evaluation:

5.6.4.1. Name and address of the applicant and, where applicable, the names and addresses of locations within Vermont where the service will be provided.

5.6.4.2. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

5.6.4.3. A detailed description of the x-ray examinations proposed in the screening program (i.e., type and number of views).

5.6.4.4. Description of the population to be examined in the screening program, (i.e., age range, gender, physical condition, and other appropriate information).

5.6.4.5. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

5.6.4.6. An evaluation conducted by a qualified expert, of the x-ray system(s) to be used in the screening program. The evaluation shall include the following:

5.6.4.6.1. Documentation that such system(s) satisfy all requirements of this Section; and

5.6.4.6.2. Estimation of patient entrance skin exposures from the x-ray examinations to be performed.

5.6.4.7. A description of the diagnostic x-ray quality control program.

5.6.4.8. Documentation of the technique protocols for the x-ray examination procedures to be used.

5.6.4.9. The name and Vermont license number of each health care provider who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

5.6.4.10. Procedures to be used in advising the individuals screened and their health care provider(s) of the results of the screening procedure and any further medical needs indicated.

DRAFT

5.6.4.11. Procedures for the retention or disposition of the images and other records pertaining to the x-ray examinations.

5.6.4.12. Frequency of screening of individuals.

5.6.4.13. The duration of the screening program.

5.6.5. The applicant shall immediately notify the Department if any information submitted to the Department becomes invalid or outdated.

5.6.6. FDA/MQSA-certified facilities that are registered with the Department for the use of dedicated mammographic equipment for mammography screening are approved for mammography screening only and are considered to have met the requirements of Section 5.6.1.

5.6.7. In addition to the requirements of Section 5.4, any research using radiation machines on humans shall be approved by an Institutional Review Board (IRB) as required by Title 45, CFR, Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one practitioner of the healing arts to direct any use of radiation in accordance with Section 8.0.

5.7. Registration of Servicing and Services

5.7.1. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of providing or offering to provide radiation machine servicing or services in Vermont shall apply for registration of such services with the Department within 30 days following the effective date of this regulation or thereafter prior to providing or offering to provide any such services.

5.7.2. Application for registration shall be completed on forms published by the Department and shall contain all information required by the Department as indicated on the forms and accompanying instructions.

5.7.3. Any individual who performs radiation machine assembly, installation or service shall meet the following educational and experience requirements:

5.7.3.1. Completion of a structured educational program that includes training in radiation machine safety, assembly, installation and service, including, but not limited to:

5.7.3.1.1. A baccalaureate degree in electrical engineering with specialized training in radiation producing devices; or

5.7.3.1.2. A one-year associate degree in biomedical equipment repair; or

5.7.3.1.3. Equivalent manufacturer, military or other technical school training; and

5.7.3.2. For each service category requested:

5.7.3.2.1. At least 6 months of supervised, documented training on assembly, installation and service of the applicable radiation machine.

5.7.4. For the purposes of Section 5.7, services may include but shall not be limited to:

5.7.4.1. Installation and/or servicing of radiation machines and associated radiation machine components;

5.7.4.2. Calibration of radiation machines or radiation measurement instruments or devices;

5.7.4.3. Radiation protection, medical physics or health physics consultations or surveys;

5.7.4.4. Personnel dosimetry services; and

5.7.4.5. Provider of equipment.

5.8. **Issuance of Notice of Registration**

5.8.1. Upon a determination that an applicant meets the requirements of this Rule, including payment of any applicable fees, the Department shall issue a notice of registration.

5.8.2. Except as provided by Section 5.9.2, each notice of registration shall expire at the end of the specified day in the month and year stated therein.

5.8.3. No individual shall perform services that are not specifically stated for that individual on the notice of registration issued by the Department.

5.9. **Renewal of Notice of Registration**

5.9.1. Application for renewal of registration shall be filed in accordance with Sections 5.4 or 5.7.

5.9.2. In any case in which a registrant not less than 30 days prior to the expiration of their existing notice of registration has filed an application in proper form for renewal, such existing notice of registration shall not expire until the application status has been finally determined by the Department.

5.10. **Report of Changes**

The registrant shall notify the Department in writing before making any change that would render the information contained in the application for registration and/or the notice of registration no longer accurate.

5.11. **Approval Not Implied**

No person, in any advertisement, shall refer to the fact that their facility is registered with the Department pursuant to the provisions of Sections 5.4 or 5.7, and no person shall state or imply that any activity under such registration has been approved by the Department.

5.12. **Assembler and/or Transfer Obligation**

5.12.1. Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in Vermont shall notify the Department via email or written notification within 15 days of:

5.12.1.1. The name and address of persons who have received these machines;

5.12.1.2. The manufacturer, model, and serial number of each radiation machine transferred; and

5.12.1.3. The date of transfer of each radiation machine.

5.12.2. Providing the Department with a copy of the completed FDA Form 2579 will satisfy the notification requirement identified in 5.12.1.

5.12.3. A person shall not make, sell, lease, transfer, lend, assemble, or install radiation machines, or the supplies used for such machines, that do not meet the requirements of this Rule.

5.13. **Reciprocal Recognition of Out-of-State Machines**

5.13.1. Whenever any radiation machine is to be brought into Vermont, for any temporary use, the person proposing to bring such machine into Vermont shall give written notice to the Department at least 3 working days before such machine is to be used in Vermont. The notice shall include:

5.13.1.1. The type of radiation machine;

5.13.1.2. The nature, duration, and scope of use;

5.13.1.3. The exact location(s) where the radiation machine is to be used; and

5.13.1.4. States in which this machine is registered.

5.13.2. If, for a specific case, the 3 working-day period would impose an undue hardship on the person, upon application to the Department, permission to proceed sooner may be granted.

5.13.3. The person referred to in Section 5.13.1 shall:

5.13.3.1. Comply with all applicable regulations of the Department;

5.13.3.2. Supply the Department with such other information as the Department may reasonably request; and

5.13.3.3. Not operate within Vermont on a temporary basis in excess of 180 calendar days per year.

5.14. **Certification of Qualified Medical Physicists for Registration**

5.14.1. All persons registered to provide medical physics services shall be certified by at least one of the organizations in the appropriate fields or specialties in which services are provided. A list of the subfields and the recognized national certifying bodies can be found on the Department's website.

5.14.2. Qualified Medical Physicists for mammography shall meet the requirements specified by the Mammography Quality Standards Act of 1992, Public Law 102-539, 42 U.S.C. 263b, and 21 CFR Part 900.

6.0 Inspections

6.1. All regulated entities who receive, possess, use, or transfer sources of ionizing radiation shall:

6.1.1. Permit the Department at all times the opportunity to inspect and evaluate sources of radiation and the premises and facilities wherein such sources of radiation are used or stored, and shall make available pertinent data, as well as records and reports as may be required by the Department.

6.1.2. Grant the Department access to all records pertaining to the radiological health and safety of employees, and to any effect of the operation of the facility upon the environment.

6.1.3. Permit the Department to make unscheduled visits to the regulated facility for the purpose of obtaining samples and surveys for analysis.

7.0 Standards for Protection Against Radiation

7.1. **Radiation Protection Programs**

7.1.1. Each registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Section 7.0. See 7.10 for recordkeeping requirements relating to these programs.

7.1.2. The registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

7.1.3. The registrant shall, at intervals not to exceed 1 year, review the radiation protection program content and implementation.

7.2. Occupational Dose Limits for Adults

7.2.1. The registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 7.3, to the following dose limits:

7.2.1.1. An annual limit, which is the more limiting of:

7.2.1.1.1. The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

7.2.1.1.2. The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

7.2.1.2. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

7.2.1.2.1. A lens dose equivalent of 0.15 Sv (15 rem); and

7.2.1.2.2. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

7.2.2. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current calendar year and during the individual's lifetime, as specified in 10 CFR 20.1206.

DRAFT

7.2.3. The registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

7.2.4. Assigned dose equivalent

7.2.4.1. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent.

7.2.4.2. The deep-dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

7.2.4.3. For sources of radiation other than radioactive material, when a protective apron is worn and monitoring is conducted, the effective dose equivalent for external radiation shall be determined as follows:

7.2.4.3.1. When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25% of the limit specified in 7.2.1, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

7.2.4.3.2. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

7.3. Planned Special Exposures for Adults

7.3.1. A registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 7.2 provided that each of the following conditions is satisfied:

7.3.1.1. The registrant authorized a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

7.3.1.2. The registrant, and the employer if the employer is not the registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

7.3.1.3. Before a planned special exposure, the registrant provides in writing to each individual involved:

7.3.1.3.1. Information regarding the purpose of the planned operation; and

7.3.1.3.2. Information regarding the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

7.3.1.3.3. Instructions regarding the measures to be taken to keep the dose ALARA considering other risks that may be present.

7.3.2. Prior to permitting an individual to participate in a planned special exposure, the registrant ascertains prior occupational doses during the lifetime of the individual for each individual involved.

7.3.3. Subject to 7.2.2, the registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

7.3.3.1. The numerical values of any of the dose limits in 7.2.1 in any year; and

7.3.3.2. Five times the annual dose limits in 7.2.1 during the individual's lifetime.

7.3.4. The registrant maintains records of the conduct of a planned special exposure in accordance with 7.11 and submits a written report in accordance with 7.16.

7.3.5. The registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special

exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 7.2.1 but shall be included in evaluations required by 7.3.2 and 7.3.3.

7.4. Occupational Dose Limits for Minors

The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 7.2.1.

7.5. Dose Equivalent to an Embryo/Fetus

7.5.1. The registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant worker, does not exceed 5 mSv (0.5 rem).

7.5.2. The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant worker so as to satisfy the limit in 7.5.1.

7.5.3. If the dose equivalent to the embryo/fetus is found to have exceeded 5 mSv (0.5 rem), or is within 0.5 mSv (0.05 rem) of this dose, by the time the worker declares the pregnancy to the registrant, the registrant shall be deemed to be in compliance with 7.5.1 if the additional dose equivalent to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

7.5.4. An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant worker wearing a protective apron shall be located under the protective apron at the waist.

7.6. Dose Limits for Individual Members of the Public

7.6.1. Each registrant shall conduct operations so that:

7.6.1.1. The total effective dose equivalent to individual members of the public from the registered operation does not exceed 1 mSv (0.1 rem) in a calendar year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, and from voluntary participation in medical research programs; and

DRAFT

7.6.1.2. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released, does not exceed 0.02 mSv (0.002 rem) in any one hour.

7.7. Surveys and Monitoring

7.7.1. Each registrant shall make, or cause to be made, surveys of areas that:

7.7.1.1. Are necessary for the registrant to comply with Section 7.0; and

7.7.1.2. Are necessary under the circumstances to evaluate:

7.7.1.2.1. The magnitude and extent of radiation levels; and

7.7.1.2.2. The potential radiological hazards.

7.7.2. The registrant shall ensure that instruments and equipment used for quantitative radiation measurements are calibrated at intervals consistent with the guidance provided by the manufacturer, but not to exceed 2 years (24 months) unless otherwise noted in these regulations.

7.7.3. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by registrants to comply with 7.2.1, shall be processed and evaluated by a dosimetry processor:

7.7.3.1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

7.7.3.2. Approved in this accreditation process for the type of radiation included in the NVLAP program that most closely approximates the type of radiation for which the individual wearing the dosimeter is monitored.

7.7.4. The registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

7.8. Conditions Requiring Individual Monitoring of Occupational Dose

7.8.1. Each registrant shall monitor occupational exposure to radiation from sources under the control of the registrant and shall supply and require the use of individual monitoring devices by:

7.8.1.1. Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 7.2.1.

7.8.1.2. Minors likely to receive, in 1 year from sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of 5 mSv (0.5 rem);

7.8.1.3. Declared pregnant workers likely to receive during the entire pregnancy, from sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem); and

7.8.1.4. Individuals entering a high radiation area or a very high radiation area.

7.8.2. Upon written approval of the Department, an acceptable alternative to the use of continuous individual monitoring devices in order to demonstrate compliance with 7.8.1 may be used.

7.8.2.1. Acceptable alternative demonstrations that doses will not exceed 10 percent of the annual limits in 7.2.1, 7.4, and 7.5 include submittal to the Department of:

7.8.2.1.1. An acceptable documentation for six months of the use of continuous individual monitoring devices; or

7.8.2.1.2. An acceptable assessment from the appropriate Qualified Expert that takes into account design configuration, workload, radiation-producing machine output, and survey data.

7.8.2.2. To maintain approval of an acceptable alternative to the use of continuous individual monitoring devices:

7.8.2.2.1. Documentation under 7.8.2.1.1 or reassessment under 7.8.2.1.2 is required for any change in configuration, equipment, or workload; and

DRAFT

7.8.2.2.2. The registrant shall include assessment of individual monitoring in the review of the radiation protection program required annually by 7.1.

7.9. Storage and Control of Radiation-Producing Machines

7.9.1. The registrant shall secure from unauthorized removal or access radiation-producing machines, including those that are stored in unrestricted areas.

7.9.2. The registrant shall maintain control of radiation-producing machines that are in an unrestricted area and that are not in storage.

7.10. Records of Radiation Protection Programs

7.10.1. Each registrant shall maintain records of the radiation protection program, including:

7.10.1.1. The provisions of the program; and

7.10.1.2. Audits and other reviews of program content and implementation.

7.10.2. The registrant shall retain the records required by 7.10.1.1 until the registration requiring the record is terminated. The registrant shall retain the records required by 7.10.1.2 for three years after the record is made.

7.11. Records of Planned Special Exposures

7.11.1. For each use of the provisions of 7.3 for planned special exposures, the registrant shall maintain records that describe:

7.11.1.1. The exceptional circumstances requiring the use of a planned special exposure;

7.11.1.2. The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

7.11.1.3. What actions were necessary;

7.11.1.4. Why the actions were necessary;

7.11.1.5. What precautions were taken to assure that doses were maintained ALARA;

DRAFT

7.11.1.6. What individual and collective doses were expected to result; and

7.11.1.7. The doses actually received in the planned special exposure.

7.11.2. The registrant shall retain the records until the registration requiring these records is terminated.

7.12. Records of Individual Monitoring Results

7.12.1. Each registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 7.8, and records of doses received during planned special exposures, accidents, and emergency conditions. These records shall include, when applicable, the deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities.

7.12.2. The registrant shall make entries of the records specified in 7.12.1 at intervals not to exceed one year.

7.12.3. The registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant worker. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

7.12.4. The registrant shall retain each required record until the registration requiring these records is terminated.

7.13. Reports of Stolen, Lost, or Missing Radiation-Producing Machines

7.13.1. Telephone Reports

7.13.1.1. Each registrant shall report by telephone to the Department that a radiation machine has been stolen, lost, or missing immediately upon knowledge of such an occurrence.

7.13.2. Written Reports

7.13.2.1. Each registrant required to make a report pursuant to 7.13.1.1 shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

7.13.2.1.1. A description of the radiation machine involved, including the manufacturer, model and serial number, type and maximum energy of radiation emitted:

7.13.2.1.2. A description of the circumstances under which the loss or theft occurred;

7.13.2.1.3. A statement of disposition, or probably disposition, of the radiation machine involved;

7.13.2.1.4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

7.13.2.1.5. Actions that have been taken, or will be taken, to recover the radiation machine; and

7.13.2.1.6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of radiation machines.

7.13.2.2. Subsequent to filing the written report, the registrant shall also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.

7.13.2.3. The registrant shall prepare any report filed with the Department pursuant to 7.13 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

7.14. **Notification of Incidents**

7.14.1. Immediate Notification. Notwithstanding other requirements for notification, each registrant shall notify the Department as soon as possible but no later than 4 hours after the discovery of an event:

7.14.1.1. Involving a radiation machine possessed by the registrant that may have caused or threatens to cause an individual to receive:

7.14.1.1.1. A total effective dose equivalent of 0.25 Sv (25 rem) or more;

7.14.1.1.2. A lens dose equivalent of 0.75 Sv (75 rem) or more; or

7.14.1.1.3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more.

7.14.1.2. That prevents immediate protective actions necessary to avoid exposures to radiation that could exceed regulatory limits.

7.14.2. Twenty-four Hour Notification. Each registrant shall, within 24 hours of discovery of the event, report to the Department:

7.14.2.1. Each event involving loss of control of a radiation machine possessed by the registrant that may have caused, or threatens to cause, an individual to receive, in a period of 24 hours:

7.14.2.1.1. A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

7.14.2.1.2. A lens dose equivalent exceeding 0.15 Sv (15 rem); or

7.14.2.1.3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem).

7.14.2.2. An event in which equipment is disabled or fails to function as designed when:

7.14.2.2.1. The equipment is required by regulation to prevent exposures to radiation exceeding regulatory limits, or to mitigate the consequences of an accident;

7.14.2.2.2. The equipment is required to be available and operable when it is disabled or fails to function during the event; and

7.14.2.2.3. No redundant equipment is available and operable to perform the required safety function.

7.15. **Preparation and Submission of Reports**

7.15.1. Reports made by registrants in response to the requirements of 7.14 must be made as follows:

7.15.1.1. Registrants shall make the reports required by 7.14.1 and 7.14.2 to the Department by telephone or email. To the extent that the information

is available at the time of notification, the information provided in these reports must include:

7.15.1.1.1. The name of the person making the report and their call-back telephone number;

7.15.1.1.2. A description of the event, including time and date;

7.15.1.1.3. The exact location of the event; and

7.15.1.1.4. Any personnel radiation exposure data available.

7.15.1.2. Each registrant who makes a report required by 7.14.1 and 7.14.2 shall submit a written follow-up report to the Department pursuant to 7.15.3 within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made.

7.15.1.3. The provisions of 7.14 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 7.16.

7.15.2. In addition to the notification required by 7.14, each registrant shall submit a written report to the Department within 30 days after learning of doses in excess of any of the following:

7.15.2.1. The occupational dose limits for adults in 7.2;

7.15.2.2. The occupational dose limits for a minor in 7.4;

7.15.2.3. The limits for an embryo/fetus of a declared pregnant person in 7.5; or

7.15.2.4. The limits for an individual member of the public in 7.6.

7.15.3. Contents of Written Reports

7.15.3.1. Each report required by 7.15.1.2 or 7.15.2 shall include the following, as appropriate:

7.15.3.1.1. A description of the event, including the possible cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

7.15.3.1.2. The exact location of the event;

7.15.3.1.3. Date and time of the event; and

7.15.3.1.4. The results of any evaluations or assessments, including:

7.15.3.1.4.1. Estimates of each individual's dose;

7.15.3.1.4.2. The levels of radiation involved;

7.15.3.1.4.3. The cause of the elevated exposures or dose rates; and

7.15.3.1.4.4. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits and ALARA constraints.

7.15.3.2. Each report filed pursuant to 7.15 shall include for each occupationally overexposed individual: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in 7.5, the identifiers should be those of the declared pregnant person. The report shall be prepared so that this information is stated in a separate and detachable portion of the report and must be clearly labeled "Privacy Act Information: Not for Public Disclosure."

7.16. Reports of Planned Special Exposures

The registrant shall submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with 7.3, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 7.11.

7.17. Posting of Notices to Workers

7.17.1. Each registrant shall post current copies of the following documents:

7.17.1.1. The Vermont Radiological Health rule;

7.17.1.2. The certificate of registration;

7.17.1.3. The operating procedures applicable to activities under the registration; and

7.17.1.4. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to these regulations, and any response from the registrant.

7.17.2. If posting of a document specified in 7.17.1.1 or 7.17.1.3 is not practicable, the registrant may post a notice which describes the document and states where it may be examined.

7.17.3. Department documents posted pursuant to 7.17.1.4 shall be posted within 5 working days after receipt of the documents from the Department; the registrant's response, if any, shall be posted within 5 working days after dispatch from the registrant.

7.17.3.1. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

7.17.4. Documents, notices, or forms posted pursuant to 7.17 shall appear in a sufficient number of places to permit individuals engaged in work under the registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

7.18. **Instructions to Workers**

7.18.1. All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem) shall be:

7.18.1.1. Kept informed of the storage, transfer, or use of sources of radiation;

7.18.1.2. Instructed in the health protection problems associated with exposure to radiation to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

7.18.1.3. Instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these regulations for the protection of personnel from exposures to radiation;

7.18.1.4. Instructed of their responsibility to report promptly to the registrant any condition which may constitute, lead to, or cause a violation of these regulations, or unnecessary exposure to radiation;

7.18.1.5. Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation; and

7.18.1.6. Advised as to the radiation exposure reports which workers shall be provided pursuant to 7.12.

7.18.2. In determining those individuals subject to the requirements of 7.18.1, registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation which can reasonably be expected to occur during the life of a registered facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

7.19. **Notification and Reports to Individuals**

7.19.1. Radiation exposure data for an individual shall be reported to the individual as specified in this section.

7.19.1.1. Each notification and report shall:

7.19.1.1.1. Be in writing;

7.19.1.1.2. Include appropriate identifying data such as the name of the registrant, the name of the individual, and the individual's identification number; and

7.19.1.1.3. Include the individual's exposure information.

7.19.2. Each registrant shall provide to each monitored worker at least annually a written report of the worker's dose as shown in records maintained by the registrant, consistent with the requirements of 7.8.

7.19.3. Each registrant shall provide a report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the registrant.

7.19.3.1. The report shall include the dose record for each year the worker was required to be monitored.

7.19.3.2. Such report shall be provided within 30 days from the date of the request or within 30 days after the dose of the individual has been determined by the registrant, whichever is later.

7.19.3.3. The report shall cover the period of time the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the registration in which the worker participated.

7.19.4. At the request of a worker who is terminating employment with the registrant in work involving exposure to radiation during the current calendar year, each registrant shall provide at termination to each such worker a written report regarding the radiation dose received by that worker from operations of the registrant during the current calendar year.

7.19.4.1. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

8.0 X-Ray Imaging in the Healing Arts and Veterinary Medicine

8.1. Purpose and Scope

8.1.1. This Section establishes requirements, for which the registrant is responsible, for use of diagnostic and interventional x-ray equipment and imaging systems by, or under the direct supervision of, an individual authorized by and licensed in accordance with State of Vermont regulations to engage in the healing arts or veterinary medicine.

8.1.2. The provisions of this Section are in addition to, and not in substitution for, other applicable provisions of this Rule.

8.2. Administrative Controls

8.2.1. Each radiation machine used in the healing arts or veterinary medicine in the State of Vermont shall be registered with the Department as required by Section 5.4.

8.2.2. The registrant shall be responsible for directing the operation of the x-ray system(s) under their administrative control. The registrant shall assure that the requirements of this Section are met in the operation of the x-ray system(s).

8.2.3. Each radiation machine used on humans shall meet the Federal Performance Standards, Subchapter J – Radiological Health, 21 CFR 1020.30 through 1020.33.

8.2.3.1. X-ray imaging systems and their associated components, certified pursuant to 21 CFR 1020.30 through 1020.33, shall be maintained in compliance with applicable requirements of 21 CFR 1020.30 through 1020.33.

8.2.3.2. Diagnostic x-ray components and systems certified in accordance with 21 CFR 1020.30 through 1020.33 shall not be modified such that the component or system fails to comply with any applicable requirement of 21 CFR Part 1020 or this rule.

8.2.3.3. The registrant shall keep a record of the date, service provider, and details of each component or system modification.

8.2.3.4. Limited exemption from this requirement may be granted by the Department for a radiation machine manufactured prior to August 4, 1974, provided the registrant demonstrates that such exemption will not result in undue risk.

8.2.3.5. An x-ray system which does not meet the provisions of this Section shall not be operated for diagnostic purposes.

8.2.4. The registrant shall use approved providers of services, consistent with Section 5.7, including but not limited to operation of equipment; inspection of radiation machines and facilities; and assembly, installation, service, and/or calibration of radiation machines.

8.2.5. A radiation machine which does not meet the provisions of this Rule shall not be operated for diagnostic purposes unless the Department determines that the non-compliance shall not pose a significant risk or significantly affect image quality, and arrangements have been made to correct the non-compliance within 30 days.

8.2.6. Individuals who will be operating the radiation machine for healing arts or veterinary medicine use shall possess a current State of Vermont professional license, when applicable, in accordance with State licensing requirements.

8.2.6.1. Use of a radiation machine in the healing arts shall be by or under the general supervision of a physician, chiropractor, dentist, podiatrist,

DRAFT

or veterinarian who has a current active State of Vermont license to practice the healing arts.

8.2.6.2. The names and licenses of all personnel operating radiation machines for healing arts must be kept on file for Department inspection at each facility location.

8.3. **Written Technique Information**

8.3.1. Written technique information shall be readily accessible to the operator. This requirement may also be met if anatomically programmable controls are used.

8.3.2. For all examinations performed with the radiation machine, the following technique information shall be provided:

8.3.2.1. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

8.3.2.2. Equivalent manual technique information if Automatic Exposure Control (AEC) is not available;

8.3.2.3. Type and size of the image receptor combination to be used, if any; and

8.3.2.4. Source to image receptor distance to be used (except for dental intraoral radiography).

8.4. **Written Safety Procedures**

8.4.1. The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular radiation machine. The operator shall be able to demonstrate familiarity with these procedures.

8.4.2. When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

8.4.2.1. The written safety procedures shall list individual projections for where holding devices cannot be utilized; and

8.4.2.2. Written safety procedures shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

8.5. **General Specifications for Facility Design, Configuration, and Preparation**

8.5.1. Evaluation of Shielding Design Prior to Commencement of Operation

8.5.1.1. The floor plan and equipment configuration of a radiation machine facility shall be designed to meet all applicable requirements of this Rule and in particular to preclude an individual from receiving a dose in excess of the limits in Sections 7.2 through 7.6.

8.5.1.2. The floor plan and equipment configuration of each radiation machine facility shall be provided to a Qualified Expert who designs or evaluates shielding, for determination of shielding requirements in accordance with the Department's Shielding Design Requirements guidance document. These submittals shall include:

8.5.1.2.1. The normal location of the x-ray imaging system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

8.5.1.2.2. The structural composition and thickness of all walls, doors, partitions, floor, and ceiling of the room(s) concerned, if that information is available.

8.5.1.2.3. The dimensions of the room(s) concerned and inter-floor distances if space above or below is occupied.

8.5.1.2.4. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned.

8.5.1.2.5. If there is an exterior wall, the distance to the closest area(s) where it is likely that individuals may be present.

8.5.1.2.6. A description of the x-ray imaging system and components, including the make and model of the equipment.

8.5.1.2.7. The type of examination(s) or treatment(s) that will be performed with the equipment.

8.5.1.2.8. Information on the anticipated workload of the x-ray imaging system(s).

8.5.1.3. The shielding design by a Qualified Expert, required by Section 8.5.1.2, shall be completed and submitted to the Department prior to:

8.5.1.3.1. Construction of a new radiation machine facility;

8.5.1.3.2. Any renovation or modification of an existing radiation machine facility that has a potential to reduce the effectiveness of existing shielding from x-ray radiation; or

DRAFT

8.5.1.3.3. Installation of a new radiation machine in an existing facility.

8.5.1.4. A Qualified Expert who completes the shielding design required by Section 8.5.1.2 shall provide the shielding design to the radiation machine facility registrant, including the dimensional drawing specified by Section 8.5.3.

8.5.1.5. The facility registrant shall construct the shielding and configure the equipment in accordance with the recommendation(s) provided by the Qualified Expert pursuant to Section 8.5.1.4.

8.5.2. Evaluation of Shielding Design After Commencement of Operations

8.5.2.1. A Qualified Expert shall review and modify shielding design, consistent with Section 8.5.1 and the Department's Shielding Design Requirements guidance document, whenever:

8.5.2.1.1. An inspection or a survey during operation shows that a dose in excess of a limit in Sections 7.2 through 7.6 is possible;

8.5.2.1.2. An existing radiation machine facility is to be modified such that the existing shielding might be inadequate;

8.5.2.1.3. The useful beam orientation is changed;

8.5.2.1.4. The primary shielding is altered due to the modification or renovation of a facility;

8.5.2.1.5. Mobile or non-handheld portable x-ray equipment is to be used regularly in the same location;

8.5.2.1.6. Radiation machine workload (for example, mA-minute-per-week workload) has increased or is projected to increase above that which was the basis for the original shielding design; or

8.5.2.1.7. The registrant is unable to produce for inspection a written shielding design completed in accordance with Section 8.5.1 and/or Section 8.5.2, as is applicable.

8.5.2.2. If Qualified Expert analysis of operating conditions required by Section 8.5.2.1 indicates that an individual is likely to receive a dose in excess of the limits in Sections 7.2 through 7.6, then the facility registrant shall modify the shielding and/or equipment configuration in accordance with the recommendation(s) of the qualified expert.

8.5.3. The registrant shall retain, for each room in which a stationary x-ray imaging system is located, a current dimensional drawing that includes indication of the:

8.5.3.1. Use of each area adjacent to the room and an estimation of the extent of occupancy in each such area; and

8.5.3.2. Results by a Qualified Expert from calculation(s) for the type and thickness of material(s) in each protective barrier (for example, lead equivalency);

8.5.3.2.1. After installation and prior to commencement of operation, consistent with Section 8.5.1; and

8.5.3.2.2. Whenever shielding is modified, consistent with Section 8.5.2.

8.5.3.3. If the registrant is unable to produce from inspection the calculation(s) required by Section 8.5.3.2, results from survey(s) conducted by a Qualified Expert to determine radiation levels present under specified test conditions at the operator's position and at cognizable points outside the room.

8.5.4. Unless exempted in accordance with Section 5.3.5, for each x-ray imaging system for which a shielding design is required, the registrant shall maintain the following for inspection:

8.5.4.1. The installation as-built drawing(s); and

8.5.4.2. A signed statement by the registrant that all floor plan and equipment configuration specifications in any applicable written shielding designs required by Section 8.5 were explicitly followed.

8.6. Design Requirements for Diagnostic X-Ray Systems

8.6.1. In addition to other requirements of this Section, all diagnostic x-ray systems shall meet the requirements of Section 8.6, except as provided by Section 8.14 for dental uses and Section 8.16 for veterinary uses.

8.6.2. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

8.6.3. Each diagnostic x-ray imaging system shall meet the following equipment design and configuration requirements, in addition to complying with the requirements of 21 CFR 1020.30:

8.6.3.1. Beam Quality

8.6.3.1.1. Beryllium window tubes, except those used for mammography, shall have a minimum of 0.5 millimeter

aluminum equivalent filtration permanently installed in the useful beam.

8.6.3.1.2. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials that are always present between the source and the patient.

8.6.3.1.3. For x-ray systems that have variable kVp and variable filtration for the useful beam, a filtration control device shall prevent an exposure unless the minimum amount of filtration required by 21 CFR 1020.30(m)(1) is in the useful beam for the given kVp that has been selected.

8.6.3.2. Tube Heads

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

8.6.3.2.2. Any information displayed at the tube head shall meet the manufacturer's specifications.

8.6.3.3. Locks

8.6.3.3.1. All position locking, holding, and centering devices on the x-ray system and/or components shall function as designed.

8.6.3.4. The x-ray control shall provide:

8.6.3.4.1. Visual indication observable at or from the operator's protected position whenever x-rays are produced; and

8.6.3.4.2. A signal audible to the operator to indicate that the exposure has terminated.

8.6.3.5. Modification of Certified Diagnostic X-ray Components and Systems

8.6.3.5.1. Diagnostic x-ray components and systems certified in accordance with 21 CFR. Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this regulation unless a variance in accordance with 21 CFR 1010.4 or an exemption under § 534(a)(5) or § 538(b) of the Federal Food, Drug, and Cosmetic Act has been granted.

8.6.3.5.2. The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of

the system or component to comply with the applicable requirements of this Rule. The owner who causes such modification need not submit the reports required by this Rule, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with this Rule.

8.7. **Measurements, Maintenance, and Design Records**

8.7.1. The registrant shall maintain for inspection by the Department records for the previous 5 years of survey measurements, calibrations, maintenance, modifications, certification evaluations, and corrective actions for each x-ray imaging system with the names of persons who performed such services.

8.7.2. The registrant shall retain a dimensional drawing and accompanying calculation(s) and/or survey(s) as required by Section 8.5.3 for each room in which a stationary x-ray system is located, except as exempted under Section 5.3.5.

8.7.3. The registrant shall retain on file at the facility for the life of the facility each shielding design along with installer as-built drawings.

8.8. **Room Occupancy During Radiographic Exposure**

8.8.1. Except for patients who cannot be moved out of the room, only the staff, or other persons required for the medical procedure or training (e.g. a caregiver) shall be in the room during the radiographic exposure. Other than the patient being examined:

8.8.1.1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by lead equivalent material. If lead equivalent material for protection would interfere with the procedure, then dosimetry shall be used instead.

8.8.1.2. The x-ray operator, other staff, ancillary personnel and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material.

8.8.1.3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the person being imaged.

DRAFT

8.8.1.4. Written safety procedures, as required by Section 8.4.1, shall describe how the requirements of this Section will be met when using mobile or portable x-ray systems.

8.9. Control of Radiation Exposure

8.9.1. Exposure under this Section of any human being to the useful beam shall be solely for healing arts purposes and only after such exposure has been authorized by a physician, chiropractor, dentist, or podiatrist who has met the requirements of Section 8.2.6.

8.9.1.1. Deliberate exposure of any human being for training, demonstration, or other non-healing-arts purposes is strictly prohibited, unless specifically permitted in writing by the Department.

8.9.2. To reduce direct radiation exposure, individual shielding shall be available for all modalities (except for a case in which shielding would interfere with the gonad, thyroid, dental, or other diagnostic procedure).

8.9.3. In a case where the patient must hold the image receptor (except during an intraoral dental examination), any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

8.9.4. Each individual, other than the patient being examined, shall be positioned such that no part of the body will be struck by the useful beam unless protected by a minimum of 0.5 millimeter lead equivalent.

8.9.5. To reduce scatter radiation exposure, individual shielding shall be provided as follows:

8.9.5.1. The operator, other staff and ancillary personnel, and each other individual required for the medical procedure or who cannot be removed from the room, shall be protected from direct scatter radiation:

8.9.5.1.1. By a protective apron or whole-body protective barrier of not less than 0.25 millimeter lead equivalent; and/or

8.9.5.1.2. Shall be so positioned that the nearest portion of the body is at least a distance of 2 meters from the:

8.9.5.1.2.1. Tube head; and

8.9.5.1.2.2. Patient;

8.9.5.1.3. Except that protective positioning shall be as determined by the operator of a portable handheld x-ray device, as described in Section 8.15.

8.9.6. When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

8.9.6.1. Mechanical holding devices shall be used when the technique permits.

8.9.6.2. The human holder shall be instructed in personal radiation safety and protected as required by Section 8.9.5;

8.9.6.3. No individual shall be used routinely to hold image receptor or patients;

8.9.6.4. In those cases where the patient must hold the image receptor, except during dental examinations per Section 8.14, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

8.9.6.5. Each facility shall have protective aprons and gloves available in sufficient numbers to provide protection for all personnel who are involved with x-ray operations and who are otherwise not shielded.

8.9.6.6. A record shall be made of the examination and shall include the name of the human holder; date of the examination, number of exposures and technique factors utilized for the exposure(s).

8.9.7. Image processing procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

8.9.7.1. The fastest imaging system consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any diagnostic radiological imaging, except:

8.9.7.1.1. For veterinary radiography; or

8.9.7.1.2. For intraoral use in dental radiography when standard film packets are used.

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

8.9.7.3. Facilities that use radiographic film shall establish and implement a quality assurance program for x-ray film processing, whether processing is manual or automatic.

8.9.7.4. Each installation using a radiographic x-ray system and using analog image receptors (e.g., radiographic film) shall have available

suitable equipment for handling and processing radiographic film in accordance with the following provisions:

8.9.7.4.1. Manual Processing of Films

8.9.7.4.1.1. The temperature of solutions in the tanks shall be maintained within the range of 60 degrees F to 80 degrees F (16 degrees C to 27 degrees C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer.

8.9.7.4.1.2. Devices shall be utilized which will:

8.9.7.4.1.2.1. Indicate the actual temperature of the developer; and

8.9.7.4.1.2.2. Give an audible or visible signal indicating the termination of a preset processing time.

8.9.7.4.1.3. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

8.9.7.4.2. Automatic Processors and Other Closed Processing Systems

8.9.7.4.2.1. Films shall be processed in accordance with the time/temperature relationships recommended by the film manufacturer; and

8.9.7.4.2.2. Processing deviations from the requirements of Section 8.9.7.4.2.1 shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

8.9.7.5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

8.9.7.5.1. Be positioned properly (i.e., tube side facing the proper direction) and grid centered to the central ray.

8.9.7.5.2. If of the focused type, be of the proper focal distance for the source-image receptor distance (SID) being used.

8.9.7.6. Other Requirements

8.9.7.6.1. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light-tight container.

8.9.7.6.2. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to assure radiographs of good diagnostic quality.

8.9.7.6.3. Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

8.9.7.6.4. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

8.10. **Quality Assurance (QA) Program**

8.10.1. All registrants of diagnostic x-ray imaging equipment shall establish and maintain a quality assurance program consisting of quality control assessments addressing at least the following items:

8.10.1.1. Written standard operating procedures on radiation protection that are reviewed annually and updated as needed by management;

8.10.1.2. Employee review and written acknowledgement of standard operating procedures and policies on radiation protection; and

8.10.1.3. Record retention in accordance with applicable Vermont statutes and regulations, but in no case less than 3 years.

8.10.2. The quality assurance program shall be in written form and available for review by the Department.

8.10.3. To avoid unnecessary or duplicative radiation exposures, each human use and veterinary facility shall have an active image processing quality control and quality assurance (QA) program that follows manufacturers' recommendations and/or the standards of one of the following organizations:

8.10.3.1. The American College of Radiology; or

8.10.3.2. American Association of Physicists in Medicine; or

8.10.3.3. National Council on Radiation Protection and Measurements (NCRP); or

8.10.3.4. The Joint Commission

8.10.4. Each registrant that uses a hard copy imaging system with transmission viewing, whether with or without liquid chemistry, shall document that quality control and quality assurance have been performed according to recommendations of the manufacturer or a Qualified Medical Physicist, including:

8.10.4.1. Periodic printing of a sensitometric strip or pattern;

8.10.4.2. Documentation of low, medium, and high-density calibration and that any calibration which failed to meet a manufacturer's recommendation was corrected before the image printer was used to print another image; and

8.10.4.3. Annual review of all quality control tests.

8.10.5. Each registrant that uses an automatic film processor shall adopt an acceptable sensitometric quality control program.

8.10.5.1. Film processors used to develop radiographs shall be adjusted and maintained to meet the technical development specifications for the radiography film in use.

8.10.5.2. For all x-ray imaging systems, a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast, and fog, shall be performed according to recommendations of the manufacturer and/or a Qualified Medical Physicist.

8.10.6. Each registrant that uses a manual film process shall:

8.10.6.1. Follow applicable manufacturer's development time and temperature recommendations, which shall be available for review;

8.10.6.2. Measure and log development temperature each day of use; and

8.10.6.3. Document in writing the change of developer chemicals at least every month.

8.10.7. The registrant shall control darkroom lighting such that:

8.10.7.1. Exposure of a film to the darkroom safelight for one minute does not increase the optical density of that film by more than 0.1 optical density units when the test film has a latent image sufficient to produce a density between 1.0 and 2.0 optical density units prior to safe light exposure.

8.10.7.2. If used, daylight film handling boxes preclude fogging of the film.

8.10.7.3. The base plus fog of an unexposed film does not exceed 0.25 optical density units when developed by the routine procedure used by the facility.

8.10.8. All film storage, including pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

8.10.9. The registrant shall ensure that each monitor used for primary image interpretation is evaluated according to recommendations of the manufacturer, a Qualified Medical Physicist and/or one of the following nationally recognized organizations:

8.10.9.1. The American Association of Physicists in Medicine; or

8.10.9.2. The American College of Radiology; or

8.10.9.3. NCRP; or

8.10.9.4. The Joint Commission

8.10.10. The registrant shall ensure that computed and digital radiography cassettes and cassette readers used for primary image interpretation are evaluated periodically according to recommendations of the manufacturer and/or a Qualified Medical Physicist and/or a nationally recognized organization listed in 8.10.9.

8.11. Reports and Notifications of Radiation Medical Events

8.11.1. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of ionizing radiation from a diagnostic radiation machine meets one or more of the following criteria for a radiation medical event:

8.11.1.1. A patient or human research subject receives an unintended skin dose greater than 2 Gy (200 rads) to the same area in a single procedure.

8.11.1.2. A patient or human research subject receives in a single procedure greater than:

8.11.1.2.1. Five times the intended dose index, and 500 mGy (50 rads) to any organ; or

8.11.1.2.2. Five times the intended dose index, and 50 mSv (5 rem) total effective dose.

8.11.1.3. Wrong patient or wrong site for the entire procedure when the resultant dose:

8.11.1.3.1. Exceeds 500 mGy (50 rads) to any organ; or

8.11.1.3.2. Total effective dose is greater than or equal to 50 mSv (5 rem).

8.11.1.4. Equipment failure, personnel error, accident, mishap or other unusual occurrence with the administration of ionizing radiation that exceeds 50 mGy (5 rads) total effective dose.

8.11.2. Any wrong patient or wrong site imaged, regardless of dose received, shall be reported, documented and addressed internally within the facility, and the records maintained for inspection.

8.11.3. The registrant shall notify the Department by telephone or email no later than the next business day after discovery of the radiation medical event.

8.11.4. The registrant shall submit a written report to the Department within 15 business days after discovery of the radiation medical event. The written report shall include:

8.11.4.1. The registrant's name;

8.11.4.2. Date of event and date discovered;

8.11.4.3. The total estimated dose received;

8.11.4.4. The imaging procedure(s) performed;

8.11.4.5. The type of equipment in use (e.g., CT, fluoroscopy, radiographic, other);

8.11.4.6. The manufacturer and model of the unit used;

8.11.4.7. Why the event occurred;

8.11.4.8. How the event was discovered;

8.11.4.9. The effect, if any, on the individuals(s) who is the subject of the radiation medical event;

8.11.4.10. Actions, if any, that have been taken, or are planned, to prevent recurrence;

8.11.4.11. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

8.11.4.12. If there was notification, what information was provided to the individual.

DRAFT

8.11.5. Records of Radiation Medical Events

8.11.5.1. A registrant shall retain a record of a radiation medical event reported in accordance with Section 8.11 as part of the patient's permanent medical record.

8.12. Special Requirements for General Purpose Radiographic Equipment

8.12.1. Administrative Controls

8.12.1.1. In addition to the provisions of Sections 8.2 through 8.11, the requirements of this Section apply to all x-ray imaging equipment and associated facilities other than:

8.12.1.1.1. Fluoroscopy (in Section 8.13);

8.12.1.1.2. Dental (in Section 8.14);

8.12.1.1.3. Handheld Diagnostic (in Section 8.15)

8.12.1.1.4. Veterinary (in Section 8.16);

8.12.1.1.5. Computed tomography (in Section 8.17);

8.12.1.1.6. Mammography (in Section 8.18)

8.12.1.1.7. Bone densitometry (in Section 8.19)

8.12.2. For each general purpose stationary, mobile, and/or portable x-ray imaging system subject to the requirements of this Section, the useful beam shall be limited to the area of clinical interest.

8.12.3. Radiation Exposure Control Devices

8.12.3.1. X-ray Control

8.12.3.1.1. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

8.12.3.1.1.1. Exposure of one-half second or less, or

8.12.3.1.1.2. During serial radiography when a means shall be provided to permit completion of any single exposure of the series in process.

8.12.3.1.2. Except for a bone densitometry system, each x-ray control shall be located in such a way as to meet the following requirements:

8.12.3.1.2.1. For stationary x-ray systems, the x-ray control shall be permanently mounted in a

separated area behind a whole body protective barrier, as described in shielding plan, where the operator is required to remain during the entire exposure. If no barrier is described in the shielding plan, then not less than 0.25 millimeter lead equivalent shall be used.

8.12.3.1.2.2. Mobile and portable x-ray systems shall be required to have an exposure switch so arranged that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube, and the useful beam, or behind a whole body protective barrier (of not less than 0.25 millimeter lead equivalent) where the operator is required to remain during the entire exposure.

8.12.3.1.3. The settings to be used during an exposure shall be indicated before the exposure begins.

8.12.3.1.3.1. When automatic exposure controls are used, the exposure settings that are set prior to the exposure shall be indicated.

8.12.3.1.3.2. On equipment having fixed exposure settings, permanent markings visible from the operator's position are acceptable.

8.12.3.2. Accuracy for a Diagnostic X-ray System with Any Certified Component

8.12.3.2.1. If manufacturer recommendations regarding exposure settings are available, those shall be followed.

8.12.3.2.2. If manufacturer recommendations are not available, the following criteria shall be used:

8.12.3.2.2.1. The kVp shall not deviate from indicated values by more than 7%.

8.12.3.2.2.2. The timer accuracy shall not deviate from indicated values by more than:

8.12.3.2.2.2.1. Ten percent for an indicated time of greater than 20 milliseconds; or

8.12.3.2.2.2.2. Fifty percent for an indicated time of 20 milliseconds or less, or 1 pulse, whichever is greater.

8.12.4. For each general-purpose x-ray imaging system, the registrant shall ensure that manufacturer maintenance recommendations are followed.

8.12.5. For each general-use diagnostic radiographic x-ray system, the registrant shall ensure that written quality control and quality assurance procedures are available and in use, including for facility operations and emergencies.

8.12.5.1. The quality control and quality assurance procedures shall be consistent with Section 8.10 and shall follow:

8.12.5.1.1. Recommendations of the manufacturer;

8.12.5.1.2. Recommendations of a Qualified Medical Physicist; and/or

8.12.5.1.3. Standards of one of the following nationally recognized organizations:

8.12.5.1.3.1. The American College of Radiology; or

8.12.5.1.3.2. The American Association of Physicists in Medicine; or

8.12.5.1.3.3. NCRP; or

8.12.5.1.3.4. The Joint Commission

8.12.5.2. Routine periodic quality control shall be comparable to the recommendations of the manufacturer and Qualified Medical Physicist, or the following:

8.12.5.2.1. Cassette maintenance (for example, erasure and/or screen cleaning);

8.12.5.2.2. Images inspected for evidence of clinically relevant artifacts (for example, dust and non-uniformities) with appropriate corrective action (for example, cleaning of screens) taken as needed and documented;

8.12.5.2.3. Analysis of repeated and/or rejected images;

8.12.5.2.4. Investigation of errors outside a control range;

8.12.5.2.5. Measurements using phantoms, if required; and

8.12.5.2.6. Measurements of scattered radiation at the operator's position, if required.

8.12.5.3. Quality assurance shall be comparable to the following:

8.12.5.3.1. All quality control tests shall be reviewed annually (in extenuating circumstances, 14 months is permissible);

8.12.5.3.2. Imaging systems shall be tested in accordance with standards and protocols published by the American College of Radiology, the American Association of Physicists in Medicine, NCRP, and/or the Joint Commission.

8.12.5.3.3. The frequency of quality control testing and corrective actions taken as a result are followed and documented.

8.13. Special Requirements for Fluoroscopy Systems

8.13.1. In addition to the provisions of Section 8.6 and Section 8.10, the requirements of this Section apply to all fluoroscopic x-ray imaging equipment and facilities.

8.13.2. Only image-intensified or direct-digital-receptor fluoroscopic equipment shall be used.

8.13.3. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

8.13.4. Each registrant that uses fluoroscopic x-ray systems shall maintain for each examination a record of:

8.13.4.1. The cumulative fluoroscopic exposure time used, and the number of images recorded from the fluoroscopic image receptor; or

8.13.4.2. The air kerma and/or dose-area product.

8.13.4.3. This record shall include patient identification, type and date of examination, the fluoroscopic system used, and operator's name. The record shall be maintained for 5 years.

8.13.5. Control of Scattered Radiation

8.13.5.1. Fluoroscopic table designs, when combined with procedures utilized, shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25-millimeter lead equivalent.

8.13.5.2. Equipment configuration, when combined with procedures, shall be such that no portion of any staff or ancillary individual's body,

DRAFT

except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

8.13.5.2.1. Is at least 120 centimeters from the center of the useful beam, or

8.13.5.2.2. The radiation has passed through not less than 0.25-millimeter lead equivalent material (e.g., drapes, Bucky-slot cover-sliding or folding panel, or self-supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in Section 8.8.1.2.

8.13.5.3. The Department may grant exemptions to the requirements of Section 8.13.5.2 where a sterile field will not permit the use of the normal protective barriers. Where the use of pre-fitted sterilized covers for the barriers is practical, the Department shall not permit such exception.

8.13.6. Patient Dose Evaluation

8.13.6.1. Each registrant performing fluoroscopically-guided interventional procedures shall develop written policies and procedures to:

8.13.6.1.1. Identify those procedures which have a potential to result in patient doses exceeding the threshold for injury;

8.13.6.1.2. Reduce the probability of such exposures; and

8.13.6.1.3. Ensure that appropriate action occurs for patients receiving doses that warrant follow-up.

8.13.6.2. The registrant shall have patient dose monitoring procedures in place and shall document (in the patient's medical record) an estimate of the absorbed dose to the skin, or sufficient information to enable this calculation. When the fluoroscopy unit is equipped with an air kerma dose readout, the recording of this value shall suffice as a patient dose record.

8.13.6.3. The registrant shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury (i.e. a cumulative absorbed dose to the skin equal to or greater than 2 Gy (200 rads)). This evaluation shall be noted in the patient's medical record and reviewed by the Radiation Safety Officer, who shall consult with other Qualified Experts as needed.

8.13.7. Radiation Therapy Simulation Systems

8.13.7.1. Radiation therapy simulation systems shall be exempt from the requirements of 21 CFR 1020.32(a), provided such systems are intended only for remote control operation.

8.13.7.2. Radiation therapy simulation systems shall be exempt from the requirements of 21 CFR 1020.32(b) and 21 CFR 1020.32(d) when used for therapy simulation purposes.

8.13.7.3. As an alternative to the requirements of 21 CFR 1020.32(g), radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

8.14. Special Requirements for Dental X-ray Imaging Systems

8.14.1. In addition to the provisions of Sections 8.2 through 8.11, the requirements of this Section apply to equipment and associated facilities used for dental x-ray imaging.

8.14.2. For each dental x-ray imaging system, manufacturer maintenance specifications shall be followed.

8.14.3. Each dental x-ray imaging system shall meet the following equipment design and configuration requirements.

8.14.3.1. Cephalometric and volumetric dental x-ray systems shall meet the equipment design and configuration requirements of Sections 8.5 and 8.12.2.

8.14.3.2. Intraoral and panoramic dental x-ray systems shall meet the following requirements:

8.14.3.2.1. kVp Limitations. Dental x-ray machines with a nominal fixed kVp of less than 60 kVp shall not be used to make diagnostic dental radiographs of humans.

8.14.3.2.2. Each x-ray imaging system designed for use with an intraoral image receptor shall be provided with means to SSD to not less than 20 centimeters. Open-ended cones are required to reduce scattered radiation.

8.14.3.2.3. Each x-ray imaging system designed for use with an intraoral image receptor shall be provided with means to limit the beam such that the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters.

DRAFT

8.14.3.2.4. As provided in Section 5.3.5, neither the shielding design described in Section 8.5 nor the dimensional drawing, calculation, or survey described in Section 8.5.3 are required for intraoral or panoramic dental equipment.

8.14.3.2.4.1. Conventional building materials in partitions, floors, and ceilings may provide adequate radiation shielding for dental installations. When a conventional building structure does not provide adequate shielding, the shielding shall be increased by providing greater thickness of building materials or by adding lead, concrete, steel, or other suitable materials to the walls, floor, and ceiling of an existing room.

8.14.3.2.5. Mechanical support of the tube head and pointer cone shall maintain the exposure position without drift or vibration of sufficient magnitude to cause the need for manually restraining the tube or retaking the x-ray.

8.14.4. Each dental x-ray imaging system shall meet the following radiation exposure operational control requirements.

8.14.4.1. Cephalometric and volumetric beam dental x-ray systems shall meet the radiation exposure control requirements of Section 8.12.3.

8.14.4.2. Intraoral and panoramic dental x-ray systems shall meet the following radiation exposure control requirements instead of the requirements of Section 8.12.3:

8.14.4.2.1. Timer Reproducibility

8.14.4.2.1.1. With a timer setting of 0.5 seconds or less, the average exposure period (T_{avg}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $T_{avg} >= 5(T_{max} - T_{min})$.

8.14.4.2.2. X-ray Control for Intraoral or Panoramic Dental X-ray Systems

8.14.4.2.2.1. A control shall be incorporated into each x-ray imaging system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.

8.14.4.2.2.2. Each control shall be located as follows:

8.14.4.2.2.2.1. For stationary x-ray systems, and mobile or non-handheld portable systems, the x-ray control shall be permanently mounted in a separated area behind a whole body protective barrier (of not less than 0.25 millimeter lead equivalent) where the operator is required to remain during the entire exposure, or the exposure control shall be such that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube, and the useful beam.

8.14.4.2.3. Exposure Reproducibility

8.14.4.2.3.1. The estimated coefficient of variation of radiation exposure shall be no greater than 0.05, for any specific combination of selected exposure settings.

8.14.4.2.4. Linearity shall be in accordance with 21 CFR 1020.31(c)(3).

8.14.4.2.5. Accuracy

8.14.4.2.5.1. Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.

8.14.4.2.5.2. If manufacturer specifications are not available, accuracy of all exposure factors shall be within 10% of the selected factor(s).

8.14.4.2.6. Beam Quality

8.14.4.2.6.1. All dental x-ray systems shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent.

8.14.4.2.6.2. Systems operating above 70 kVp are subject to the filtration requirements of 21 CFR 1020.30(m)(1).

8.14.4.2.7. Patient and image receptor holding devices shall be used when the techniques permit.

8.14.4.2.8. The tube housing and the position indicator device (PID) shall not be handheld during an exposure, except as provided in Section 8.15 for portable handheld x-ray equipment.

8.14.4.2.9. The x-ray system shall be operated in such a manner that the area of the useful beam at the patient's skin is minimized.

8.14.4.2.10. Dental fluoroscopy shall not be used.

8.14.4.2.11. Image receptors of speeds slower than ANSI Speed Group E/F shall not be used for intraoral radiography (i.e., D-speed film shall not be used).

8.14.4.2.12. Screen-film systems of speeds slower than ANSI 400 shall not be used for panoramic or cephalometric imaging. Rare-earth systems shall be used.

8.14.4.3. The x-ray control shall provide:

8.14.4.3.1. Visual indication observable at the operator's protected position whenever x-rays are produced; and

8.14.4.3.2. A signal audible to the operator shall indicate that the exposure has terminated.

8.14.4.4. A thyroid shield shall be used for patients to reduce patient exposure to scattered radiation (except for a case in which shielding would interfere with the diagnostic procedure).

8.14.4.5. Absent structural protection against scatter radiation, during radiation machine operation at least a 2-meter distance (more than 6 feet) shall be maintained from any bystander location and between patient operating chairs.

8.14.5. For each dental x-ray imaging system, written quality control and quality assurance procedures shall include:

8.14.5.1. For processing of intraoral and panoramic films, performance of the following:

8.14.5.1.1. Follow applicable manufacturer's time and temperature specifications, which shall be available for review;

8.14.5.1.2. Measure and log temperature each day of use; and

8.14.5.1.3. Document in a written log the change of developer chemicals at least every month.

8.14.5.2. For volumetric dental systems, conduct periodic calibrations and annual quality control tests according to the manufacturer's specifications, including any additional or more frequent testing necessary at the recommendation of a Qualified Medical Physicist.

8.14.5.3. Annual review of all quality control tests.

8.15. Special Requirements for Handheld Dental Diagnostic X-Ray Imaging Systems

8.15.1. In addition to the provisions of Section 8.2 through 8.11, the requirements of this Section apply to equipment and associated facilities used for handheld dental diagnostic x-ray imaging.

8.15.2. For each handheld x-ray imaging system, manufacturer maintenance specifications shall be followed.

8.15.3. The registrant shall follow all applicable requirements set forth in Section 8.14, as well as all manufacturer requirements.

8.15.4. The following requirements are applicable to intraoral dental radiographic units designed to be operated as a handheld unit for human or veterinary use:

8.15.4.1. Intraoral dental radiographic units designed to be operated as a handheld unit for human or veterinary use must be approved in writing by the Department prior to being used in Vermont.

8.15.4.2. The machine shall be used only for dental diagnostic imaging or identification of a decedent.

8.15.4.3. Operators of handheld intraoral dental radiographic units shall be specifically trained to operate such equipment, and the registrant shall maintain proof of training for all operators.

8.15.4.4. The registrant shall provide a copy of their operating, safety and security procedures to operators to prevent unauthorized or improper use.

8.15.4.5. When operating a handheld intraoral dental radiographic unit, operators shall be protected from direct scatter radiation by protective material of not less than 0.25 millimeter lead equivalent to protect the operator's torso, hands, face, and gonads.

8.15.4.5.1. A backscatter shield attached to the unit is required and shall be positioned as close to the patient as possible and the operator shall take care to remain in a protective position.

8.15.4.5.2. The protective shielding on the unit shall not be removed or modified.

DRAFT

8.15.4.6. A separate exposure switch is not required for portable handheld x-ray equipment that has the control on the device.

8.15.4.7. A handheld intraoral dental radiographic unit shall be held with minimal motion during a patient examination such that the image produced is diagnostically useable. A tube stand may be utilized to immobilize a handheld intraoral dental radiographic unit during patient examination.

8.15.4.8. The operator shall ensure there are no bystanders within a radius of 6 feet from the patient being examined with a handheld intraoral radiographic unit.

8.15.4.8.1. The device shall not be operated if a person other than the patient, operator, and others directly involved in providing care, are present in the room in which the x-ray device will be operated. As provided in 8.8.1.1, if such person(s) are required to be present for the purpose of aiding in the procedure, such person(s) shall be provided with and required to wear full body shielding of no less than 0.25 millimeter lead equivalent and shall be required to remain out of the direct beam.

8.15.4.9. Handheld intraoral dental radiographic units shall not be used for patient examinations in hallways and waiting rooms.

8.15.4.10. The registrant shall comply with any facility-specific requirements established by the Department.

8.15.4.11. For battery-powered units, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

8.15.4.12. Handheld devices shall only be used with dental film speeds E or faster or with digital imaging.

8.15.4.13. A handheld intraoral dental radiographic unit shall not be left unattended without locking the unit, room, or building in some manner which prevents use of the unit by unauthorized persons.

8.15.4.14. Missing or stolen handheld devices shall be reported to the Department immediately. A written report of the loss including all available details shall be submitted to the Department within 24 hours.

8.15.4.15. The device shall have an inherent safety mechanism to prevent accidental exposures when the device is “on” but not active between imaging procedures. The device shall be maintained in lock down

(safety engaged) mode at all times between patient exposures so that the device cannot be accidentally operated.

8.16. Special Requirements for Veterinary Medicine Imaging Systems

8.16.1. In addition to the provisions of Section 8.2 through 8.11, and as appropriate also 8.13 and 8.17, the requirements in this Section apply to equipment and associated facilities used for veterinary x-ray imaging.

8.16.2. Each veterinary x-ray imaging system shall follow manufacturer maintenance specifications.

8.16.3. Each veterinary medicine installation shall meet the following equipment design and configuration requirements.

8.16.3.1. Equipment

8.16.3.1.1. The protective tube housing shall be equivalent to the requirements of 10 CFR 1020.30(k).

8.16.3.1.2. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

8.16.3.1.3. The local filtration permanently in the useful beam shall meet the requirement of 10 CFR 1020.30(m)(1).

8.16.3.2. A method shall be provided for visually defining the perimeter of the x-ray field.

8.16.3.2.1. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

8.16.3.3. Structural Shielding

8.16.3.3.1. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with Sections 7.2 and 7.4 through 7.6.

8.16.3.3.2. A veterinary installation shall meet the requirements of Section 8.5 in order to minimize radiation exposure to personnel and individual members of the public.

8.16.3.3.3. Veterinary facilities are exempt from the requirements of the Department's Shielding Design Requirements guidance

document as long as the requirements of Section 8.16.3.3 are met.

8.16.3.4. Linearity shall be in accord with 21 CFR 1020.31(c)(3).

8.16.3.5. Accuracy

8.16.3.5.1. Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.

8.16.3.5.2. If manufacturer specifications are not available, the following criteria shall be used:

8.16.3.5.2.1. The kVp shall not deviate from indicated values by more than 10%.

8.16.3.5.2.2. The timer accuracy shall not deviate from indicated values by more than:

8.16.3.5.2.2.1. Ten percent for an indicated time of greater than 20 milliseconds; or

8.16.3.5.2.2.2. Fifty percent for an indicated time of 20 milliseconds or less, or 1 pulse, whichever is greater.

8.16.3.6. Exposure Reproducibility

8.16.3.6.1. The coefficient of variation of exposure shall not exceed 0.05 when all exposure settings are held constant.

8.16.3.7. A dead-man type of exposure switch or equivalent remote device shall enable the operator to stand out of the useful beam.

8.16.4. Each veterinary medicine installation shall have the following operating and radiation exposure control procedures.

8.16.4.1. Whenever possible, the operator shall be positioned during radiographic exposures so that the nearest portion of the body is at least 2 meters (more than 6 feet) from both the tube head and the nearest edge of the image receptor.

8.16.4.1.1. For mobile or portable radiographic equipment, the radiographic exposure control switch shall be located on the machine where adequate personnel protection is provided to attenuate the direct and scatter radiation, or the length of the switch cord shall be such that the operator shall be able to

DRAFT

stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube, and out of the useful beam. A coil type extension switch cord capable of providing more than 2 meters of distance protection is recommended.

8.16.4.2. No individual, other than the operator, shall be in the x-ray room while exposures are being made, unless such individual's assistance is required, and the person is adequately protected by shielding and/or distance.

8.16.4.2.1. All other staff and ancillary personnel required for the procedure shall be protected from direct scatter radiation by protective aprons or whole-body protective barriers of not less than 0.25-millimeter lead equivalent.

8.16.4.3. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used.

8.16.4.3.1. Each individual other than the animal being examined shall be positioned such that no part of the body will be struck by the useful beam.

8.16.4.3.2. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and the individual shall be so positioned so that no part of the individual's body will be struck by the useful beam.

8.16.4.3.3. The exposure of any individual used for this purpose shall be maintained below the limits specified in Sections 7.2, 7.4, and 7.5.

8.16.4.4. Use of portable handheld x-ray equipment shall be consistent with Section 8.15.

8.16.4.5. Mobile or portable diagnostic x-ray equipment used regularly (e.g. greater than one week) in one location shall be considered a fixed installation and shall meet the requirements of Section 8.16.3.

8.16.5. Each veterinary x-ray imaging system shall have written quality control and quality assurance procedures that include:

8.16.5.1. For processing of veterinary films, performance of the following:

8.16.5.1.1. Follow applicable manufacturer's time and temperature specifications, which shall be available for review;

8.16.5.1.2. Measure and log temperature each day of use; and

DRAFT

8.16.5.1.3. Document in a written log the change of developer chemicals at least every month.

8.16.5.2. Annual review of all quality control tests.

8.17. Special Requirements for Computed Tomography (CT)

8.17.1. In addition to the provisions of Section 8.2 through 8.11, the requirements of Section 8.17 apply to equipment and associated facilities used for CT.

8.17.2. For a CT machine used only for veterinary applications, or a cone-beam CT used only for dental applications, the registrant may request from the Department exemption from any requirement of this Section that is not applicable to the practices of the registrant.

8.17.3. Each CT facility shall meet the following equipment design and configuration requirements:

8.17.3.1. Termination of Exposure

8.17.3.1.1. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection.

8.17.3.1.1.1. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices that monitor equipment function.

8.17.3.1.2. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by Section 8.17.3.1.1.

8.17.3.1.3. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

8.17.3.2. Patient Communication

8.17.3.2.1. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

8.17.3.2.2. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation

DRAFT

of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

8.17.3.2.3. Patient scanning shall be allowed only when a viewing system is available and in use.

8.17.4. Each CT facility shall have the following operating procedures and radiation exposure controls.

8.17.4.1. Console Performance

8.17.4.1.1. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

8.17.4.1.2. Information shall be readily available regarding the operation of the system.

8.17.4.1.3. Information regarding calibration of the system shall be readily available, including:

8.17.4.1.3.1. Dates of the latest calibration and routine quality checks (QCs) and the location within the facility where the results of those tests may be obtained;

8.17.4.1.3.2. Instructions on the use of the CT performance phantom(s) including a schedule of routine QCs appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent routine QCs conducted on the system;

8.17.4.1.3.3. When operators must select exposure settings, a current protocol shall be available at the control panel that specifies for each routine examination the CT conditions of operation and the typical number of scans per examination, including guidance for age-appropriate scanning.

8.17.4.2. Extraneous Radiation

8.17.4.2.1. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 21 CFR 1020.30(k).

8.17.4.3. Additional Requirements Applicable to CT x-ray Systems Containing a Gantry Manufactured After September 2, 1992.

8.17.4.3.1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

8.17.4.3.2. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the useful beam is possible.

8.17.4.3.3. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kg resting on the support device.

8.17.4.3.3.1. The patient support device shall be incremented from a typical starting position to the maximum incremented distance, the manufacturer's specified distance, or 30 centimeters, whichever is less, and then returned to the starting position.

8.17.4.3.3.2. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

8.17.4.3.3.3. When table increment is not the primary means of slice position location, the Qualified Medical Physicist may provide alternative measurement procedures to determine the accuracy of slice position, which shall be documented.

8.17.4.3.4. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

8.17.5. Each CT facility shall conduct required surveys, evaluations, calibrations, and routine QCs.

8.17.5.1. Surveys and Evaluations

8.17.5.1.1. A radiation survey, or inspection during construction, shall be made by, or under the direct supervision of, a Qualified Medical Physicist, to verify and document compliance with Section 7.6 for:

8.17.5.1.1.1. Any change in the facility or equipment that might cause a significant increase in radiation hazard; or

8.17.5.1.1.2. Any initial or new location for a CT imaging system that is designed to be transported from place to place.

8.17.5.1.2. CT x-ray systems that have undergone an x-ray tube change within 14 months of the last annual evaluation do not require a complete calibration at the time of the x-ray tube change, provided that:

8.17.5.1.2.1. The CT x-ray system operation after the tube change meets the criteria established by the Qualified Medical Physicist or the manufacturer of the x-ray tube.

8.17.5.1.2.2. Each CT system shall receive a survey by a Qualified Medical Physicist at least within 14 months of the previous survey.

8.17.5.2. Radiation Dosimetry

8.17.5.2.1. The radiation output of the CT x-ray system shall be measured by, or under the personal supervision of, a Qualified Medical Physicist:

8.17.5.2.1.1. At intervals (not exceeding 14 months) specified by a Qualified Medical Physicist;

8.17.5.2.1.2. In accordance with protocols published by a relevant nationally recognized organizations (e.g. AAPM Report 96), unless the Qualified Medical Physicist determines that a particular recommendation of such report is not warranted for the clinical tasks for which the equipment will be used;

8.17.5.2.1.3. With a calibrated dosimetry system:

8.17.5.2.1.3.1. That shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited

DRAFT

Dosimetry Calibration Laboratory (ADCL); and

8.17.5.2.1.3.2. Calibrated within the preceding 2 years.

8.17.5.2.2. CT dosimetry shall be evaluated by a Qualified Medical Physicist in accordance with protocols published by one of the following nationally recognized organizations:

8.17.5.2.2.1. The American Association of Physicists in Medicine; or

8.17.5.2.2.2. The American College of Radiology; or

8.17.5.2.2.3. NCRP; or

8.17.5.2.2.4. The Joint Commission

8.17.5.2.3. Records of measurements performed shall be maintained for a period of 3 years for inspection by the Department.

8.17.5.3. Routine QCs

8.17.5.3.1. The routine QC procedures shall be in writing and shall have been approved by a Qualified Medical Physicist.

8.17.5.3.2. The routine QC procedures shall incorporate the use of a commensurate CT performance phantom.

8.17.5.3.3. All routine QCs shall be performed at time intervals and under system conditions specified by a Qualified Medical Physicist.

8.17.5.3.4. Images shall be retained, at least until a new QC test is performed, as follows:

8.17.5.3.4.1. Photographic copies of the images obtained from the image recording device; or

8.17.5.3.4.2. Images stored in digital form on a storage medium compatible with the CT x-ray system.

8.17.5.3.5. Written or electronic records of the routine QCs performed shall be maintained for inspection by the Department.

8.17.6. Each CT system shall have written quality control and quality assurance procedures, including:

DRAFT

8.17.6.1. If a calibration required by Section 8.17.5.2 or a routine QC required by Section 8.17.5.3 identifies that a system operating parameter is outside a specified or recommended tolerance or range:

8.17.6.1.1. The CT x-ray system shall not be used on a patient except as permitted by documented instructions of the Qualified Medical Physicist (or by the radiologist in instances of artifacts); and

8.17.6.1.2. Correction or modification shall be made within 30 days of the date of the test identifying the problem.

8.17.6.2. The CT system shall meet the recommendations of the manufacturer or Qualified Medical Physicist and/or appropriate nationally recognized organization, or equivalent approved by the Department, for:

8.17.6.2.1. Alignment light accuracy;

8.17.6.2.2. Slice thickness;

8.17.6.2.3. Image quality; and

8.17.6.2.4. CT number accuracy.

8.17.6.3. All quality control tests shall be reviewed by a Qualified Medical Physicist at least annually.

8.18. Special Requirements for Mammography

8.18.1. In addition to the provisions of Sections 8.2 through 8.11, the requirements of this Section apply to equipment and associated facilities used for mammography.

8.18.2. Each facility performing mammography shall:

8.18.2.1. Meet the requirements of 21 CFR 900;

8.18.2.2. Have a valid certificate issued by the U.S. Department of Health and Human Services (HHS) pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 CFR 900;

8.18.2.3. Ensure that 21 CFR 900 quality control and quality assurance standards for maintaining viewing conditions and interpretation of an image are met.

8.18.3. The regulatory requirements of Section 8.0 shall also apply as appropriate to radiography of the breast performed:

8.18.3.1. During invasive interventions for localization or biopsy (for example, stereotactic biopsy procedures); or

8.18.3.2. With an investigational device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or

8.18.3.3. During any other procedure for radiography of the breast that the Department determines and designates.

8.19. **Special Requirements for Bone Densitometry**

8.19.1. In addition to the provisions of Sections 8.2 through 8.11, the requirements of this Section apply to equipment and associated facilities used for bone densitometry.

8.19.2. Bone densitometry systems shall be:

8.19.2.1. Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C - Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act; and

8.19.2.2. Maintained and operated in accordance with the manufacturer's specification and recommendations.

8.19.3. Bone densitometry systems with stepless collimators shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond 2% of the SID.

8.19.4. During the operation of any bone densitometry system:

8.19.4.1. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

8.19.4.2. The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure.

8.19.5. The registrant shall keep maintenance records for bone densitometry systems as prescribed by Section 8.19.2.2. These records shall be maintained for inspection by the Department for 3 years from the date the maintenance action was completed.

8.19.6. Bone densitometry on human patients shall be conducted only:

8.19.6.1. Under a prescription of a licensed practitioner of the healing arts; or

8.19.6.2. Under a screening program approved by the Department.

8.19.6.2.1. Any person proposing to conduct a bone densitometry screening program shall submit the information outlined in Section 5.6 and include the name and address of the licensed practitioner of the healing arts who will interpret the screening results.

9.0 Particle Accelerators and Therapeutic Radiation Machines in the Healing Arts

9.1. Purpose and Scope

9.1.1. This Section establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of this Section are in addition to, and not in substitution for, other applicable provisions of this Rule.

9.1.2. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Department. The registrant shall ensure that the requirements of this Section are met in the operation of the therapeutic radiation machine(s).

9.2. Administrative Controls

9.2.1. Each therapeutic radiation machine shall be registered with the Department.

9.2.2. The applicant shall have appointed a Radiation Safety Officer and include this information on the registration form.

9.2.3. A therapeutic radiation machine that does not meet the provisions of this Rule shall not be used for irradiation of patients.

9.2.4. For a therapeutic radiation machine used only for veterinary applications, the registrant may request from the Department exemption from any requirement of this Section that is not applicable to the practices of veterinary medicine.

9.3. Training for Qualified Medical Physicist

The registrant for any therapeutic radiation machine subject to the provisions of this Section shall require the Qualified Medical Physicist to be registered with the Department, under the provisions of Sections 5.7 and 5.14, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units.

9.4. Qualifications of Operators

9.4.1. Individuals who will be operating a therapeutic radiation machine for medical use on humans shall be licensed as a Radiation Therapist.

9.4.2. Each individual who will be operating a therapeutic radiation machine for veterinary use shall meet qualification criteria specified by the supervising radiation therapy veterinarian.

9.4.3. The names and training of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least 2 years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

9.5. **Written Safety Procedures**

9.5.1. Written (which can be in a digital format) safety procedures and rules shall be developed by a Qualified Medical Physicist that is certified in radiation therapy physics, and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine.

9.5.2. The operator shall be able to demonstrate to the Department familiarity with these rules.

9.6. **Exposure Prohibited**

9.6.1. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a Radiation Oncologist or radiation therapy physician.

9.6.2. The deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes is prohibited.

9.7. **Quality Management Program**

9.7.1. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in, and shall comply with, the provisions of the registrant's quality management program.

9.7.2. Each registrant subject to Sections 9.18, 9.19, or 9.21 shall develop, implement and maintain a written quality management program to provide high confidence that radiation will be administered by the operator as directed. The quality management program shall address, at a minimum, the following specific objectives:

9.7.2.1. Written Directive

9.7.2.1.1. A written directive must be dated and signed by a Radiation Oncologist or radiation therapy physician prior to the administration of radiation;

9.7.2.1.2. Notwithstanding Section 9.7.2.1.1, if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in writing in the patient's record and a revised written directive is signed by a Radiation Oncologist or radiation therapy physician within 48 hours of the oral revision.

9.7.2.1.3. The written directive shall contain the patient's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

9.7.2.1.4. A written revision to an existing written directive may be made provided that the revision is dated and signed by a Radiation Oncologist or radiation therapy physician prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

9.7.2.1.5. The registrant shall retain a copy of each written directive, in an auditable form, for 3 years after the date of each administration.

9.7.2.2. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

9.7.2.2.1. Prior to the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;

9.7.2.2.2. Therapeutic radiation machine final plans of treatment and related calculations are developed under the direct supervision of a therapeutic QMP, and in accordance with the respective written directives by:

9.7.2.2.2.1. Checking both manual and computer-generated dose calculations to verify they are correct and in accordance with the written directive; and

9.7.2.2.2.2. Verifying that any manual and computer-generated calculations are correctly transferred into the consoles of therapeutic radiation machines;

9.7.2.2.3. Each administration is in accordance with the written directive; and

9.7.2.2.4. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

9.7.2.2.5. A registrant shall retain a copy of the procedures required by Section 9.7.2.2 for the duration of the registration.

9.7.3. Each registrant using radiation therapy equipment shall have a quality management program that includes the following:

9.7.3.1. The specific staff, staff duties and responsibilities, equipment, and procedures,

9.7.3.2. An evaluation of a representative sample of patient administrations and a review of all recordable events, and all misadministrations, if any, to verify compliance with all aspects of the quality management program;

9.7.3.3. Reviews conducted at intervals not to exceed 1 year;

9.7.3.4. An evaluation of each review to determine the effectiveness of the quality management program and, if necessary, to make modifications to meet the requirements of these rules; and

9.7.3.5. Records of each review, including the evaluations and findings of the review, which shall be retained for 3 years.

9.7.4. The registrant shall submit a written copy of this quality management program to the Department.

9.7.5. The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

9.8. Shielding and Safety Design Requirements

9.8.1. Primary and Secondary Barriers

9.8.1.1. Each therapeutic radiation machine subject to Section 9.18 or Section 9.19 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with Sections 7.2 and 7.6.

9.8.2. Facility Design Information

9.8.2.1. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for Department approval prior to actual

installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is:

9.8.2.1.1. For any therapeutic radiation machine, the following basic facility information:

9.8.2.1.1.1. Facility name;

9.8.2.1.1.2. Facility telephone number;

9.8.2.1.1.3. Name of the individual responsible for preparation of the shielding plan;

9.8.2.1.1.4. Name and telephone number of the facility supervisor;

9.8.2.1.1.5. The facility street address;

9.8.2.1.1.6. The facility room number for the therapeutic radiation machine;

9.8.2.1.1.7. Indication if this is a new structure or a modification to existing structure(s);

9.8.2.1.1.8. The primary barriers for all wall, floor, and ceiling areas struck by the useful beam;

9.8.2.1.1.9. All secondary barriers provided in all wall, floor, and ceiling areas not having primary barriers;

9.8.2.1.1.10. If commercial software is used to generate shielding requirements, the software name, version, and date of revision;

9.8.2.1.1.11. If the software used to generate shielding requirements is not in the open literature, quality control sample calculations to verify the result obtained with the software;

9.8.2.1.1.12. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

9.8.2.1.1.13. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned, and any exterior wall(s), with distance to the closest area(s) where it is likely that individuals may be present; and

DRAFT

9.8.2.1.1.14. At least one example calculation which shows the methodology used to determine the amount of shielding required for each primary and secondary/leakage barrier, restricted and unrestricted areas, entry door(s), and shielding material in the facility.

9.8.2.1.2. In addition to the requirements listed in Section 9.8.2.1.1, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

9.8.2.1.2.1. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

9.8.2.1.2.2. Maximum design workload for the facility to include:

9.8.2.1.2.2.1. Total weekly radiation output expressed in gray (rad) or air kerma at 1 meter;

9.8.2.1.2.2.2. Total beam-on time per day or week;

9.8.2.1.2.2.3. The average treatment time per patient; and

9.8.2.1.2.2.4. The anticipated number of patients to be treated per day or week; and

9.8.2.1.2.3. A facility blueprint/drawing indicating:

9.8.2.1.2.3.1. Scale;

9.8.2.1.2.3.2. Direction of North;

9.8.2.1.2.3.3. Normal location of the therapeutic radiation machine's radiation port(s);

9.8.2.1.2.3.4. The port's travel and traverse limits;

9.8.2.1.2.3.5. General direction(s) of the useful beam;

9.8.2.1.2.3.6. Locations of any windows and doors;

DRAFT

9.8.2.1.2.3.7. The location of the therapeutic radiation machine control panel;

9.8.2.1.2.3.8. The location of the operator's booth if the control panel is located inside the therapeutic radiation machine treatment room; and

9.8.2.1.2.3.9. The operator's station at the control panel has a protective barrier sufficient to ensure compliance with Section 7.2.

9.8.2.1.3. In addition to the requirements listed in Section 9.8.2.1.1, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

9.8.2.1.3.1. Equipment specifications to include:

9.8.2.1.3.1.1. The manufacturer;

9.8.2.1.3.1.2. The model number of the therapeutic radiation machine;

9.8.2.1.3.1.3. The energy(s) and type(s) of radiation produced; and

9.8.2.1.3.1.4. The target to isocenter distance;

9.8.2.1.3.2. Maximum design workload for the facility including:

9.8.2.1.3.2.1. Total weekly radiation output expressed in gray or rad at 1 meter;

9.8.2.1.3.2.2. Total beam-on time per day or week;

9.8.2.1.3.2.3. The average treatment time per patient; and

9.8.2.1.3.2.4. The anticipated number of patients to be treated per day or week;

9.8.2.1.3.3. Facility blueprint or drawing indicating:

9.8.2.1.3.3.1. The floor plan and elevation views each indicating relative orientation of the therapeutic radiation machine;

9.8.2.1.3.3.2. Type(s), thickness, and minimum density of shielding material(s);

9.8.2.1.3.3.3. Direction of North; and

9.8.2.1.3.3.4. The locations and size of all beam penetrations through each ceiling, wall, floor, details of the door(s) and maze shielding barrier; and

9.8.2.1.3.4. A description of all assumptions that were in the shielding calculations including, but not limited to:

9.8.2.1.3.4.1. Design energy;

9.8.2.1.3.4.2. Workload;

9.8.2.1.3.4.3. Presence of integral beam-stop in unit;

9.8.2.1.3.4.4. Occupancy and use(s) of adjacent areas;

9.8.2.1.3.4.5. Fraction of time that useful beam will intercept each permanent barrier for all walls, floor and ceiling; and

9.8.2.1.3.4.6. Potential radiation exposure in both restricted and unrestricted areas.

9.8.2.1.4. In addition to the requirements listed in Section 9.8.2.1.3, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as minimum, the following additional information:

9.8.2.1.4.1. The structural composition, thickness, minimum density, and location of all neutron shielding material;

9.8.2.1.4.2. Description of all assumptions that were used in neutron shielding calculations including, but not limited to;

9.8.2.1.4.2.1. Neutron spectra as a function of energy;

9.8.2.1.4.2.2. Neutron fluence rate; and

DRAFT

9.8.2.1.4.2.3. Absorbed dose and dose equivalent for neutrons in both restricted and unrestricted areas;

9.8.2.1.4.3. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each restricted and unrestricted areas, entry door(s), maze and the neutron shielding material utilized in the facility; and

9.8.2.1.4.4. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

9.9. **Protection Surveys**

9.9.1. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with Section 9.11. The radiation protection survey shall be performed by, or under the direction of, a Qualified Medical Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

9.9.1.1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in Section 7.2; and

9.9.1.2. Radiation levels in unrestricted areas do not exceed the limits specified in Section 7.6.

9.9.2. In addition to the requirements of Section 9.9.1, a radiation protection survey shall also be performed prior to any subsequent medical use and:

9.9.2.1. After making any change in the treatment room shielding;

9.9.2.2. After making any change in the location of the therapeutic radiation machine within the treatment room;

9.9.2.3. After relocating the therapeutic radiation machine; or

9.9.2.4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

9.9.3. The survey record shall indicate all instances where the radiation levels exceed the requirements of Sections 7.2 or 7.6, as applicable. The survey record shall include:

9.9.3.1. The date of the measurement(s);

9.9.3.2. The reason the survey is required;

9.9.3.3. The name of the manufacturer of the therapeutic radiation machine;

9.9.3.4. The model number and serial number of the therapeutic radiation machine;

9.9.3.5. The instrument(s), with calibration details, used to measure the radiation levels;

9.9.3.6. A map of the areas surrounding the treatment room that were surveyed;

9.9.3.7. The measured dose rate at several points in each area expressed in microsievert (or millirem) per hour;

9.9.3.8. The calculated maximum radiation dose for each restricted and unrestricted area to demonstrate compliance with 7.6; and

9.9.3.9. The signature of the individual performing or exercising personal supervision of the survey.

9.9.4. If the results of the surveys required by Section 9.9.1 and Section 9.9.2 indicate any radiation levels in excess of the respective limit specified in Section 9.9.1, the registrant shall lock the control in the "OFF" position and not use the unit:

9.9.4.1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

9.9.4.2. Until the registrant has received a specific exemption from the Department.

9.10. Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program

9.10.1. If the survey required by Section 9.9 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by Section 7.6, before beginning the treatment program the registrant shall:

9.10.1.1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with Section 7.6;

9.10.1.2. Perform the survey required by Section 9.9 again; and

9.10.1.3. Include in the report required by Section 9.13 the results of the initial survey, a description of the modification made to comply with Section 9.10.1 and the results of the second survey.

9.11. Calibration of Survey Instruments

9.11.1. Calibration Required

9.11.1.1. The registrant shall ensure that the survey instruments used to show compliance with Section 9.0 have been calibrated before first use, at intervals not to exceed 12 months and following repair.

9.11.2. Calibration Protocols

9.11.2.1. To satisfy the requirements of Section 9.11.1.1, the registrant shall:

9.11.2.1.1. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST).

9.11.2.1.2. Calibrate at least 2 points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale.

9.11.2.2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10%.

9.11.2.3. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20% if a correction factor or graph is conspicuously attached to the instrument.

9.11.3. Record Retention

9.11.3.1. The registrant shall retain a record of each calibration required in Section 9.11.1.1 for 3 years. The record shall include:

9.11.3.1.1. A description of the calibration procedure; and

9.11.3.1.2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

9.11.4. Use of Calibration Services

9.11.4.1. The registrant may obtain the services of individuals licensed by the Department, the U.S. Nuclear Regulatory Commission or another Agreement State to perform calibrations of

survey instruments. Records of calibrations which contain information required by Section 9.11.3 shall be maintained by the registrant.

9.12. **Dosimetry Equipment**

9.12.1. The registrant shall have a calibrated dosimetry system available for use.

9.12.1.1. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL).

9.12.1.2. The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

9.12.1.3. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

9.12.1.4. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

9.12.2. The registrant shall have available for use a dosimetry system for quality assurance check measurements.

9.12.2.1. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with Section 9.12.1.

9.12.2.2. This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration.

9.12.2.3. The quality assurance check system may be the same system used to meet the requirement in Section 9.12.1.

9.12.3. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record shall include:

9.12.3.1. The date;

9.12.3.2. The model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by Sections 9.12.1 and 9.12.2;

9.12.3.3. The correction factors that were determined;

9.12.3.4. The names of the individuals who performed the calibration, intercomparison, or comparison; and

9.12.3.5. Evidence that:

9.12.3.5.1. Calibration was performed by the Accredited Dosimetry Calibration Laboratory (ADCL); or

9.12.3.5.2. The intercomparison was performed by, or under the direct supervision of, a Qualified Medical Physicist.

9.13. Reports of External Beam Radiation Therapy Surveys and Measurements

The registrant for any therapeutic radiation machine subject to Section 9.18 or 9.19 shall submit a copy of the records required in Section 9.9 and Section 9.10 to the Department within 30 days following completion of the action that initiated the record requirement.

9.14. Reports of Misadministrations

9.14.1. A registrant shall report to the Department any event resulting from intervention by a patient in which the administration of therapeutic radiation machine radiation results in, or is likely to result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

9.14.2. Except for an event resulting from intervention by a patient, a registrant shall report to the Department any event regarding the administration of a therapeutic radiation machine therapy dose:

9.14.2.1. Involves the wrong patient, wrong treatment modality, or wrong treatment site; or

9.14.2.2. The calculated weekly administered dose differs from the weekly prescribed dose by more than 30% (An event is not required to be reported as a misadministration if a dose deviation occurs due to the omission of a scheduled patient treatment which resulted from equipment failure, failure by the patient to be present for the treatment, or decision by the prescribing radiation therapy physician to delay or pause treatment.); or

9.14.2.3. The calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

9.14.3. The registrant shall notify the Department's Radiological Health Program by telephone or email within 24 hours after discovery of the misadministration.

DRAFT

9.14.4. The registrant shall submit a written report to the Department within 15 days after discovery of the misadministration. The written report shall include:

9.14.4.1. The registrant's name;

9.14.4.2. The name of the prescribing physician;

9.14.4.3. A brief description of the event;

9.14.4.4. Why the event occurred;

9.14.4.5. The effect, if any, on the individual(s) who received the misadministration;

9.14.4.6. Actions, if any, that have been taken, or are planned, to prevent recurrence;

9.14.4.7. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

9.14.4.8. If there was notification, what information was provided to the individual.

9.14.5. The report shall not contain the individual's name or any other information that could lead to the identification of the individual.

9.15. **Notifications of Misadministrations**

9.15.1. The registrant shall provide notification of an event of misadministration within 24 hours after its discovery:

9.15.1.1. To the referring physician;

9.15.1.2. To the individual who is the subject of the misadministration, or their responsible relative or guardian, unless the referring physician personally informs the registrant:

9.15.1.2.1. That based on medical judgment, telling the individual would be harmful; or

9.15.1.2.2. That he or she will inform the individual directly.

9.15.2. The registrant is not required to notify the individual without first consulting the referring physician.

9.15.3. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter.

9.15.4. The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

9.15.5. The registrant shall inform the individual who is the subject of the misadministration, or appropriate responsible relative or guardian, that a copy of the report was submitted to the Department;

9.15.6. Upon request by the individual who is the subject of the misadministration, the registrant shall provide a written description of both the event and the potential consequences as they may affect them.

9.15.6.1. The registrant shall provide a copy of the record shall be to the referring physician within 15 days after discovery of the misadministration.

9.15.7. Aside from the notification requirement, nothing in Section 9.15 affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

9.16. **Record Maintenance and Retention**

9.16.1. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Department:

9.16.1.1. Reports of acceptance testing, as described in Section 9.19.20;

9.16.1.2. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this Rule, as well as the name(s) of person(s) who performed such activities;

9.16.1.3. Records of maintenance and/or modifications performed on the therapeutic radiation machine as well as the name(s) of person(s) who performed such services; and

9.16.1.4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

9.16.1.5. Records of Misadministrations

9.16.1.5.1. A registrant shall retain a record of misadministrations reported in accordance with Section 9.14.4**.** The record shall contain the following:

9.16.1.5.1.1. The registrant's name and the names of the individuals involved (including the prescribing

physician, allied health personnel, the individual who received the misadministration, and the individual's referring physician, if applicable);

9.16.1.5.1.2. The Medical Record Number, or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

9.16.1.5.1.3. A brief description of the event; why it occurred; the effect, if any, on the individual;

9.16.1.5.1.4. The actions, if any, taken or planned to prevent recurrence; and

9.16.1.5.1.5. Whether the registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

9.16.2. All records required by this Section shall be retained in an active file for a period of at least 3 years from the date of completion.

9.17. **Follow-up Required for Recordable Event**

9.17.1. The registrant shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

9.17.1.1. Assembling the relevant facts including the cause;

9.17.1.2. Identifying what, if any, corrective action is required to prevent recurrence; and

9.17.1.3. Retaining a record, in an auditable form, for 3 years, of the relevant facts and what corrective action, if any, was taken.

9.18. **Therapeutic Radiation Machines of Less than 500 kV**

9.18.1. Leakage Radiation

9.18.1.1. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall meet the following requirements:

9.18.1.1.1. 5-50 kV Systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in any 1 hour.

9.18.1.1.2. For >50 and <500 kV systems:

9.18.1.1.2.1. The leakage air kerma rate measured at a distance of 1 meter from the target in any direction shall not exceed 1 cGy (1 rad) in any 1 hour period;

9.18.1.1.2.2. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters (100 cm^2); and

9.18.1.1.2.3. The air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

9.18.1.1.3. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in Section 9.18.1.1.1 and Section 9.18.1.1.2.1 for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

9.18.2. Permanent Beam Limiting Devices

9.18.2.1. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

9.18.3. Adjustable or Removable Beam Limiting Devices

9.18.3.1. All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than 5% of the useful beam for the most penetrating beam used.

9.18.3.2. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

9.18.4. Filter System

9.18.4.1. The filter system shall be so designed that:

9.18.4.1.1. Filters cannot be accidentally displaced at any possible tube orientation;

9.18.4.1.2. For equipment installed after August 1, 1978, an interlock system prevents irradiation if the proper filter is not in place;

9.18.4.1.3. The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at 1 meter under any operating conditions; and

9.18.4.1.4. Each filter shall be marked as to its material of construction and its thickness.

9.18.5. Tube Immobilization

9.18.5.1. The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

9.18.5.2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

9.18.6. Source Marking

9.18.6.1. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

9.18.7. Beam Block

9.18.7.1. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

9.18.8. Timer

9.18.8.1. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

9.18.8.2. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator.

9.18.8.3. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator.

9.18.8.4. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

9.18.8.5. The timer shall permit accurate pre-setting and determination of exposure times as short as 1 second.

9.18.8.6. The timer shall not permit an exposure if set at zero.

9.18.8.7. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

9.18.8.8. Timer shall be accurate to within 1% of the selected value or 1 second, whichever is greater.

9.18.9. Control Panel Functions

9.18.9.1. The control panel, in addition to the displays required by other provisions in Section 9.18, shall have:

9.18.9.1.1. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

9.18.9.1.2. An indication of whether x-rays are being produced;

9.18.9.1.3. Means for indicating x-ray tube potential and current;

9.18.9.1.4. The means for terminating an exposure at any time;

9.18.9.1.5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

9.18.9.1.6. For therapeutic radiation machines manufactured after August 1, 1978, a positive display of specific filter(s) in the beam.

9.18.10. Multiple Tubes

9.18.10.1. When a control panel may energize more than one x-ray tube:

9.18.10.1.1. It shall be possible to activate only one x-ray tube at any time;

9.18.10.1.2. There shall be an indication at the control panel identifying which x-ray tube is activated; and

9.18.10.1.3. There shall be an indication at the tube housing assembly when that tube is energized.

9.18.11. Target-to-Skin Distance (TSD)

There shall be a means of determining the central axis TSD to within 1 centimeter and of reproducing this measurement to within 2 millimeters thereafter.

9.18.12. Shutters

9.18.12.1. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

9.18.12.2. After the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel.

9.18.12.3. An indication of shutter position shall appear at the control panel.

9.18.13. Low Filtration X-ray Tubes

9.18.13.1. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall:

9.18.13.1.1. Be clearly labeled as such on the tube housing assembly; and

9.18.13.1.2. Be provided with a permanent warning device on the control panel that is activated when there is no additional filtration present, in order to indicate that the dose rate is very high.

9.18.14. Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV

9.18.14.1. In addition to shielding adequate to meet requirements of Section 9.8, the treatment room shall meet the following design requirements:

9.18.14.1.1. Aural Communication. Provision shall be made for continuous two-way aural communication between the patient/human research subject and the operator at the control panel.

9.18.14.1.2. Viewing Systems. Provision shall be made to permit continuous observation of the patient/human research subject during irradiation and the viewing system shall be so located that the operator can observe the patient/human research subject from the control panel. The therapeutic radiation machine shall not be used for patient/human research subject irradiation unless at least one viewing system is operational.

9.18.15. Additional Requirements

9.18.15.1. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

9.18.15.1.1. All protective barriers shall be fixed except for entrance doors or beam interceptors;

9.18.15.1.2. The control panel shall be located outside the treatment room;

9.18.15.1.3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

9.18.15.1.4. When any door referred to in Section 9.18.15.1.3 is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

9.18.16. Full Calibration Measurements

9.18.16.1. Full calibration of a therapeutic radiation machine subject to Section 9.18 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist:

9.18.16.1.1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine; and

9.18.16.1.2. At intervals not exceeding 12 calendar months; and

9.18.16.1.3. Before medical use under the following conditions:

9.18.16.1.3.1. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled; and

9.18.16.1.3.2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

9.18.16.1.4. Notwithstanding the requirements of Section 9.18.16.1.3:

9.18.16.1.4.1. Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and

9.18.16.1.4.2. If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in Section 9.18.16.1.3.1.

9.18.16.2. To satisfy the requirement of Section 9.18.16.1, full calibration shall include all measurements recommended for annual calibration by "AAPM Protocol for 40-300 kV X-ray Beam Dosimetry in Radiotherapy and Radiobiology": AAPM Report No. 76, prepared by AAPM Radiation Therapy Committee Task Group #61.

9.18.16.3. The registrant shall maintain a record of each calibration for the duration of the registration, to include:

9.18.16.3.1. The date of the calibration;

9.18.16.3.2. The manufacturer's name, model number, and serial number for both the therapeutic machine and the x-ray tube;

9.18.16.3.3. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and

9.18.16.3.4. The signature of the Qualified Medical Physicist responsible for performing the calibration.

9.18.17. Periodic Quality Assurance Checks

9.18.17.1. Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to Section 9.18, which are capable of operation at greater than or equal to 50 kV.

9.18.17.2. To satisfy the requirement of Section 9.18.17.1, quality assurance checks shall meet the following requirements:

9.18.17.2.1. The registrant shall perform quality assurance checks in accordance with written procedures established by the Qualified Medical Physicist; and

9.18.17.2.2. The quality assurance check procedures shall specify:

9.18.17.2.2.1. The frequency at which tests or measurements are to be performed;

9.18.17.2.2.2. That the quality assurance check be performed during the calibration specified in Section 9.18.16.1; and

9.18.17.2.2.3. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration as specified by Section 9.18.16.1.

9.18.17.3. The cause for a parameter exceeding a tolerance set by the Qualified Medical Physicist shall be investigated and corrected before the system is used for patient/human research subject irradiation.

9.18.17.4. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Qualified Medical Physicist's quality assurance check procedures, those elements of a full calibration shall be performed, as required in Section 9.18.16.1, that are necessary to determine that all affected parameters are within acceptable limits. Other quality assurance check procedures should be repeated, as necessary, to ensure that all system parameters are within acceptable limits.

9.18.17.5. The registrant shall use the dosimetry system described in Section 9.12.2 to make the quality assurance check required in Section 9.18.17.2.

9.18.17.6. The registrant shall have the Qualified Medical Physicist review and sign the results of each radiation output quality assurance check within 30 days of the date that the check was performed.

9.18.17.7. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to Section 9.18 are performed at intervals not to exceed 30 days.

9.18.17.8. Notwithstanding the requirements of Section 9.18.17.6 and Section 9.18.17.7, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by those Sections have been performed within the 30 day period immediately prior to said administration.

9.18.17.9. To satisfy the requirement of Section 9.18.17.7, safety quality assurance checks shall ensure proper operation of:

9.18.17.9.1. Electrical interlocks at each external beam radiation therapy room entrance;

9.18.17.9.2. Proper operation of the "BEAM-ON" and termination switches;

9.18.17.9.3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

9.18.17.9.4. Viewing systems;

9.18.17.9.5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

9.18.17.10. The registrant shall maintain a record of each quality assurance check required by Sections 9.18.17.1 and 9.18.17.7 for 3 years. The record shall include:

9.18.17.10.1. The date of the quality assurance check;

9.18.17.10.2. The manufacturer's name, model number, and serial number for the therapeutic radiation machine;

9.18.17.10.3. The manufacturer's name, model number, and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and

9.18.17.10.4. The signature of the individual who performed the periodic quality assurance check.

9.18.18. Operating Procedures

9.18.18.1. The therapeutic radiation machine shall not be used for irradiation of patients/human research subjects unless the requirements of Sections 9.18.16 and 9.18.17 have been met.

9.18.18.2. Therapeutic radiation machines shall not be left unattended unless secured pursuant to Section 9.18.9.1.5.

9.18.18.3. When a patient/human research subject must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

9.18.18.4. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV.

DRAFT

9.18.18.5. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

9.18.18.6. No individual other than the patient/human research subject shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV.

9.18.18.7. At energies less than or equal to 150 kV, any individual, other than the patient/human research subject, in the treatment room shall be protected by a barrier sufficient to meet the requirements of Section 7.2.

9.18.19. Possession of Survey Instrument(s)

9.18.19.1. Each facility location authorized to use a therapeutic radiation machine in accordance with Section 9.18 shall possess appropriately calibrated portable monitoring equipment.

9.18.19.1.1. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour.

9.18.19.1.2. The survey instrument(s) shall be operable and calibrated in accordance with Section 9.11.

9.19. Therapeutic Radiation Machines – Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above)

9.19.1. Possession of Survey Instrument(s)

9.19.1.1. Each facility location authorized to use a therapeutic radiation machine in accordance with this Section shall possess appropriately calibrated portable monitoring equipment.

9.19.1.1.1. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour.

9.19.1.1.2. The survey instrument(s) shall be operable and calibrated in accordance with Section 9.11.

9.19.2. Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes

9.19.2.1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius 2 meters which is perpendicular to and centered on the

central axis of the useful beam at the nominal treatment distance (i.e. patient/human research subject plane), shall not exceed a maximum of 0.2% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 cm^2 at a minimum of 16 points uniformly distributed in the plane.

9.19.2.2. Except for the area defined in Section 9.19.2.1, the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 cm^2.

9.19.2.3. For equipment manufactured after July 1, 1999, the neutron absorbed dose outside the useful beam shall comply with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision); and

9.19.2.4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in Section 9.19.2.1 through Section 9.19.2.3 for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

9.19.3. Leakage Radiation Through Beam Limiting Devices

9.19.3.1. Photon Radiation. All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 2% of the maximum absorbed dose on the central axis of the useful beam measured in a 100 cm^2 radiation field, or maximum available field size if less than 100 cm^2.

9.19.3.2. Electron Radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

9.19.3.2.1. A maximum of 2% and average of 0.5% of the absorbed dose on the central axis of the useful beam at the nominal

treatment distance. This limit shall apply beyond a line 7 centimeters outside the periphery of the useful beam; and

9.19.3.2.2. A maximum of 10% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line 2 centimeters outside the periphery of the useful beam.

9.19.3.3. Measurement of Leakage Radiation

9.19.3.3.1. Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be:

9.19.3.3.1.1. Made with the beam limiting devices closed;

9.19.3.3.1.2. Made with any residual aperture blocked by at least 2 tenth value layers of suitable absorbing material;

9.19.3.3.1.3. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose; and

9.19.3.3.1.4. Measurements shall be made using a radiation detector of area not exceeding 10 cm^2.

9.19.3.3.2. Electron Radiation. Measurements of leakage radiation through the electron applicators shall be:

9.19.3.3.2.1. Made with the electron beam directed into the air;

9.19.3.3.2.2. Made using a radiation detector of area up to but not exceeding 1 cm^2 suitably protected against radiation which has been scattered from material beyond the radiation detector; and

9.19.3.3.2.3. Made using 1 centimeter of water equivalent build up material.

9.19.3.3.3. Leakage radiation through beam limiting devices shall be determined for photon radiation and for electron radiation in radiation therapy machines which operate in both modes.

9.19.4. Filters/Wedges. Filters and wedges used in therapeutic radiation machines shall meet the following requirements:

9.19.4.1. Each wedge filter which is removable from the system shall be clearly marked with an identification number;

9.19.4.2. Each removable wedge filter shall have the nominal wedge angle appear on the wedge or wedge tray if permanently mounted to the tray;

9.19.4.3. If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

9.19.4.4. If the absorbed dose rate information required by Section 9.19.9 relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools.

9.19.4.5. For equipment manufactured after January 1, 1985 which utilize a system of wedge filters, inter-changeable field flattening filters, or interchangeable beam scattering foils:

9.19.4.5.1. Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

9.19.4.5.2. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

9.19.4.5.3. A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and

9.19.4.5.4. An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

9.19.5. Stray Radiation in the Useful Beam

9.19.5.1. For equipment manufactured after July 1, 1999, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (or the most current revision).

9.19.6. Beam Monitors

9.19.6.1. All therapeutic radiation machines subject to Section 9.19 shall be provided with redundant beam monitoring systems. The detectors for

these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

9.19.6.2. Equipment manufactured after January 1, 1985 shall be provided with at least 2 independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

9.19.6.3. Equipment manufactured on or before January 1, 1985 shall be provided with at least 1 radiation detector. This detector shall be incorporated into a useful beam monitoring system.

9.19.6.4. The detector and the system into which that detector is incorporated shall meet the following requirements:

9.19.6.4.1. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

9.19.6.4.2. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

9.19.6.4.3. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation;

9.19.6.4.4. For equipment manufactured after January 1, 1985, the design of the beam monitoring systems shall ensure that the:

9.19.6.4.4.1. Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

9.19.6.4.4.2. Failure of either system shall terminate irradiation or prevent the initiation of radiation; and

9.19.6.4.5. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after January 1, 1985, each display shall:

9.19.6.4.5.1. Maintain a reading until intentionally reset;

9.19.6.4.5.2. Have only 1 scale and no electrical or mechanical scale multiplying factors;

9.19.6.4.5.3. Utilize a design such that increasing dose is displayed by increasing numbers; and

DRAFT

9.19.6.4.5.4. In the event of power failure, the beam monitoring information required in Section 9.19.6.4.5 displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

9.19.7. Beam Symmetry

9.19.7.1. A bent-beam linear accelerator with beam flattening filter(s) subject to Section 9.19 shall be provided with auxiliary device(s) to monitor beam symmetry.

9.19.7.2. The device(s) referenced in Section 9.19.7.1 shall be able to detect field asymmetry greater than 10%.

9.19.7.3. The device(s) referenced in Section 9.19.7.1 shall be configured to terminate irradiation if the specifications in Section 9.19.7.2 cannot be maintained.

9.19.8. Selection and Display of Dose Monitor Units

9.19.8.1. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

9.19.8.2. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

9.19.8.3. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated.

9.19.8.4. For equipment manufactured after January 1, 1985, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

9.19.9. Air Kerma Rate/Absorbed Dose Rate

9.19.9.1. For equipment manufactured after January 1, 1985, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in Section 9.19.6 may form part of this system. In addition:

9.19.9.1.1. The dose monitor unit rate shall be displayed at the treatment control panel;

9.19.9.1.2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates

irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

9.19.9.1.3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than 10 times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

9.19.9.1.4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in Section 9.19.9.1.2 and Section 9.19.9.1.3 for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the Department.

9.19.10. Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy

9.19.10.1. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

9.19.10.2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15% or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

9.19.10.3. For equipment manufactured after January 1, 1985, an indicator on the control panel shall show which monitoring system has terminated irradiation.

9.19.11. Termination of Irradiation

9.19.11.1. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

9.19.12. Interruption of Irradiation

9.19.12.1. If a therapeutic radiation machine has an interrupt mode:

9.19.12.1.1. It shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel;

9.19.12.1.2. Following an interruption, it shall be possible to restart irradiation by operator action without any re-selection of operating conditions; and

9.19.12.1.3. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

9.19.13. Timer

9.19.13.1. An irradiation control device that will terminate the irradiation after a pre-set time interval shall be provided.

9.19.13.2. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.

9.19.13.3. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator.

9.19.13.4. The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

9.19.14. Selection of Radiation Type

9.19.14.1. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

9.19.14.1.1. Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

9.19.14.1.2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

9.19.14.1.3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

DRAFT

9.19.14.1.4. An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

9.19.14.1.5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

9.19.14.1.6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

9.19.15. Selection of Energy

9.19.15.1. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

9.19.15.1.1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

9.19.15.1.2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

9.19.15.1.3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

9.19.15.1.4. For equipment manufactured after July 1, 1999, the selection of energy shall comply with International Electrotechnical Commission (IEC) Document 601-2-1 (Edition 3.1 - July 2014).

9.19.16. Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy

9.19.16.1. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

9.19.16.1.1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel.

DRAFT

9.19.16.1.2. The mode of operation shall be displayed at the treatment control panel.

9.19.16.1.3. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.

9.19.16.1.4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel.

9.19.16.1.5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement:

9.19.16.1.5.1. For equipment manufactured after January 1, 1985:

9.19.16.1.5.1.1. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5% from the dose monitor unit value selected;

9.19.16.1.5.1.2. An interlock shall be provided to prevent motion of more than 5 degrees or 1 centimeter beyond the selected limits during moving beam radiation therapy;

9.19.16.1.5.1.3. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

9.19.16.1.5.2. For equipment manufactured after July 1, 1999:

9.19.16.1.5.2.1. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 centimeter of linear motion differs by more than 20% from the selected value;

DRAFT

9.19.16.1.5.2.2. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

9.19.16.1.6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by Section 9.19.10.

9.19.16.1.7. An interlock system shall be provided to terminate irradiation if movement:

9.19.16.1.7.1. Occurs during stationary beam radiation therapy; or

9.19.16.1.7.2. Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

9.19.17. Facility Design Requirements for Therapeutic Radiation Machines Operating Above 500 kV

9.19.17.1. In addition to shielding adequate to meet requirements of Section 9.8, the following design requirements shall be made:

9.19.17.1.1. Protective Barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

9.19.17.1.2. Control Panel. In addition to other requirements specified in this Section, the control panel shall also:

9.19.17.1.2.1. Be located outside the treatment room;

9.19.17.1.2.2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

9.19.17.1.2.3. Provide an indication of whether radiation is being produced; and

9.19.17.1.2.4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine. This locking device

DRAFT

may be in the form of computer software requiring a password for access.

9.19.17.1.3. Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient/human research subject following positioning and during irradiation and shall be so located that the operator may observe the patient/human research subject from the treatment control panel.

9.19.17.1.3.1. The therapeutic radiation machine shall not be used for patient/human research subject irradiation unless at least one viewing system is operational.

9.19.17.1.4. Aural Communications. Provision shall be made for continuous two-way aural communication between the patient/human research subject and the operator at the control panel.

9.19.17.1.4.1. The therapeutic radiation machine shall not be used for irradiation of patients/human research subjects unless continuous two-way aural communication is possible.

9.19.17.1.5. Room Entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate whether the useful beam is "ON."

9.19.17.1.6. Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued.

9.19.17.1.6.1. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

9.19.17.1.7. Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with Section 7.6, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

9.19.17.1.8. Emergency Cutoff Switches. At least 1 emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion for the radiation producing unit. This switch is in addition to the termination switch required by Section 9.19.11.

9.19.17.1.8.1. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

9.19.17.1.9. Safety Interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

9.19.17.1.10. Surveys for Residual Radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

9.19.18. Qualified Medical Physicist Support

9.19.18.1. The services of a Qualified Medical Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Qualified Medical Physicist shall be responsible for:

9.19.18.1.1. Full calibration(s) required by Section 9.19.20 and protection surveys required by Section 9.9.1;

9.19.18.1.2. General supervision and review of medical dosimetry/treatment planning;

9.19.18.1.3. Beam data acquisition and transfer for computerized dosimetry, and general supervision of its use;

9.19.18.1.4. Quality assurance, including quality assurance check review required by Section 9.19.21.5;

9.19.18.1.5. Consultation with the Radiation oncologist or radiation therapy physician in treatment planning, as needed; and

9.19.18.1.6. Performing calculations/assessments regarding misadministrations.

9.19.18.2. The operating procedures required by Section 9.19.19 shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

9.19.19. Operating Procedures

9.19.19.1. The following operating procedures shall be required:

9.19.19.1.1. No individual, other than the patient/human research subject, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes.

9.19.19.1.2. Therapeutic radiation machines shall not be made available for medical use unless the requirements of Section 9.9.1, Section 9.19.20, and Section 9.19.21 have been met.

9.19.19.1.3. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use. This may be by means of physical devices (e.g. keys) or software (password requirement).

9.19.19.1.4. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

9.19.19.1.5. If a patient/human research subject must be held in position during treatment, mechanical supporting or restraining devices shall be used.

9.19.19.2. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

9.19.20. Acceptance Testing, Commissioning, and Full Calibration Measurements

9.19.20.1. Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to Section 9.19 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist.

9.19.20.2. Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47", prepared by AAPM Radiation Therapy Task Group 45 (or a superseding document published by the

same organization), and the manufacturer's contractual specifications. Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

9.19.20.3. Full calibration shall include measurement of all applicable parameters required by "Quality Assurance of Medical Accelerators: AAPM Report No. 142" and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47" (or a superseding document published by the same organization), prepared by AAPM Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding 14 calendar months, unless a more frequent interval is required in AAPM Report No. 142 (or a superseding document published by the same organization).

9.19.20.3.1. AAPM Report 142 supersedes Table II of "Comprehensive QA for Radiation Oncology: AAPM Report No. 46", prepared by AAPM Radiation Therapy Task Group 40.

9.19.20.4. The Qualified Medical Physicist shall perform or directly supervise all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

9.19.20.4.1. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and

9.19.20.4.2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in Section 9.19.20.4.1.

9.19.20.5. The registrant shall use the dosimetry system described in Section 9.12.1 to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in Section

9.19.20.2, Section 9.19.20.3, and Section 9.19.20.4 may then be made using a dosimetry system that indicates relative dose rates.

9.19.20.6. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include:

9.19.20.6.1. The date of the calibration;

9.19.20.6.2. The manufacturer's name;

9.19.20.6.3. Model and serial number of the therapeutic machine;

9.19.20.6.4. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and

9.19.20.6.5. The signature of the Radiation Therapy Physicist responsible for performing the calibration.

9.19.20.7. Therapy-Related Computer Systems

The registrant shall perform acceptance testing on the treatment planning system of therapeutic radiation machine-related computer systems in accordance with current published recommendations from the American Association of Physicists in Medicine. In the absence of an acceptance testing protocol published by the American Association of Physicists in Medicine, the manufacturer's acceptance testing protocol shall be followed.

9.19.20.7.1. Acceptance testing shall be performed by, or under the direct supervision of, a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

9.19.20.7.1.1. The source-specific input parameters required by the dose calculation algorithm;

9.19.20.7.1.2. The accuracy of dose calculations at representative points;

9.19.20.7.1.3. The accuracy of isodose plots and graphic displays;

9.19.20.7.1.4. The accuracy of the software used to determine radiation source positions from radiographic images; and

9.19.20.7.1.5. If the treatment-planning system is different from the treatment-delivery system, the accuracy of

electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

9.19.20.7.2. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the Qualified Medical Physicist, and either the Radiation Oncologist or the radiation therapy physician for correctness through means independent of that used for the determination of the parameters.

9.19.21. Periodic Quality Assurance Checks

9.19.21.1. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to Section 9.19 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46, prepared by AAPM Radiation Therapy Committee Task Group 40. All periodic quality assurance checks with an annual frequency do not have to be performed at the same time but shall be completed during an interval not to exceed 12 consecutive calendar months.

9.19.21.2. The registrant shall use a dosimetry system which has been inter-compared within the previous 12 months with the dosimetry system described in Section 9.12.1 to make the periodic quality assurance checks required in Section 9.19.21.1.

9.19.21.3. The registrant shall perform periodic quality assurance checks required by Section 9.19.21.1 in accordance with procedures established by the Qualified Medical Physicist.

9.19.21.4. The registrant shall review the results of each periodic radiation output check according to the following procedures:

9.19.21.4.1. The Radiation Oncologist, radiation therapy physician or Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

9.19.21.4.2. If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Radiation Oncologist, radiation therapy physician or Qualified Medical Physicist within 3 treatment days; and

9.19.21.4.3. The Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

9.19.21.5. Therapeutic radiation machines subject to Section 9.19 shall have the following safety quality assurance checks performed at intervals not to exceed 1 week:

9.19.21.5.1. Proper operation of the "BEAM-ON", interrupt and termination switches;

9.19.21.5.2. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

9.19.21.5.3. Electrically operated treatment room door(s) from inside and outside the treatment room.

9.19.21.6. The registrant shall promptly repair any system identified in Section 9.19.21.1 and Section 9.19.21.5 that is not operating properly.

9.19.21.7. The registrant shall maintain a record of each quality assurance check required by Section 9.18.21.1 and Section 9.18.21.5 for 3 years. The record shall include:

9.19.21.7.1. The date of the quality assurance check;

9.19.21.7.2. The manufacturer's name;

9.19.21.7.3. The machine model and serial number;

9.19.21.7.4. The manufacturer's name, model number, and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and

9.19.21.7.5. The signature of the individual who performed the periodic quality assurance check.

9.19.22. Quality Assurance Checks for Intensity Modulated Radiation Therapy (IMRT)

9.19.22.1. Quality assurance checks for IMRT shall:

9.19.22.1.1. Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans; and

9.19.22.1.1.1. IMRT is a rapidly evolving modality and the QA program shall also evolve to handle new issues that arise. "Guidance document on delivery, treatment

planning, and clinical implementation of IMRT: AAPM Report No. 82", prepared by the IMRT subcommittee of the AAPM radiation therapy committee, provides some suggestions on establishing such a QA program.

9.19.22.1.2. Be performed in accordance with the manufacturer's contractual specifications.

9.20. **Quality Assurance for Radiation Therapy Simulation Systems**

9.20.1. Quality assurance for a conventional or virtual simulator shall include acceptance testing and periodic verification of system performance; and

9.20.2. Be performed in accordance with "Comprehensive QA for Radiation Oncology: AAPM Report No. 46", prepared by AAPM Radiation Therapy Committee Task Group 40, for a conventional simulator; or

9.20.3. Be performed in accordance with "Quality assurance for computed tomography simulators and the computed tomography-simulation process: AAPM Report No. 83", prepared by AAPM Radiation Therapy Committee Task Group 66, for a virtual simulator.

9.21. **Electronic Brachytherapy**

9.21.1. Applicability

9.21.1.1. Electronic brachytherapy devices shall be subject to the requirements of this Section and shall be exempt from the requirements of Section 9.18.

9.21.1.2. An electronic brachytherapy device that does not meet the requirements of this Section shall not be used for irradiation of patients.

9.21.1.3. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

9.21.2. Possession of Survey Instrument(s)

9.21.2.1. Each facility location authorized to use an electronic brachytherapy device in accordance with Section 9.21 shall possess appropriately calibrated portable monitoring equipment which shall as a minimum:

9.21.2.1.1. Include a portable radiation measurement survey instrument capable of measuring dose rate over the range of 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour, and

9.21.2.1.2. Be operable and calibrated in accordance with Section 9.11 for the applicable electronic brachytherapy source energy.

9.21.3. Facility Design Requirements for Electronic Brachytherapy Devices

9.21.3.1. In addition to shielding adequate to meet requirements of Section 9.8, the treatment room shall meet the following design requirements:

9.21.3.1.1. If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.

9.21.3.1.2. Access to the treatment room shall be controlled by a door at each entrance.

9.21.3.1.3. Each treatment room shall have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed.

9.21.3.1.4. For electronic brachytherapy devices capable of operating below 50 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield and/or as localized shielded material around the treatment site.

9.21.3.1.5. For electronic brachytherapy devices capable of operating at greater than 150 kV:

9.21.3.1.5.1. The control panel shall be located outside the treatment room;

9.21.3.1.5.2. Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the electronic brachytherapy device to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

9.21.3.1.5.3. When any door referred to in Section 9.21.3.1.5.2 is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

9.21.4. Electrical Safety for Electronic Brachytherapy Devices

DRAFT

9.21.4.1. The high voltage transformer shall be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

9.21.4.2. The high voltage transformer shall be isolated from personnel (e.g., operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

9.21.4.3. The high voltage transformer shall have appropriate safety labels warning personnel of potential electrical shock and/or heat related injuries.

9.21.4.4. Equipment manufactured after January 1, 2006 shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

9.21.4.4.1. IEC 60601-1:1998+A1+A2:1995;

9.21.4.4.2. IEC 60601-1-2:2001;

9.21.4.4.3. IEC 60601-2-8:1999; and

9.21.4.4.4. IEC 60601-2-17:2004.

9.21.5. Control Panel Functions

9.21.5.1. The control panel, in addition to the displays required by other provisions in Section 9.21, shall:

9.21.5.1.1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

9.21.5.1.2. Provide an indication of whether x rays are being produced;

9.21.5.1.3. Provide a means for indicating electronic brachytherapy source potential and current;

9.21.5.1.4. Provide the means for terminating an exposure at any time; and

9.21.5.1.5. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

9.21.6. Timer

9.21.6.1. A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

9.21.6.2. A timer shall be provided at the treatment control panel. The timer shall indicate the planned setting and the time elapsed or remaining.

9.21.6.3. The timer shall not permit an exposure if set at zero.

9.21.6.4. The timer shall be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator.

9.21.6.5. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.

9.21.6.6. The timer shall permit setting of exposure times as short as 0.1 second.

9.21.6.7. The timer shall be accurate to within 1% of the selected value or 0.1 second, whichever is greater.

9.21.7. Qualified Medical Physicist Support

9.21.7.1. The services of a Qualified Medical Physicist shall be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist shall be responsible for:

9.21.7.1.1. Evaluation of the output from the electronic brachytherapy source;

9.21.7.1.2. Generation of the necessary dosimetric information;

9.21.7.1.3. Supervision and review of treatment calculations prior to initial treatment of any treatment site;

9.21.7.1.4. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in Section 9.21.11;

9.21.7.1.5. Consultation with the Radiation Oncologist or radiation therapy physician in treatment planning, as needed; and

9.21.7.1.6. Performing calculations/assessments regarding patient treatments that may constitute a misadministration.

9.21.7.2. If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by Section 9.21.8 shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific

actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

9.21.8. Operating Procedures

9.21.8.1. Operating procedures shall be as follows:

9.21.8.1.1. Only individuals approved by the Radiation Oncologist, radiation therapy physician, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment;

9.21.8.1.2. Electronic brachytherapy devices shall not be made available for medical use unless the requirements of Sections 9.9 through 9.13, 9.21.9, and 9.21.10 have been met;

9.21.8.1.3. The electronic brachytherapy device shall be rendered inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

9.21.8.1.4. During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent unshielded exposure from the treatment beam;

9.21.8.1.5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

9.21.8.1.6. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

9.21.8.1.6.1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and

9.21.8.1.6.2. The names and telephone numbers of the Radiation Oncologist, radiation therapy physician, Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

9.21.8.1.7. A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console;

9.21.8.1.7.1. If the control console is integral to the electronic brachytherapy device, the required

procedures shall be kept where the operator is located during electronic brachytherapy device operation.

9.21.8.1.8. Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the Radiation Oncologist, radiation therapy physician, Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally; and

9.21.8.1.9. The Radiation Safety Officer, or his/her designee, and a Radiation Oncologist or radiation therapy physician shall be notified as soon as possible if the patient has a medical emergency, suffers injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist shall inform the manufacturer of the event.

9.21.9. Safety Precautions for Electronic Brachytherapy Devices

9.21.9.1. A Qualified Medical Physicist shall determine which persons in the treatment room require monitoring when the beam is energized;

9.21.9.2. A Qualified Medical Physicist and either a Radiation Oncologist or a radiation therapy physician shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

9.21.9.3. A Qualified Medical Physicist and either a Radiation Oncologist, radiation therapy physician, or a physician or electronic brachytherapy device operator who has been trained in the operation and emergency response for the electronic brachytherapy device and is under the general supervision of a Radiation Oncologist or radiation therapy physician, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device;

9.21.9.4. When shielding is required by Section 9.21.3.1.4, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Qualified Medical Physicist shall designate shield locations sufficient to meet the requirements of Section 7.2 for any individual, other than the patient, in the treatment room; and

9.21.9.5. All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

9.21.10. Electronic Brachytherapy Source Calibration Measurements

9.21.10.1. Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to Section 9.21 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist;

9.21.10.2. Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

9.21.10.3. Calibration of the electronic brachytherapy source output shall utilize a dosimetry system as described in Section 9.12;

9.21.10.4. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

9.21.10.4.1. The output within 2% of the expected value, if applicable, or determination of the output if there is no expected value;

9.21.10.4.2. Timer accuracy and linearity over the typical range of use;

9.21.10.4.3. Proper operation of back-up exposure control devices;

9.21.10.4.4. Evaluation that the relative dose distribution about the source is within 5% of that expected; and

9.21.10.4.5. Source positioning accuracy to within 1 millimeter within the applicator;

9.21.10.5. Calibration of the x-ray source output required by Section 9.21.10.1 through Section 9.21.10.4 shall be in accordance with current published recommendations from a recognized national professional association, such as AAPM, with expertise in electronic brachytherapy (if available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.

9.21.10.6. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include:

9.21.10.6.1. The date of the calibration;

9.21.10.6.2. The manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source;

9.21.10.6.3. The model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and

9.21.10.6.4. The name and signature of the Qualified Medical Physicist responsible for performing the calibration.

9.21.11. Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices

9.21.11.1. Quality assurance checks shall be performed on each electronic brachytherapy device subject to Section 9.21:

9.21.11.1.1. At the beginning of each day of use;

9.21.11.1.2. After each x-ray tube installation; and

9.21.11.1.3. Each time the device is moved to a new room or site;

9.21.11.1.3.1. Site is intended to include each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer. See Section 9.21.14 for additional clarification.

9.21.11.2. The registrant shall perform periodic quality assurance checks required by Section 9.21.11.1 in accordance with procedures established by the Qualified Medical Physicist;

9.21.11.3. To satisfy the requirements of Section 9.21.11.1, radiation output quality assurance checks shall include as a minimum:

9.21.11.3.1. Verification that output of the electronic brachytherapy source falls within 3% of expected values, as appropriate for the device, as determined by:

9.21.11.3.1.1. Output as a function of time, or

9.21.11.3.1.2. Output as a function of setting on a monitor chamber.

9.21.11.3.2. Verification of the consistency of the dose distribution to within 3% of that found during calibration required by Section 9.21.10; and

9.21.11.3.3. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within 1 millimeter; and

9.21.11.4. The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry

system described in Section 9.12.1 to make the quality assurance checks required in Section 9.21.11.3;

9.21.11.5. The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

9.21.11.5.1. A Radiation Oncologist or radiation therapy physician and a Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

9.21.11.5.2. If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Radiation Oncologist or radiation therapy physician, or Qualified Medical Physicist within 2 days; and

9.21.11.5.3. The Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

9.21.11.6. To satisfy the requirements of Section 9.21.11.1, safety device quality assurance checks shall, at a minimum, assure:

9.21.11.6.1. Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;

9.21.11.6.2. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

9.21.11.6.3. Proper operation of radiation monitors, if applicable;

9.21.11.6.4. The integrity of all cables, catheters or parts of the device that carry high voltages; and

9.21.11.6.5. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

9.21.11.7. If the results of the safety device quality assurance checks required in Section 9.21.11.6 indicate any malfunction, a registrant shall secure the control console in the "OFF" position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning items.

9.21.11.8. The registrant shall maintain a record of each quality assurance check required by Section 9.21.11.3 and Section 9.21.11.7 in an auditable form for 3 years. The record shall include:

9.21.11.8.1. Date of the quality assurance check;

9.21.11.8.2. Manufacturer's name, model number and serial number for the electronic brachytherapy device;

9.21.11.8.3. Name and signature of the individual who performed the periodic quality assurance check; and

9.21.11.8.4. Name and signature of the Qualified Medical Physicist who reviewed the quality assurance check.

9.21.11.8.5. For radiation output quality assurance checks required by Section 9.21.11.3, the record shall also include:

9.21.11.8.5.1. The unique identifier for the electronic brachytherapy source; and

9.21.11.8.5.2. The manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

9.21.12. Therapy-Related Computer Systems

9.21.12.1. The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association, such as AAPM, with expertise in electronic brachytherapy (when available).

9.21.12.1.1. In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

9.21.12.2. Acceptance testing shall be performed by, or under the direct supervision of, a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

9.21.12.2.1. The source-specific input parameters required by the dose calculation algorithm;

9.21.12.2.2. The accuracy of dose, dwell time, and treatment time calculations at representative points;

9.21.12.2.3. The accuracy of isodose plots and graphic displays;

9.21.12.2.4. The accuracy of the software used to determine radiation source positions from radiographic images; and

9.21.12.2.5. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

9.21.12.3. The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

9.21.12.4. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the Radiation Oncologist or radiation therapy physician and the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

9.21.13. Training

9.21.13.1. A registrant shall provide instruction, initially and at intervals not to exceed 12 months, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in Section 9.21.8.

9.21.13.1.1. If the interval between patients exceeds one year, retraining of the individuals shall be provided before the next treatment is administered.

9.21.13.2. Radiation Oncologists, radiation therapy physicians and Qualified Medical Physicists shall also receive device specific instruction initially from the manufacturer, and at intervals not to exceed 12 months from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available), such as AAPM. In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:

9.21.13.2.1. Device-specific radiation safety requirements;

9.21.13.2.2. Device operation;

9.21.13.2.3. Clinical use for the types of use approved by the FDA;

9.21.13.2.4. Emergency procedures, including an emergency drill; and

9.21.13.2.5. The registrant's Quality Assurance Program.

9.21.13.3. A registrant shall retain a record of individuals receiving instruction required by Section 9.21.13.1 and Section 9.21.13.2 for 3 years. The record shall include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

9.21.14. Mobile Electronic Brachytherapy Service

9.21.14.1. A registrant providing mobile electronic brachytherapy service shall, as a minimum:

9.21.14.1.1. Check each survey instrument for consistent response with a dedicated check source before medical use at each address of use or on each day of use, whichever is more restrictive. The registrant is not required to keep records of these checks.

9.21.14.1.2. Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

9.21.14.1.3. Perform, at each location on each day of use, all of the required quality assurance checks specified in Section 9.21.11 to assure proper operation of the device.

9.22. **Other Use of Electronically Produced Radiation to Deliver Therapeutic Radiation Dosage**

9.22.1. Prohibition on Use

9.22.1.1. A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

9.22.1.1.1. The applicant or registrant has, at a minimum, provided the Department with:

9.22.1.1.1.1. A detailed description of the device and its intended application(s);

9.22.1.1.1.2. Facility design requirements, including shielding and access control;

9.22.1.1.1.3. Documentation of appropriate training for Radiation Oncologists, radiation therapy physicians and Qualified Medical Physicist(s);

9.22.1.1.1.4. Methodology for measurement of dosages to be administered to patients or human research subjects;

9.22.1.1.1.5. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

9.22.1.1.1.6. Radiation safety precautions and instructions; and

9.22.1.1.1.7. Other information requested by the Department in its review of the application; and

9.22.1.1.2. The applicant or registrant has received written approval from the Department to utilize the device in accordance with the regulations and specific conditions the Department considers necessary for the medical use of the device.

10.0 Radiation Safety Requirements for Radiation Generating Machines Not Used in the Healing Arts

10.1. Purpose and Scope

10.1.1. This Section establishes requirements, for which the registrant is responsible, for use of non-healing-arts radiation generating machines not otherwise covered by this Rule. The provisions of this Section are in addition to, and not in substitution for, other applicable provisions of this Rule.

10.1.2. The registrant shall be responsible for directing the operation of the radiation generating machines which have been registered with the Department, and for ensuring compliance with this Rule.

10.2. Applicability

The relevant special requirements of Section 10.0 also apply if an image receptor is used to transform incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformation.

10.3. Registration Requirement

The owner of a non-healing-arts radiation machine in the State of Vermont shall register each machine with the Department as required by Section 5.0.

10.4. Equipment Requirements

10.4.1. All open-beam configurations shall be provided with a safety device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path.

10.4.1.1. A registrant may apply to the Department for an exemption from the requirement of a safety device. An application for exemption shall include:

10.4.1.1.1. A description of the various safety devices that have been evaluated;

10.4.1.1.2. The reason each of these devices cannot be used;

10.4.1.1.3. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure; and

10.4.1.1.4. The procedures followed to assure that operators and others in the area will be informed of the absence of safety devices.

10.4.2. Warning Devices

10.4.2.1. Open-beam configurations shall be provided with a readily discernible indication of x-ray tube "on-off" status located near the radiation source housing, if the useful beam is controlled in this manner.

10.4.2.2. Each analytical x-ray machine shall have an easily visible warning light labeled with the words "X-RAY ON" located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized.

10.4.2.3. Warning devices shall be labeled so that their purpose is easily identified.

10.4.2.4. Warning devices shall have fail-safe characteristics.

10.4.3. Labeling

10.4.3.1. All analytical x-ray equipment shall be labeled with a readily discernable sign(s) bearing the radiation symbol and the words:

10.4.3.1.1. "CAUTION – HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the x-ray source housing; and

10.4.3.1.2. "CAUTION – RADIATION – THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube.

10.4.4. Radiation Source Housing

10.4.4.1. Each radiation machine source housing shall be equipped with an interlock that shuts off the tube if the tube is removed from the radiation source housing or if the housing is disassembled.

10.4.4.2. Each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from the source housing at any specified tube rating is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in 1 hour.

10.4.5. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.5 millirem (5 µSv) in 1 hour.

10.5. **Operating Requirements**

10.5.1. Normal and emergency operating procedures shall be written and available to all analytical x-ray equipment workers. These procedures shall include:

10.5.1.1. Sample insertion and manipulation;

10.5.1.2. Equipment alignment;

10.5.1.3. Routine maintenance procedures to be performed by the registrant; and

10.5.1.4. Data recording procedures, which are related to radiation safety.

10.5.2. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the registrant's Radiation Safety Officer.

10.5.3. No individual shall bypass a safety device or interlock unless such individual has obtained written approval of the Radiation Safety Officer.

10.5.3.1. Such approval shall be for a specified period of time.

10.5.3.2. When a safety device or interlock has been bypassed, a sign bearing the words "SAFETY DEVICE NOT WORKING" shall be placed on the radiation source housing.

10.5.4. Repair or Modification of X-ray Tube Systems

10.5.4.1. Except as specified in Section 10.4.3, no operation involving removal of covers, shielding materials, or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored.

10.5.4.2. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

10.5.5. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION – X-RAY EQUIPMENT" or words having a similar intent.

10.5.6. Handheld Devices

10.5.6.1. The operator shall be protected from direct scatter radiation by material of not less than 0.25 millimeter lead equivalent unless the Radiation Safety Officer and Department determine that no added protection is needed for the device use and/or model.

10.6. Personnel Requirements

10.6.1. No individual shall be permitted to operate or maintain analytical x-ray equipment unless such individual has received instruction and demonstrated competence as to:

10.6.1.1. Identification of radiation hazards associated with the use of the equipment;

10.6.1.2. The significance of the various radiation warning devices, safety devices, and interlocks incorporated into the equipment, or the reasons such devices have not been installed on certain equipment;

10.6.1.3. Any extra precautions required relevant to the use of the equipment;

10.6.1.4. Proper operating and safety procedures for the equipment;

10.6.1.5. Recognition of symptoms of an acute localized exposure; and

10.6.1.6. Proper procedures for reporting an actual or suspected exposure.

10.6.2. Training for use of Bomb Detection Radiation Machines

10.6.2.1. In addition to the requirements of Section 10.5.1, all personnel operating bomb detection radiation machines shall be trained in the set-up and operation of the Bomb Detection radiation machine and in establishing a restricted area.

10.7. Special Requirements for Security Screening Systems on Humans

10.7.1. In addition to the provisions of Sections 10.1 through 10.5, security screening systems designed to admit humans shall comply with the following equipment standards:

DRAFT

10.7.1.1. Indicators that light only when a scan is in process shall be provided and clearly visible to all security screening system operators and anyone approaching the restricted area;

10.7.1.2. Power to the system shall be controlled by a key switch;

10.7.1.3. A device to terminate x-ray exposure at any time during a scan shall be provided;

10.7.1.4. Access panels to x-ray source and detector shall be provided with at least one safety interlock;

10.7.1.5. Operational safety interlocks must terminate the x-ray exposure in the event of any system problem that could result in abnormal or unintended radiation emission;

10.7.1.6. Following any premature termination, the security screening system must prohibit resumption of x-ray generation until the normal control sequence is reset for a new scan;

10.7.1.7. Equipment designed to control the exposure output using multiple modes of operation shall indicate the selected mode prior to each scan;

10.7.1.8. Technique factors may not be adjustable and shall be preset by the manufacturer for each mode of operation;

10.7.1.9. A means shall be provided to terminate the exposure at a preset time interval or exposure;

10.7.1.10. When the x-ray tube is operated at its maximum rated tube current for the maximum kilovoltage, the leakage dose shall not be greater than 2.5 mSv (0.25 mrem) in any one hour at any point 30 centimeters from any external surface; and

10.7.1.11. The primary x-ray beam shall be attenuated by at least one millimeter of aluminum-equivalent total filtration.

10.7.2. Operators of security screening systems designed to admit humans shall comply with the following operating requirements:

10.7.2.1. No individual shall be exposed to the useful beam unless authorized by a law enforcement agency for security benefit;

10.7.2.2. No individual shall be exposed to the useful beam for demonstration or frivolous purpose;

10.7.2.3. The individual responsible for radiation protection shall ensure that all operators are trained in the safe operation of the security screening systems;

10.7.2.4. Any radiation-generating equipment that does not meet the provisions set forth in this Rule shall not be used to irradiate individuals unless the Department determines that the continued use will not pose a radiation risk and arrangements have been made to promptly correct the deficiency;

10.7.2.5. The operator shall follow the manufacturer's recommended maintenance schedule;

10.7.2.6. Radiation-generating equipment shall bear a warning label on the control panel or by the exposure switch which cautions individuals that radiation is produced when it is energized; and

10.7.2.7. All position locking, holding, and centering devices on radiation-generating equipment components shall function as designed by the manufacturer.

10.7.3. Each registrant operating a security screening system shall have a written quality assurance program that includes the following:

10.7.3.1. Policy prohibiting the frivolous use of security screening systems where no security benefit is to be derived;

10.7.3.2. Policy requiring individuals undergoing screening to be positioned facing away from the source of radiation when using transmission security screening systems;

10.7.3.3. Policy requiring consent to exposure by a pregnant individual;

10.7.3.4. Policy that operator training must follow the topics listed in the "Personnel Training" section of the American National Standards Institute publication "ANSI/HPS N43.17-2009 Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation."

10.7.3.5. For general-use full-body security screening systems capable of delivering a maximum effective dose equivalent less than or equal to 0.1 μSv (10 μrem) per scan: policies and records to show that administrative controls are applied to limit the number of screenings received by any individual such that the reference effective dose equivalent shall not exceed:

10.7.3.5.1. 0.25 μSv (25 μrem) per screening; and

10.7.3.5.2. 250 μSv (25 mrem) over any 12 month period;

10.7.3.6. For limited-use full-body security screening systems capable of delivering a maximum effective dose equivalent greater than 0.1 μSv

(10 μrem) per scan: policies and records to show that administrative controls are applied to limit the number of screenings received by any individual such that the reference effective dose equivalent shall not exceed:

10.7.3.6.1. 10 μSv (1 mrem) per screening; and

10.7.3.6.2. 250 μSv (25 mrem) over any 12 month period;

10.7.3.7. For general-use partial-body security screening systems capable of delivering a maximum effective dose equivalent less than or equal to 0.1 μSv (10 μrem) per scan: policies and records to show that administrative controls will be applied to limit the number of screenings received by any individual, such that:

10.7.3.7.1. The ADAP shall not exceed 0.03 μSv per square meter (3 μrem per square meter) per scan; and

10.7.3.7.2. The total number of scans received at the facility in a 12 month period shall not exceed N, where N = 75 μSv per square meter per ADAP (7500 μrem per square meter per ADAP);

10.7.3.8. For limited-use partial-body security screening systems capable of delivering a maximum effective dose equivalent greater than 0.1 μSv (10 μrem) per scan: policies and records to show that administrative controls will be applied to limit the number of screenings received by any individual, such that:

10.7.3.8.1. The ADAP shall not exceed 3 μSv per square meter (300 μrem per square meter) per scan; and

10.7.3.8.2. The total number of scans received at the facility in a 12 month period shall not exceed N, where N = 75 μSv per square meter per ADAP (7500 μrem per square meter per ADAP).

10.7.4. Each registrant operating a security screening system shall meet the following facility, design, shielding, and restricted area requirements:

10.7.4.1. A clearly marked restricted area shall be established. The dose outside of the restricted area shall not exceed 20 μSv (2 mrem) in any one hour;

10.7.4.2. A means shall be provided for the operator responsible for initiating the scan to maintain a full visual surveillance of the screening and restricted area; and

10.7.4.3. Engineering or administrative controls shall be provided to ensure that individuals do not reenter the scanning area from the exit while x-rays are being produced.

10.7.5. Screening systems capable of delivering an effective dose equivalent greater than 10 μSv (1 mrem) per scan shall not be used for non-medical screening of humans for security purposes.

10.8. Measurements, Monitoring, and Surveys

10.8.1. Radiation Levels

10.8.1.1. X-ray equipment shall be located and arranged with sufficient shielding and area access control to ensure compliance with Section 7.0.

10.8.1.2. The registrant shall assure that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits in Section 7.6.

10.8.2. The registrant shall document performance of radiation surveys, as required by Section 7.7, sufficient to show compliance with Section 10.7.1:

10.8.2.1. Upon installation of the equipment, and at least once every 12 months thereafter;

10.8.2.2. Following any change in the initial arrangement, number, or type of local components in the system;

10.8.2.3. Following any maintenance requiring the disassembly or removal of a local component in the system;

10.8.2.4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

10.8.2.5. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

10.8.2.6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in Section 7.2.

10.8.3. Radiation survey measurements shall not be required if a registrant can demonstrate, to the satisfaction of the Department, that the local components of an analytical x-ray system shall be located and arranged and include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which result in a dose to an individual present therein in excess of the dose limits given in Section 7.0.

DRAFT

10.8.4. Personnel Monitoring Requirements

10.8.4.1. Each individual who is associated with the operation of a non-healing-arts radiation generating machine shall meet the requirements of Sections 7.2 through 7.6.

10.8.4.1.1. Each operator of portable handheld x-ray equipment shall wear whole-body and extremity personnel dosimetric monitoring devices.

10.8.4.1.2. Deliberate exposure of a personnel dosimetric monitoring device to deceptively indicate a dose delivered to an individual is strictly prohibited.

10.8.4.2. Finger or wrist dosimetric devices shall be provided to and shall be used by:

10.8.4.2.1. Analytical x-ray equipment operators using systems having an open-beam configuration if and when a safety device is not present, is not in use, or is disabled; and

10.8.4.2.2. Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

10.8.4.3. Reported dose values shall not be used for the purpose of determining compliance with Section 7.2 unless evaluated by a qualified expert.

10.9. **Quality Assurance Requirements**

10.9.1. Each non-healing-arts radiation generating machine shall have written quality control and quality assurance procedures that follow:

10.9.1.1. Recommendations of the manufacturer;

10.9.1.2. Recommendations of the Radiation Safety Officer; and/or

10.9.1.3. Standards of an appropriate nationally recognized organization.

10.9.2. Records that demonstrate compliance with Section 10.5 and Section 10.7 shall be maintained by the registrant for 10 years for inspection by the Department. In addition to complying with the requirements of Section 10.5 and Section 10.7, records of individual monitoring results shall be maintained by the registrant in accordance with Section 7.12.

11.0 Radiation Safety Requirements for Industrial Radiographic Machines

11.1. **Purpose and Scope**

11.1.1. This Section establishes requirements, for which the registrant is responsible, for use of industrial radiographic machines not otherwise covered by this Rule, except those which contain radioactive materials, which are addressed in Part B of this Rule. The provisions of this Section are in addition to, and not in substitution for, other applicable provisions of this Rule.

11.1.2. The registrant shall be responsible for directing the operation of the radiation generating machines which have been registered with the Department. The registrant shall ensure that the requirements of this Section are met in the operation of the industrial radiographic machine(s).

11.1.3. This Section applies to all registrants who use radiation generating machines for industrial radiography.

11.2. **Exemptions**

11.2.1. Uses of certified and certifiable (per FDA 21 CFR 1020.40(d)) cabinet x-ray systems are exempt from the requirements of Section 11.0 except for the following:

11.2.1.1. For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

11.2.1.1.1. No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use.

11.2.1.1.1.1. Records that demonstrate compliance with Section 11.2.1.1.1 shall be maintained for at least 3 years after the individual stops operation the unit.

11.2.1.1.2. Tests for proper operation of interlocks must be conducted and recorded by the registrant at intervals not to exceed 6 months.

11.2.1.1.2.1. Records of these tests shall be maintained for 3 years after the record was made.

11.2.1.1.3. The registrant shall perform an evaluation of the radiation exposure to determine compliance with Section 7.6.1 and 21 CFR 1020.40 (April 1, 2004) (Cabinet X-Ray Systems, 39 Federal Register 12986, April 10, 1974), at intervals not to exceed 1 year.

11.2.1.1.3.1. Records of these evaluations shall be maintained for Department inspection for 3 years after the evaluation.

11.2.1.2. Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 (April 1, 2004) (Cabinet X-Ray Systems, 39 Federal Register 12986, April 10, 1974), and no modification shall be made to the system unless prior Department approval has been granted.

11.2.2. Industrial uses of handheld light intensified imaging devices are exempt from the requirements of this Part if the dose rate 45 centimeters (18 inches) from the source of radiation to any individual does not exceed 0.02 mSv (2 mrem) per hour. When this dose rate is exceeded, such devices shall meet the applicable requirements of this Rule and the registration requirements of Section 5.0.

11.3. **Training of Radiographer and Radiographer's Assistant**

11.3.1. The registrant shall not permit any individual to act as a radiographer unless and until the individual has provided evidence of having:

11.3.1.1. Satisfactorily completed 40 hours of training, including each of the following:

11.3.1.1.1. Fundamentals of radiation safety, including:

11.3.1.1.1.1. Characteristics of x-radiation;
11.3.1.1.1.2. Units of radiation dose;
11.3.1.1.1.3. Hazards of exposure to radiation;
11.3.1.1.1.4. Levels of radiation from sources of radiation;
11.3.1.1.1.5. Methods of controlling radiation dose (time, distance, and shielding);

11.3.1.1.2. Radiation detection instruments including:

11.3.1.1.2.1. Use, operation, calibration, and limitations of radiation survey instruments;
11.3.1.1.2.2. Survey techniques;
11.3.1.1.2.3. Use of personnel monitoring equipment;

11.3.1.1.3. Equipment to be used including:

11.3.1.1.3.1. Operation and control of radiation machines;

11.3.1.1.3.2. Storage, control, and disposal of sources of radiation;

11.3.1.1.3.3. Inspection and maintenance of equipment;

11.3.1.1.4. The requirements of this Rule.

11.3.1.2. Completed hands-on and on-the-job training in the performance of industrial radiography. The on-the-job training shall include a minimum of 160 hours (1 month) of on-the-job active participation utilizing radioactive machines.

11.3.1.2.1. The hours of on-the-job training do not include safety meetings, classroom training, travel, darkroom activities, film development and interpretation, or use of a cabinet x-ray unit.

11.3.2. The registrant shall not permit any individual to act as a radiographer's assistant unless and until the individual has received initial radiation safety training.

11.3.2.1. The radiographer's assistant shall be under the direct supervision of a radiographer whenever a radiographer assistant:

11.3.2.1.1. Uses radiation machines or associated equipment; or

11.3.2.1.2. Performs radiation surveys to determine that the radiation machine has stopped producing radiation.

11.3.3. Radiographers and radiographer's assistants shall receive annual refresher radiation safety training at intervals not to exceed 12 months.

11.4. **Locking of Industrial Radiographic Machines**

11.4.1. The control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an x-ray system or the accidental production of radiation.

11.4.2. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

11.5. **Inspection and Maintenance**

DRAFT

11.5.1. The registrant shall perform visual and operability checks on radiation machines and associated equipment before each day's use, or work shift, to ensure that the equipment is in good working condition.

11.5.2. If equipment problems are found, the equipment must be removed from service until repaired.

11.5.3. Each registrant shall have written procedures for, and perform inspection and routine maintenance of, radiation machines and associated equipment. The inspection and maintenance must be performed at intervals not to exceed 3 months, or before the first use thereafter, to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

11.5.4. Each registrant shall maintain records of equipment problems found in daily checks and quarterly inspections of radiation machines and associated equipment and retain each record for 3 years after it is made.

11.5.4.1. The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

11.6. Operating and Emergency Procedures

11.6.1. Operating and emergency procedures must include, as a minimum, instructions in the following:

11.6.1.1. Appropriate handling and use of radiation machines so that no person is likely to be exposed to radiation doses in excess of the limits established in Section 7.0;

11.6.1.2. Methods for posting and controlling access to radiographic areas;

11.6.1.3. Methods and occasions for locking and securing radiation machines;

11.6.1.4. Personnel monitoring and use of personnel monitoring equipment;

11.6.1.5. Transporting equipment to field locations, including packing of radiation machines;

11.6.1.6. The inspection, maintenance, and operability checks of radiation machines and associated equipment;

11.6.1.7. The procedure for notifying proper persons in the event of an accident or incident; and

DRAFT

11.6.1.8. Maintenance of records.

11.6.2. The registrant shall maintain copies of current operating and emergency procedures for the duration of registration.

11.6.2.1. Superseded material must be retained for 3 years after the change is made.

11.7. Utilization Logs

11.7.1. Each registrant shall maintain utilization logs showing for each radiation machine the following information:

11.7.1.1. A description, including the make, model, and serial number of the radiation machine;

11.7.1.2. The identity and signature of the radiographer to whom assigned;

11.7.1.3. The location and dates of use, including the dates removed and returned to storage; and

11.7.1.4. For permanent radiographic installations, the dates each radiation machine is energized.

11.7.2. The registrant shall retain the logs required by Section 11.7.1 for 3 years.

11.7.3. The registrant shall maintain adequate safeguards against tampering with and loss of records.

12.0 Radiation Safety Requirements for Particle Accelerators Not Used in the Healing Arts

12.1. Purpose and Scope

12.1.1. This Section establishes requirements, for which the registrant is responsible, for use of particle accelerators not used in the healing arts not otherwise covered by this Rule. The provisions of this Section are in addition to, and not in substitution for, other applicable provisions of this Rule.

12.1.2. The registrant shall be responsible for directing the operation of the radiation generating machines which have been registered with the Department. The registrant shall ensure that the requirements of this Section are met in the operation of particle accelerators not used in the healing arts.

12.2. General Requirements for the Issuance of a Registration for Particle Accelerators Not Used in the Healing Arts

12.2.1. In addition to the requirement of Section 5.0, a registration application for use of a particle accelerator will be approved only if the Department determines that:

12.2.1.1. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this Section and Section 5.0 in such a manner as to minimize danger to public health and safety or property;

12.2.1.2. The applicant's proposed equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

12.2.1.3. The issuance of the registration will not be inimical to the health and safety of the public;

12.2.1.4. The applicant has appointed a Radiation Safety Officer;

12.2.1.5. The applicant and/or his staff has substantial experience in the use of particle accelerators for the intended uses; and

12.2.1.6. The applicant has an adequate training program for particle accelerator operators.

12.3. **Radiation Safety Requirements for the Use of Particle Accelerators Not Used in the Healing Arts**

12.3.1. A registrant shall use the accelerator in accordance with the manufacturer's radiation safety and operating instructions.

12.3.2. Limitations

12.3.2.1. No registrant shall permit any person to act as a particle accelerator operator until such person:

12.3.2.1.1. Has been instructed in radiation safety and shall have demonstrated an understanding thereof to the satisfaction of the Radiation Safety Officer;

12.3.2.1.2. Has received copies of, and instructions required by, this Section and the applicable requirements of Sections 5.0 and 7.0, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

12.3.2.1.3. Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment to the satisfaction of the Radiation Safety Officer.

12.3.2.2. The Radiation Safety Officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

12.3.3. Shielding and Safety Design Requirements

12.3.3.1. A Qualified Expert, registered with the Department, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

12.3.3.2. Each particle accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to assure compliance with Sections 7.2 and 7.6.

12.3.4. Particle Accelerator Controls and Interlock System

12.3.4.1. Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

12.3.4.2. Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

12.3.4.3. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped, and lastly at the main control console.

12.3.4.4. Each safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.

12.3.4.5. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

12.3.4.6. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

12.3.5. Warning Devices

12.3.5.1. Each location designated as high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

12.3.5.2. Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

12.3.5.3. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA," or "DANGER, HIGH RADIATION AREA."

12.3.6. Operating Procedures

12.3.6.1. Each particle accelerator, when not in operation, shall be secured to prevent unauthorized use.

12.3.6.2. Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

12.3.6.3. Safety Checks

12.3.6.3.1. All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed 3 months. Safety checks shall assure, as appropriate, proper operation of:

12.3.6.3.1.1. Electrical interlocks at each room entrance;

12.3.6.3.1.2. Timer, dose terminator, emergency off, and door interlocks;

12.3.6.3.1.3. Beam condition indicator lights on the accelerator unit, on the control panel, and in the facility;

12.3.6.3.1.4. Viewing systems;

12.3.6.3.1.5. Doors from inside and outside the accelerator room; and

12.3.6.3.1.6. Electrically assisted room doors with the accelerator unit electrical power turned off.

12.3.6.3.2. A registrant shall promptly repair any system identified in Section 12.3.6.3.1 that is not operating properly. The accelerator shall not be used until all repairs are completed, except as may be necessary to repair, replace, or check the malfunctioning system.

12.3.6.3.3. A registrant shall maintain a record of the results of each safety check required by Section 12.3.6.3.1 for 3 years at the accelerator facility for inspection by the Department. The record shall include:

12.3.6.3.3.1. The date of the safety check;

12.3.6.3.3.2. The manufacturer's name, model number, and serial number for the accelerator;

12.3.6.3.3.3. The manufacturer's name, model number, serial number, and calibration date of the instrument used to conduct any measurements.

12.3.6.3.3.4. Notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors; and

12.3.6.3.3.5. The signature of the individual who performed the periodic routine QCs.

12.3.6.4. Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the Department and available to the operator at each accelerator facility.

12.3.6.5. If it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

12.3.6.5.1. Authorized by the Radiation Safety Officer;

12.3.6.5.2. Recorded in a permanent log and a notice posted at the accelerator control console; and

12.3.6.5.3. Terminated as soon as possible.

12.3.6.6. Current operating and the emergency procedures shall be developed. These instructions shall be maintained at the accelerator control panel and shall inform the operator of:

12.3.6.6.1. The procedure to be followed if the operator is unable to turn the accelerator off with controls at the control panel or any other abnormal operation occurs; and

12.3.6.6.2. The names and telephone numbers of the Radiation Safety Officer to be immediately contacted if the accelerator or console operates abnormally.

12.3.6.7. A registrant shall provide instruction in the topics identified in Section 12.3.6.6 to each individual who operates an accelerator and shall provide appropriate refresher training to each individual operator at intervals not to exceed 1 year.

12.3.6.8. A registrant shall maintain a record of each individual receiving instructions required by Section 12.3.6.7, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 3 years.

12.3.7. Radiation Monitoring Requirements

12.3.7.1. There shall be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility.

12.3.7.1.1. Such equipment shall be tested for proper functioning prior to each day of accelerator operation and calibrated at intervals not to exceed 12 months and after each servicing and repair.

12.3.7.2. A radiation protection survey shall be performed and documented by a Qualified Expert when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

12.3.7.2.1. A registrant shall maintain a record of the radiation measurements made following installation of the accelerator for the duration of the registration and when subsequent changes occur that could potentially affect the radiation levels in adjacent areas. The record shall include:

12.3.7.2.1.1. The date of the measurements;

12.3.7.2.1.2. The manufacturer's name, model number, and serial number of the accelerator;

12.3.7.2.1.3. A description of the accelerator configuration including whether there were any test objects in the accelerator beam;

12.3.7.2.1.4. The instrument used to measure radiation levels;

12.3.7.2.1.5. A plan of the areas surrounding the accelerator that were surveyed;

12.3.7.2.1.6. The measured dose rate at several points in each area expressed in microsievert (millirem) per hour;

12.3.7.2.1.7. The calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and

12.3.7.2.1.8. The signature of the Radiation Safety Officer.

12.3.7.3. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

12.3.7.4. All area monitors shall be calibrated at intervals not to exceed 3 months.

12.3.7.5. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.

12.3.7.6. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.

12.3.7.7. All area surveys shall be made in accordance with the written procedures established by a qualified expert or the Radiation Safety Officer of the particle accelerator facility.

12.3.7.8. Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be maintained for 3 years at the accelerator facility for inspection by the Department.

12.3.8. Ventilation Systems

12.3.8.1. Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in 10 CFR Part 20, Appendix B, Table 1.

12.3.8.2. A registrant shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which exceed the limits specified in 10 CFR Part 20, Appendix B, Table 1.

12.3.8.3. For purposes of Section 12.3.8.1 and Section 12.3.8.2, concentrations may be averaged over a period not greater than 12 months.

12.3.8.4. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below the limits prescribed in Section 12.3.8.1 and Section 12.3.8.2 as is reasonably achievable.

13.0 Record Keeping Requirements

13.1. Each record required by this Rule must be legible throughout the specified retention period. The record may be the original or a reproduced copy provided that the copy is authenticated by authorized personnel.

13.2. Records may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.

13.3. Records such as letters, drawings, and specifications must include all pertinent information, such as stamps, initials, and signatures.

14.0 Notice, Corrective Actions, and Enforcement

14.1. If an inspection indicates that the regulated entity is not in compliance with the requirements of this Rule, the Department may issue a notice of non-compliance to the regulated entity, detailing any deficiencies.

14.1.1. The notice shall include specific required corrective actions necessary for the regulated entity to take to regain compliance with this Rule, and may include interim corrective actions, such as requiring further investigation of the circumstances giving rise to the notice, or ceasing use of the source of radiation until such time as full compliance is restored, or such other action deemed necessary by the Department to protect the public health and safety is completed.

14.1.2. A regulated entity shall respond to the Department within the time specified in the notice, which shall be determined by the risk associated with the alleged non-compliance.

14.2. If the Department determines that an enforcement action is appropriate, or if timely and satisfactory compliance with a notice issued pursuant to Section 14.2 has not been achieved, the Department may issue a notice of violation to the regulated entity. The notice shall specify the nature of the violation and required action to restore full compliance.

14.3. An appeal of any order issued by the Board pursuant to this Section shall be to the Civil Division of the Superior Court as provided in 18 V.S.A. § 1655(c).

DRAFT

Part B: Radioactive Materials

Section I. Overview

1.0 General Provisions

1.1 Purpose.

Part B of this Rule establishes requirements for the protection of public health and safety as related to radioactive materials and implements the requirements of 18 V.S.A. §§ 1652 and 1653.

1.2 Scope.

1.2.1 This regulation, except as otherwise specifically provided, applies to persons who use, manufacture, produce, transport, transfer, receive, acquire, possess, own or dispose of radioactive materials.

1.2.2 A person, when required, shall obtain a license for radioactive materials in the possession or control of the person, and shall comply with the statute and this regulation.

1.2.3 As established in 18 V.S.A. § 1653 (c) this Rule does not regulate materials or activities reserved to the Nuclear Regulatory Commission (NRC) under 42 U.S.C. § 2021 (c) and 10 C.F.R. Part 150.

1.2.4 Notwithstanding the requirements incorporated by reference, nothing in this Rule relieves or limits a person from complying with the laws of the State of Vermont, including Vermont Statutes Title 18: Chapter 32, Title 10: Chapter 161, Title 10: Chapter 162 and Title 18: Chapter 31.

1.2.5 Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61.55, 61.56, 61.57, 70, 71, 150.1, 150.2, 150.3, 150.11, 150.20, 170, and 171 of the C.F.R. are incorporated by reference with the exceptions set forth in the relevant subsections, which either do not apply or are under the authority of the NRC. The unofficial version of these parts may be accessed at: **http://www.nrc.gov/.** An official version is also available by hard copy.

1.2.6 To reconcile differences between this regulation and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations:

1.2.6.1 With the exception of 10 CFR 30.4 and in the definition of Special Nuclear Material in 10 CFR 20.1003 which are incorporated by reference, a reference to ‘‘NRC’’ or ‘‘Commission’’ means the Vermont Department of Health.

1.2.6.2 A reference to ‘‘NRC or agreement state’’ means the Vermont Department of Health, NRC, or agreement state.

1.2.6.3 A reference to “the Act” means a reference to Vermont statute 18 V.S.A. § 1651-1658.

~~1.2.6.4 The definition of ‘‘sealed source’’ means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.~~

1.2.6.5 A reference to ‘‘byproduct material’’ includes naturally occurring or accelerator-produced radioactive material (NARM). ~~In 10 C.F.R. 40.4, the definition of “Byproduct Material” includes naturally occurring or accelerator-produced material (NARM).~~

1.2.6.6 In 10 CFR 40.4 the terms “Foreign Obligations” and Reconciliation” are not incorporated. In 10 CFR 40.4, in the definition of “Special Nuclear Material”, the sentence “and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material”, remains preserved.

1.2.6.7 With the exception of criminal history records required by 10 C.F.R. 37.27 (relating to requirements for criminal history checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material), notifications, reports and correspondence referenced in the incorporated parts of 10 C.F.R. shall be directed to the Vermont Department of Health after agreement state status is in effect, and, for NRC licenses, to the NRC until agreement state status is in effect. Criminal history records required by 10 C.F.R. 37.27 are to be sent to the NRC. Communications and reports concerning these regulations and applications filed under it shall be addressed to the Radiological & Toxicological Sciences Program, Vermont Department of Health, 108 Cherry Street, Burlington, Vermont, 05401.

1.2.6.8 Instructions in 10 C.F.R. to use forms of the NRC means to use forms of the Department, which will be available on the Department website at http://healthvermont.gov

1.2.6.9 In 10 C.F.R. 30.18(d), 30.32(g), 31.5(b)(1)(ii), 31.5(c)(3)(ii), 31.5(c)(8)(i), 31.6, 31.7(a), 31.10(a), 31.10(b)(1), 31.12(c)(4), 32.13, 32.51(a), 32.51(c), 32.56, 32.59, 32.72(b)(5)(ii), 40.13(c)(10), 40.22(e), 40.25(b), 40.25(d)(3), 40.54, 40.55(c), (c)(1), (d)(1)(ii), (d)(2) and (d)(3), where a reference is made to

DRAFT

"an Agreement State", it means "an Agreement State or the NRC".

1.2.6.10 In 10 C.F.R. 70.19(a) (1) and 70.19(c)(3), the terms "Commission or the Atomic Energy Commission" remains and does not mean the "Department". In 10 CFR 70.42(b)(1) the word "Department" means the "US Department of Energy".

1.2.6.11 In 10 CFR 150.20, where the words "non-agreement states", "areas of exclusive federal jurisdiction within agreement states", or "offshore waters" are used in 150.20(a)(1)(i), (ii), (iii), (b), (b)(3), and (b)(4) substitute the words "the State of Vermont". Where the words "agreement state license" are used in 10 CFR 150.20, also add the words "Nuclear Regulatory Commission license". Where the words "license issued by an agreement state" are used in 10 CFR 150.20 also add the words "license issued by the Nuclear Regulatory Commission". Where the words "license from an agreement state" are used in 10 CFR 150.20 also add the words "license from the Nuclear Regulatory Commission".

1.2.6.12 In 10 CFR 31, where the words "any non-agreement state" or "offshore waters" are used in 31.6 substitute the words "State of Vermont".

1.2.7 This Part does not regulate x-ray and other radiographic diagnostic or therapeutic equipment use by physicians, dentists, and other health professionals, occupational sources of radiation from machines and the radiation exposure values at the site boundary of the Vermont Yankee Nuclear Power Station.

1.3 Definitions

The definitions in 10 C.F.R. Chapter I, Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, 71,150, 170 and 171 are incorporated by reference in this Rule unless indicated otherwise.

1.3.1 "Agreement State" means any State with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended.

1.3.2 "Department" means the Vermont Department of Health unless the provision of the rule states that the term references the Department of Energy as referenced in 10 C.F.R. 70.42(b)(1).

DRAFT

1.3.3 "Disposal" means the isolation of radioactive wastes from the biosphere inhabited by man and containing his food chains by emplacement in a land disposal facility.

1.3.4 "Hazardous waste" means those wastes designated as hazardous by Environmental Protection Agency regulations in 40 CFR Part 261.

1.3.5 "Licensed practitioner of the healing arts" means an individual licensed by the State of Vermont pursuant to Title 26 to practice the healing arts, which for the purposes of this Rule shall be limited to medicine, surgery, dentistry, osteopathy, podiatry and chiropractic.

~~1.3.6~~ "NARM" means a naturally occurring or accelerator-produced radioactive material. The term does not include by-product, source or special nuclear material. ~~In 10 C.F.R. 40.4, the definition of "Byproduct Material" includes NARM.~~

1.3.7 "Radioactive material" means any material, whether solid, liquid, or gas, that emits ionizing radiation spontaneously. The term includes material made radioactive by a particle accelerator, byproduct material, naturally occurring radioactive material, source material, and special nuclear material.

1.3.8 "Regulated entity" means any individual, person, organization or corporation that is subject to the regulatory jurisdiction of the Department within the scope of this Rule.

1.3.9 "Source material" means: (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of: (1) uranium, (ii) thorium or (iii) any combination thereof. Source materials does not include special nuclear material.

1.3.10 "Special nuclear material" means: (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing, but does not include source material.

1.3.11 "Traceable to a National Standard" means a system which has been calibrated by the National Institute of Science and Technology or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine.

1.3.12 Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting or beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

1.3.13 "Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a

DRAFT

land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in § 20.1003 of this chapter.

1.3.14 The definition of regulated entities in 10 CFR 19.3 is not incorporated by reference.

2.0 Compliance Monitoring

2.1 Records

2.1.1 Licensees shall maintain records showing the receipt, transfer and disposal of radioactive material as described in 10 C.F.R. 30.51, relating to records.

2.1.2 Additional record requirements are specified elsewhere in these regulations.

2.2 Inspections and investigations

2.2.1 The Department may conduct inspections and investigations of the facilities and regulated activities of radioactive material necessary to demonstrate compliance with these regulations.

2.2.2 *Maintenance of records*. Licensees shall maintain records under this Rule and have these records available for inspection by the Department at permanent sites or facilities of use identified in a license issued under this regulation.

2.2.3 Licensees will permit the Department to:

2.2.3.1 Have access to, and require the production of, books, papers, documents and other records and physical evidence pertinent to a matter under inspection or investigation.

2.2.3.2 Require a licensee to make reports and furnish information to the Department.

2.2.3.3 Enter the premises of a licensee for the purpose of investigation or inspection of radioactive materials and the premises and facilities where radioactive materials are used or stored, necessary to ascertain the compliance or noncompliance with these regulations and this subsection and to protect health, safety and the environment.

2.2.4 The Department may conduct additional follow-up inspections and investigations if violations of the regulations promulgated thereunder were noted at the time of the original inspection, or if a person presents information, or circumstances arise, which give the Department reason to

believe that the health and safety of a person is threatened or that these regulations are being violated.

2.3 Tests

2.3.1 Licensees, upon instruction from the Department, shall perform, or permit the Department to perform, reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:

2.3.1.1 Radioactive materials.

2.3.1.2 Facilities in which radioactive materials are used or stored.

2.3.1.3 Radiation detection and monitoring instruments.

2.3.1.4 Other equipment and devices in connection with utilization or storage of licensed radioactive materials.

2.4 The Department may impose upon a person, requirements additional to those established in these regulations which it may deem reasonable and necessary to protect the public health and safety. As an example, when necessary or desirable to determine the extent of an individual's exposure to concentrations of radioactive material, the Department may require a licensee to provide to the individual appropriate bioassay services, medical services and the services of a qualified expert and to furnish a copy of the reports of these services to the Department.

3.0 Prohibitions, Restrictions and Additional Requirements

3.1 Sale of radioactive materials.

No person may sell within the State of Vermont radioactive materials which do not meet the requirements of these regulations.

3.2 Human use

3.2.1 No use of radioactive materials on humans may be permitted except under this regulation, and limited to the following license or certificate holders under Vermont Statutes Annotated, Title 26 Professions and Occupations:

Podiatry (Chapter 7); Chiropractic (Chapter 10); Dentists, Dental Hygienists, and Dental Assistants (Chapter 12); Medicine (Chapter 23); Physician Assistants (Chapter 31); Osteopathy (Chapter 33); Radiology (Chapter 51); Radiologist Assistants (Chapter 52).

3.2.2 Auxiliary personnel employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices may use radioactive materials in the healing arts provided those individuals comply with the applicable requirements in 3.2.1.

3.2.3 Auxiliary personnel employed by a health care facility regulated by the Department of Health may only use radioactive materials in the healing arts in accordance with written job descriptions and employee qualifications.

3.2.4 Paragraphs 3.2.2 and 3.2.3 notwithstanding, human use of radioactive materials is permitted by individuals enrolled in clinical training programs that satisfy the related accreditation requirements of the boards in paragraph 3.2.1 and who are under the supervision of a licensed practitioner of the healing arts or of auxiliary personnel authorized under paragraphs 3.2.2 and 3.2.3 to use radioactive materials sources in the healing arts.

3.3 Deliberate misconduct.

The requirements under 10 C.F.R. 30.10 (relating to deliberate misconduct) are incorporated by reference. In 10 C.F.R. 30.10(b), the reference to 10 C.F.R. 2, relating to deliberate misconduct, is replaced with 18 VSA § 1651 – 1657 and Radioactive Material Program Procedure Section 2.5, Enforcement, Escalated Enforcement and Administrative Actions.

3.4 Employee protections.

The requirements under 10 C.F.R. 30.7 (relating to employee protection) are incorporated by reference.

3.5 Vacating premises.

In addition to the decommissioning requirements of 10 C.F.R. 30.36 (relating to expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas) that are incorporated by reference under Subsection 11.0 (relating to licensing of radioactive material), a licensee shall notify the Department in writing of intent to vacate at least 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's activities. When deemed necessary by the Department, the licensee shall decontaminate the premises as the Department may specify.

3.6 Improper use of a monitoring device.

The deliberate exposure of, failure to use, or improper use of, an individual monitoring device or area monitoring device by an individual is prohibited.

3.7 Penalties.

A person who violates this Rule is subject to the civil and criminal penalties in 18 V.S.A. §§ 1651-1657. At a minimum, civil penalties may be assessed in an

amount sufficient to recover the costs expended by the Department in the correction of the violation or abatement of the resulting radiological nuisance.

4.0 Exemptions

4.1 Granting exemptions

The Department may, upon application therefore or upon its own initiative, grant exemptions from this regulation when the Department makes a finding that the exemption(s) do not result in significant risk to the health and safety of the public and safeguards that provide equivalent levels of protection in this Rule are implemented.

4.2 Exemption Qualifications.

The following sources, uses and types of users are exempt from this subchapter:

4.2.1 Federal government agencies

4.2.1 Electrical equipment

4.2.1.1 Equipment that produces radiation incidental to its operation for other purposes if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.005 mSv (0.5 mrem) per hour at 5 centimeters from an accessible surface.

4.2.1.2 The equipment is not exempt when operated without adequate shielding during testing and servicing if radiation levels exceed those specified. Electron beam welders and electron microscopes are not exempt.

4.2.3 A material, product or use specifically exempted from licensing requirements by the NRC, the Department or an agreement state or authorized for distribution to persons exempt from license requirements.

5.0 Fees

5.1 Scope.

5.1.1 This subsection establishes fees for licensing of radioactive materials and provides for their payment. The fee schedule for licensing materials is found at 18 V.S.A. § 1653 (b)(3).

5.1.2 For the purpose of this subsection, radioactive materials under the same administrative control in a single building are licensed as a single facility. Radioactive materials under the same administrative control at the same address or in a contiguous group of buildings may be licensed as a single facility if the Department determines that it is appropriate.

5.1.3 Except as otherwise specifically provided, this subsection applies to a person who: Is an applicant for or holder of a radioactive material license

issued under Subsection 11.0 (relating to licensing of radioactive materials).

5.2 Incorporation by reference.

5.2.1 Notwithstanding the requirements incorporated by reference, Sections 170.2(d), 170.2(e), 170.2(g) through 170.2(p), 170.2(r), 170.2(t), 170.4, 170.5, 170.8, 170.11, 170.12(c)(1), 170.12(c)(3), 170.12(d) through 170.12(f), 170.21, 170.51, 171.8, 171.9, 171.11, 171.13, 171.15, 171.16(a)(1)(v), 171.17(a), 171.19, 171.23 and 171.25 are not incorporated by reference.

5.2.2 The following categories of materials licenses and types of fees are also not incorporated from 10 C.F.R. 170.31 and 171.16: 1.A, 1.B, 1.E, 1.F, 2.A.(1), 2.A.(2)(a) – 2.A.(2)(e), 2.A.(3), 2.A.(4), 2.C, 3.D, 3.H, 9, 10, 11, 12, 13, 15, 17 and 18.

5.3 Radioactive Materials fees.

5.3.1 Annual license fees for radioactive material are set forth in 10 C.F.R. 171. Other radioactive materials fees are described in 10 C.F.R. 170.

5.3.1.1 No refund will be made for termination of a license.

5.3.1.2 If, by amendment or otherwise, a license changes to another fee category, the fee for the new category will take effect on the anniversary date of the license.

5.3.2 An initial application for a license or reciprocity shall be accompanied by a check payable to the Department in accordance with the fee schedules in 10 C.F.R. 170 and 171. Thereafter, the Department will issue an annual fee invoice in accordance with the appropriate fee schedule at least 2 months prior to the license expiration. Fees are payable by the last day of the license expiration month as shown on the license fee invoice. This provision is not applicable to full cost recovery licenses.

5.3.3 The Department will not accept an initial application for a license prior to payment of the fees required by paragraphs 5.3.1 and 5.3.2.

5.3.4 If a license involves more than one of the categories in paragraph 5.3.2, the highest applicable fee applies.

5.3.5 Special provisions for calculating annual fees during agreement state transition period.

5.3.5.1 The annual fees for the NRC licenses that are transferred to the State of Vermont on the date the State of Vermont becomes an agreement state will be invoiced on the license's next anniversary date.

5.3.5.2 During the first year after the date the Department attains agreement state status, the annual fee for each NRC license transferred to the State of Vermont will include a proportional amount, based on the schedule of fees in 10 C.F.R. 171, for the period from the date agreement state status is attained until the license's next anniversary date, in addition to the amount assessed for the year following the license's anniversary date.

6.0 Standards for Protection Against Radiation

6.1 Purpose and scope

6.1.1 This subsection establishes standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Department. Licensees shall comply with this subsection.

6.1.2 The requirements of this subsection are designed to control the receipt, possession, use, transfer and disposal of radioactive materials by a licensee so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this subsection. This subsection does not limit actions that may be necessary to protect health and safety in an emergency. In the event of an emergency, the Department will provide temporary guidance for dose management and other health protections.

6.1.3 Except as specifically provided in other subsections of this Rule, this subsection applies to persons licensed by the Department to receive, possess, use, transfer or dispose of radioactive materials.

6.1.4 The limits in this subsection do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material in accordance with Subsection 14.0 (related to medical use of byproduct material) or to voluntary participation in medical research programs.

6.2 Incorporation by reference

6.2.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 20 (relating to standards for protection against radiation) are incorporated by reference. An unofficial version can be accessed at http://www.nrc.gov. The official version is also available in hard copy.

6.2.2 Notwithstanding the requirements incorporated by reference, Sections 20.1006; 20.1009; 20.1405(b); 20.1406(b); 20.1905 (g); 20.2203(c); 20.2206(a)(1), (3), (4) and (5); 20.2401 and 20.2402 are not incorporated.

DRAFT

6.2.3 Effect of incorporation of 10 C.F.R. 20.1403 ‘‘Criteria for license termination under restricted conditions.’’

The Department will not terminate a license under the conditions of restricted release as provided for in 10 C.F.R. 20.1403 (relating to criteria for license termination under restricted conditions) until a license termination plan (LTP), approved by the Department, has been in effect for a period of time demonstrating to the Department that continued implementation of the plan will be effective in maintaining compliance with the required conditions of the plan. The Department may choose to implement the license termination process in one or more of the following steps:

6.2.3.1 The license is amended to authorize activities necessary to begin decommissioning under the LTP.

6.2.3.2 After decommissioning activities are complete and the provisions of 10 C.F.R. 20.1403 are in effect under the LTP, the license may be amended to end authorization of licensed activities. The license shall remain in effect for up to 5 years being limited to ownership/possession of the decommissioned material.

6.2.3.3 At the end of the period prescribed in paragraph 6.2.3.2, the Department will make a determination of the effectiveness of the established LTP. If the LTP has demonstrated the ability to maintain compliance with 10 C.F.R. 20.1403, the license will be terminated subject to the revisitation provision of 10 C.F.R. 20.1401(c) (relating to general provision and scope) regarding new evidence of a significant threat to health and safety. Otherwise, the licensee will be directed by the Department to take corrective actions as necessary to conform to 10 C.F.R. 20.1403 and the process shall revert back to paragraph 6.2.3.2.

6.2.4 Reports of leaking or contaminated sealed sources. If the test for leakage or contamination indicates a sealed source is leaking or contaminated, a report of the test shall be filed within 5 days with the Department describing the equipment involved, the test results and the corrective action taken.

7.0 Notices, Instructions and Reports to Workers; Inspections and Investigations

7.1 Purpose and scope.

7.1.1 This subsection establishes requirements for notices, instructions and reports by licensees to individuals engaged in activities under a license. This subsection also establishes options available to the individuals in connection with Department inspections of licensees to

ascertain compliance with the provisions of the Vermont State Statutes and regulations, orders and licenses issued thereunder regarding radiological working conditions.

7.1.2 This subsection applies to persons who receive, possess, use, own or transfer radioactive materials licensed by the Department under Subsection 11.0(relating to licensing of radioactive material, services and associated healthcare professionals).

7.2 Incorporation by reference.

7.2.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 19 (relating to notices, instructions and reports to workers; inspections and investigations) are incorporated by reference. The unofficial version can be accessed at **http://www.nrc.gov/.** The official version is also available in hard copy.

7.2.2 Notwithstanding the requirements incorporated by reference, Sections 19.4; 19.5; 19.8; 19.11(a)(4), (b) and (e); 19.14(a); 19.30 and 19.40 are not incorporated. The definition of "regulated entities" as stated in 10 CFR 19.3 is not incorporated. In 10 C.F.R. 19.13(a), where it says "Commission" and "Nuclear Regulatory Commission" this means the Department.

8.0 Reserved

9.0 Reserved

10.0 Enforcement

10.1 Purpose and Scope

10.1.1 Whenever the Department has reasonable grounds to believe that there has been a violation of any of the provisions of this Rule, the Department may take appropriate action as provided in this subsection or otherwise provided in law at 18 V.S.A. Ch. 32, to protect the public health and safety.

10.1.2 If an inspection indicates that the regulated entity is not in compliance with the requirements of this Rule, the Department shall notify the regulated entity in writing regarding any deficiencies.

10.1.3 The notice shall include specific required corrective actions necessary for the regulated entity to take to regain compliance with this Rule and may include interim corrective actions, such as requiring further investigation of the circumstances giving rise to the

notice, or ceasing use of radioactive materials until full compliance is restored, or such other action deemed necessary by the Department to protect the public health and safety is completed.

10.1.4 If the Department determines that an enforcement action is appropriate, or if timely and satisfactory compliance with a notice issued pursuant to paragraph 10.1.2 has not been achieved, the Department shall issue a notice of violation in writing.

10.2 Denial, Amendment, Suspension, Revocation or Waiver.

10.2.1 In any proceeding for granting denying, amending, suspending or revoking a license, determining compliance with, or granting exemptions from, rules or regulations of the Department the Department shall hold a public hearing upon the request of any person whose interest may be affected. Any such person shall become a party to the proceeding. Proceedings shall be conducted in accordance with 18 V.S.A. § 1655 and 3 V.S.A. § 814 (the Administrative Procedures Act).

10.2.2 Any final order entered in any proceeding under 10.2.1 may be appealed to the Civil Division of the Superior Court.

10.3 Emergency Orders.

If the Department finds that an emergency exists that requires immediate action to protect the public health and safety the Department may, without notice or hearing, issue an order requiring such action as is necessary to address the emergency in accordance with 18 V.S.A. § 1655 (b). Such orders must include a description of the nature of the emergency. Emergency orders take immediate effect and any person to whom the order is directed shall immediately comply. Any person(s) subject to such an order may make application to the Department for a hearing which shall be held within ten days. A decision shall be issued within ten days of the hearing that will continue, modify, or revoke the emergency order.

10.4 Whenever, in the judgment of the Department, any person has engaged in or is about to engage in any acts or practices which constitute or will constitute a violation of this Rule, or its authorizing statute, the Department will refer the matter to the Attorney General who can seek relief in accordance with 18 V.S.A. § 1656.

DRAFT

Section II. Radioactive Material

11.0 Licensing of Radioactive Materials

11.1 Purpose and scope.

11.1.1 This subsection establishes requirements for the licensing of radioactive material. A person may not manufacture, produce, receive, possess, use, transfer, own, dispose or acquire radioactive material except as authorized in a specific or general license issued under this subsection or otherwise provided in this subsection.

11.1.2 A licensee is also subject to Section I. Overview and other relevant subsections of Section II Radioactive Material.

11.2 The use of radioactive material in the State of Vermont under a license issued by the NRC is exempt from the licensing requirements of this subsection.

12.0 Rules of general applicability to licensing of radioactive materials.

12.1 Persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date Vermont becomes an Agreement State as published in the *Federal Register:*

On the date the State of Vermont becomes an agreement state as published in the Federal Register, a person who possesses a general or specific license issued by the NRC for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass, is deemed to possess a like license issued under this subsection and the statutes. The license shall expire either 90 days after receipt from the Department of a notice of expiration of the license, or on the date of expiration specified in the NRC license, whichever is earlier.

12.2 Incorporation by reference.

12.2.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 30 (relating to rules of general applicability to domestic licensing of byproduct material) are incorporated by reference. The unofficial version can be accessed at http://www.nrc.gov/**.** The official version is also available in hard copy. In 10 C.F.R. 30.10(b), the reference to 10 C.F.R. 2 relating to deliberate misconduct is replaced with 18 VSA § 1651 – 1657 and Radioactive Material Program Procedure Section 2.5, Enforcement, Escalated Enforcement and Administrative Actions. In 10 C.F.R. 30.50(c)(1), a reference to "NRC Operations Center" means "Department". In 10 C.F.R. 30.50(c)(2), reference to written reports means 'Written reports must be sent to: Vermont Department of

Health, 108 Cherry Street, Suite 201, Burlington Vermont 05401, Attn: Radioactive Materials Program."

12.2.2 Notwithstanding the requirements incorporated by reference, Sections 30.5; 30.6; 30.8; 30.21(c); 30.34(d) and (e)(1) and (3); 30.41(b)(6); 30.55; 30.63; 30.64 and the words "common defense and security" in the definitions for "Commencement of Construction" and "Construction" in 10 C.F.R. 30.4 are not incorporated. In 10 C.F.R. 30.10(b), the reference to 10 C.F.R. 2, relating to deliberate misconduct, is replaced with 18 V.S.A. § 1651 – 1657 and Radioactive Material Program Procedure Section 2.5, Enforcement, Escalated Enforcement and Administrative Actions. In 10 C.F.R. 30.50 (c)(1), a reference to "NRC Operations Center" means "Department." In 10 C.F.R. 30.50(c)(2), reference to written reports means written reports must be sent to: Vermont Department of Health, 108 Cherry Street, Suite 201, Burlington, Vermont 05401, Attn: Radioactive Materials Program.

12.2.3 Only the NRC can issue a license under 10 C.F.R. 32.11, 32.22, 32.26 and 32.30.

12.3 Filing applications for specific license

In addition to incorporation by reference, an application for a specific license shall be accompanied by the fee required under Subsection 5.0 (relating to fees).

12.4 Renewal of licenses.

An application for renewal of a specific license shall be filed under Subsection 11.0 (relating to licensing of radioactive material).

12.4.1 If a renewal application is filed prior to 30 days before the expiration of a license, the existing license does not expire until definitive notice has been given by the Department of its action on the renewal application.

12.4.2 This paragraph also applies to new license applications incorporating other licenses.

12.5 General licenses for radioactive material

12.5.1 Incorporation by reference.

12.5.1.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 31 (relating to general domestic licenses for byproduct material) are incorporated by reference. The

unofficial version can be accessed at http://www.nrc.gov/**.** The official version is also available in hard copy.

12.5.1.2 Notwithstanding the requirements incorporated by reference, Sections 31.4, 31.22 and 31.23 are not incorporated. In 10 C.F.R. 31.5(c)(7), the phrase "part 110" is replaced by "10 C.F.R. part 110." In 10 C.F.R. 31, the term "any non-agreement state" means "Vermont."

12.5.2 Certain measuring, gauging or controlling devices.

12.5.2.1 In addition to the parts of 10 C.F.R. 31.5 (relating to certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere) incorporated by reference, general licensees subject to registration under 10 C.F.R. 31.5(c)(13)(i) or possessing general licensed devices containing 37 MBq (1 mCi) or more of accelerator-produced material, as determined on the date of manufacture, or 3.7 MBq (0.1 mCi) or more of radium-226 shall also comply with the following:

12.5.2.2 Conduct a physical inventory every six months to account for all sources or devices, or both, received and possessed under this subsection and do the following:

12.5.2.2.1 Maintain the physical inventory records for three years from the date of each inventory.

12.5.2.2.2 Furnish a report to the Department annually showing to the extent practicable, the make, model, serial number, isotope, source activity and location of each device. The report shall list an individual to contact regarding questions about this report.

12.5.3 For portable devices, also comply with the following:

12.5.3.1 A person who initiates acquisition, transfer or disposal of a portable device shall notify the Department within 15 days of the action. Sending a portable device for calibration, maintenance or source replacement does not constitute transfer.

12.5.3.2 Portable devices may only be used by or under the direct supervision of individuals who have been instructed in the operating and emergency procedures necessary to ensure safe use.

12.5.3.3 For each individual that the licensee permits to use a portable device, the licensee shall maintain a record showing the type of device use permitted and the basis,

such as training certificates, for that authorization. An individual's record shall be kept for at least 3 years after the individual terminates association with the licensee.

12.5.3.4 Portable devices shall be secured from access by unauthorized personnel whenever the device is not under the direct surveillance of an individual authorized to use the device.

12.5.3.5 The licensee shall maintain a current sign out log at the permanent storage location of the portable device. Log entries shall be available for inspection by the Department for 3 years from the date of entry. The following information shall be recorded for each portable device:

12.5.3.5.1 The model and serial number of the device.
12.5.3.5.2 The name of the assigned user.
12.5.3.5.3 The locations and dates of use.

12.5.3.6 Emergency instructions shall accompany each portable device taken off the premises of the licensee.

12.5.4 Incidental radioactive material produced by a particle accelerator

12.5.4.1 A general license is issued to possess radioactive material produced incidentally to the operation of a particle accelerator. The general license is also subject to the applicable provisions of this subsection and Subsections 1.0, 6.0, and 7.0 (relating to general provisions; standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations).

12.5.4.2 A licensee may transfer this radioactive material only under Subsection 6.0 and Subsection 18.0 (relating to transfer of radioactive material; and packaging and transportation of radioactive material).

12.5.4.3 A licensee may dispose of this radioactive material only with Department approval.

12.6 Specific licenses to manufacture or transfer certain items containing radioactive material.

12.6.1 Incorporation by reference

12.6.1.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 32 (relating to specific domestic licenses to manufacture or transfer certain items containing byproduct material) are incorporated by reference. The unofficial

version can be accessed at http://www.nrc.gov/**.** The official version is also available in hard copy.

12.6.1.2 Notwithstanding the requirements incorporated by reference, Sections 32.1(c)(1), 32.8, 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29, 32.30, 32.31 and 32.32 are not incorporated.

12.6.1.3 Only the NRC can issue a license under 10 CFR 32.11, 32.22, 32.26 and 32.30.

~~12.6.2 Licensing the incorporation of NARM into gas and aerosol detectors.~~

~~An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Subchapter B (relating to general provisions for radioactive material) will be approved if the application satisfies requirements equivalent to those in 10 C.F.R. 32.26—32.29. The maximum quantity of radium-226 may not exceed 3.7 kBq (0.1 microcuries).~~

12.7 Specific Domestic Licenses of Broad Scope for Radioactive Material.

12.7.1 Incorporation by reference

12.7.1.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 33 (relating to specific domestic licenses of broad scope for byproduct material) are incorporated by reference. The unofficial version can be accessed at http://www.nrc.gov/. The official version is also available in hard copy.

12.7.1.2 Notwithstanding the requirements incorporated by reference, Sections 33.8, 33.21 and 33.23 are not incorporated.

12.7.2 Inclusion of naturally occurring or accelerator-produced radioactive material (NARM)

The requirements of 10 C.F.R. 33, relating to specific licenses of broad scope for radioactive material, also apply to NARM.

12.8 Licensing of source material

12.8.1 Incorporation by reference. Except as provided in this subsection, the requirements of 10 C.F.R. Part 40 (relating to domestic licensing of source material) are incorporated by reference. The unofficial version can be accessed at http://www.nrc.gov/**.** The official version is also available in hard copy.

12.8.2 Notwithstanding the requirements incorporated by reference, Sections 40.6; 40.8; 40.12(b); 40.13 (c)(5)(iv), ~~(j) and (m)~~; 40.23; 40.27; 40.28; 40.31(j),(k),(l) and (m); 40.32(d) and (g) and those portions of paragraph (e) which apply to uranium enrichment and uranium hexafluoride facilities; 40.33; 40.38; 40.41(d), (e)(1), (e)(3), (g) and (h); 40.51(b)(6); 40.52; 40.53; 40.56; 40.64; 40.66; 40.67; 40.81; and 40.82; Appendix A to Part 40; and the words "common defense and security" in the definitions for "Commencement of Construction" and "Construction" in 10 C.F.R. 40.4 are not incorporated. ~~In 10 C.F.R. 40.4, the definition of "Byproduct Material" includes NARM.~~ In 10 C.F.R. 40.10, the reference to 10 C.F.R. 2, relating to deliberate misconduct, is replaced with 18 V.S.A. § 1651-1657 and Radioactive Material Program Procedure Section 2.5, Enforcement, Escalated Enforcement and Administrative Actions. In 10 C.F.R. 40.4 the terms "Foreign Obligations" and "Reconciliation" are not incorporated. In 10 C.F.R. 40.4, the phrase "and any other material which the Commission, pursuant to the provision of section 51 of the Act, determines to be special nuclear material" is preserved without change. In 10 C.F.R. 40.10(b) the reference to 10 C.F.R. 2 subpart B is replaced by 18 V.S.A. § 130. In 10 CFR 40.60, reference to written reports means "Written reports must be sent to: Vermont Department of Health, 108 Cherry Street, Suite 201, Burlington, Vermont 05401, Attn: Radioactive Materials Program."

12.8.3 Only the NRC can issue a license pursuant to 10 C.F.R. 40.52.

12.9 Licensing of special nuclear material

12.9.1 *Incorporation by reference*. Except as provided in this subsection, the requirements of 10 C.F.R. Part 70 (relating to domestic licensing of special nuclear material) are incorporated by reference. The unofficial version can be accessed at http://www.nrc.gov/**.** The official version is also available in hard copy. In section 70.10, the phrase "the procedures in 10 C.F.R. part 2 subpart B" is replaced with 18 V.S.A. § 130. In 70.19(a)(1), the terms Commission and Atomic Energy Commission remain.

12.9.2 Notwithstanding the requirements incorporated by reference, Sections 70.1(c), (d) and (e); 70.5; 70.6; 70.8; 70.13; 70.14; 70.20a; 70.20b; 70.21(a)(1), (c), (f), (g) and (h); 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m) and (n); 70.23(a)(6), (7), (8), (9), (10), (11) and (12) and (b); 70.23a; 70.24; 70.25(a)(1); 70.31(c), (d) and (e); 70.32(a)(1), (4), (5), (6) and (7); 70.32(b)(1), (3) and (4), (c), (d), (e), (f), (g), (h), (i), (j) and (k); 70.37; 70.40; 70.42(b)(6); 70.44; 70.51(c); 70.52; 70.55(c)(1), (2) and (3); 70.56(c) and (d); 70.59; 70.60; 70.61; 70.64; 70.65; 70.66; 70.72; 70.73; 70.74; 70.76; 70.82; Appendix A to Part 70 and the words "common defense and security" in the definitions for

"Commencement of Construction" and "Construction" in 10 C.F.R. 70.4 are not incorporated. In 10 C.F.R. 70.10, the reference to 10 C.F.R. 2, relating to deliberate misconduct, is replaced with 18 V.S.A. § 1651-1657 and Radioactive Material Program Procedures Section 2.5, Enforcement, Escalated Enforcement and Administrative Action. In 70.19(a)(1) and 70.19(c)(3), the terms "Commission or the Atomic Energy Commission" remains and does not mean the "Department." In 10 C.F.R. 70.4, the phrase "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is preserved without change. In 10 CFR 70.50(c), preparation and submission of reports, all communications are to be made to the Vermont Department of Health 108 Cherry Street, Suite 201, Attn: Radioactive Materials Program, Burlington Vermont 05401, and by telephone at 802-863-7200 for immediate and 24-hour reports.

12.9.3 In 10 C.F.R. 70.42(b)(1), the word "Department" means the "US Department of Energy."

12.10 Transfer of radioactive material

The requirements of 10 C.F.R. 30.41 (relating to transfer of byproduct material) also apply to NARM.

12.10.1 *Incorporation by reference.* Except as provided in this subsection, the requirements of 10 C.F.R. 150.1, 150.2, 150.3 (excluding the definition of "Foreign Obligations"), 150.11 and 150.20 are incorporated by reference. The unofficial version may be accessed at **http://www.nrc.gov/.** An official hard copy version is also available.

12.10.2 The Department may withdraw, limit or qualify its acceptance of a specific license or equivalent licensing document issued by another agency, or product distributed under the licensing document, upon determining that the action is necessary to prevent a public health hazard as defined in 18 V.S.A. §2 (9).

12.10.3 Implementation of the requirements of this subsection regarding byproduct, source and special nuclear material is subject to paragraph 12.2 (relating to persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date Vermont becomes an agreement state as published in the Federal Register).

13.0 Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

13.1 Purpose and scope

13.1.1 This subsection establishes the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to 10 C.F.R. Part 37 Category 1 and Category 2 Radioactive Materials.

13.1.2 No provision of this subsection authorizes possession of licensed material.

13.2 Incorporation by reference

13.2.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 37 (relating to physical protection of category 1 and category 2 quantities of radioactive materials) are incorporated by reference. The unofficial version can be accessed at **http://www.nrc.gov.** The official version is also available in hard copy.

13.2.2 Notwithstanding the requirements incorporated by reference, Sections 37.3(b)(2), 37.13, 37.73(d) and (e), 37.107 and 37.109 are not incorporated.

14.0 Medical Use of Byproduct Material

14.1 Purpose and scope

14.1.1 This subsection prescribes requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of radioactive material. These requirements and provisions provide for the protection of the public health and safety.

14.1.2 The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements in these regulations.

14.2 Incorporation by reference.

14.2.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 35 (relating to medical use of byproduct material) are incorporated by reference. The unofficial version can be accessed at http://www.nrc.gov**.** The official version is also available in hard copy.

14.2.2 Notwithstanding the requirements incorporated by reference, Sections 35.8, 35.11(c)(1), 35.13(a)(1), 35.4001 and 35.4002 are not incorporated.

DRAFT

14.3 Authorization for calibration, transmission and reference sources

Notwithstanding the incorporation by reference of 10 C.F.R. 35.65 (relating to authorization for calibration, transmission, and reference sources), a licensee authorized for medical use of radioactive materials may not receive, possess or use radium in total quantity of 3.7 MBq (100 µci) or more for check, calibration, transmission and reference use except as specifically authorized by the Department.

15.0 Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations

15.1 Purpose and Scope

This subsection establishes radiation safety requirements for persons using radioactive materials for industrial radiography.

15.2 Incorporation by reference

15.2.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 34 (relating to licenses for industrial radiography and radiation safety requirements for industrial radiographic operations) are incorporated by reference. The unofficial version can be accessed at http://www.nrc.gov/**.** The official version is also available in hard copy.

15.2.2 Notwithstanding the requirements incorporated by reference, Sections 34.5, 34.8, 34.121 and 34.123 are not incorporated.

15.3 Prohibitions

Use of radiation sources covered under this subsection for diagnosis or therapy on humans or animals is not permitted.

16.0 Licenses and Radiation Safety Requirements for Well Logging

16.1 Purpose and Scope.

This subsection establishes radiation safety requirements for persons using radiation sources for well logging in a single well, radioactive markers, uranium sinker bars and subsurface tracer studies. Persons who use radiation sources for well logging operations shall comply with this subsection, which is in addition to and not in substitution for other applicable requirements of this Rule.

16.2 Incorporation by reference

16.2.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 39 (relating to licenses and radiation safety requirements for well logging) are incorporated by reference. The unofficial version can be accessed at http://www.nrc.gov/. The official version is also available in hard copy.

16.2.2 Notwithstanding the requirements incorporated by reference, Sections 39.5, 39.8, 39.101 and 39.103 are not incorporated.

17.0 Licenses and Radiation Safety Requirements for Irradiators

17.1 Purpose and scope

17.1.1 This subsection contains the requirements for the issuance of a license authorizing the use of radioactive materials in sealed sources to irradiate objects or materials with gamma radiation.

17.1.2 The requirements of this subsection are in addition to, and not in substitution for, other applicable requirements in this regulation.

17.2 Incorporation by reference

17.2.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 36 (relating to licenses and radiation safety requirements for irradiators) are incorporated by reference. The unofficial version can be accessed at http://www.nrc.gov/**.** The official version is also available in hard copy.

17.2.2 Notwithstanding the requirements incorporated by reference, Sections 36.5, 36.8, 36.91, 36.93 and the words "common defense and security" in the definitions for "Commencement of Construction" and "Construction" in 10 C.F.R. 36.2 are not incorporated.

18.0 Packaging and Transportation of Radioactive Material

18.1 Purpose and scope

This subsection establishes requirements for packaging, preparation for shipment and transportation of radioactive material. This subsection applies to a person who transports radioactive material or delivers radioactive material to a carrier for transport.

18.2 Incorporation by reference.

18.2.1 Except as provided in this subsection, the requirements of 10 C.F.R. Part 71 (relating to packaging and transportation of radioactive material) are incorporated by reference. The unofficial version can be accessed at http://www.nrc.gov/**.** The official version is also available in hard copy.

18.2.2 Notwithstanding the requirements incorporated by reference, Sections 71.2; 71.6; 71.11; 71.14(b); 71.19; 71.31; 71.33; 71.35; 71.37; 71.38; 71.39; 71.41; 71.43; 71.45; 71.51; 71.55; 71.59; 71.61; 71.63; 71.64; 71.65; 71.70; 71.71; 71.73; 71.74; 71.75; 71.77; 71.85(a), (b) and (c); 71.91(b); 71.99; 71.100; 71.101(c)(2), (d) and (e); 71.107; 71.109; 71.111; 71.113; 71.115; 71.117; 71.119; 71.121; 71.123 and 71.125 are not incorporated. In 10 C.F.R. 71 Subpart H the terms "Certificate of Compliance," "certificate holder," and "applicant for CoC" apply only to the NRC. In 10 C.F.R. 71.17(c)(3), the submission required before the first use of an NRC approved package should be sent to the NRC, ATTN: Document Control Desk, Director, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

18.3 Transportation of licensed material

In addition to the incorporation by reference of 10 C.F.R. Part 71 (relating to packaging and transportation of radioactive material), if VSA Title 23 (relating to interstate motor carrier safety requirements; intrastate motor carrier requirements; and hazardous materials transportation) or the regulations of the United States Department of Transportation in 49 C.F.R. Parts 171—180 and 388—397 do not apply to a shipment of licensed material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

19.0 Waste Classification, Characteristics and Labeling: The requirements of 10 C.F.R. 61. 55, 61.56 and 61.57 (relating to classification characterization and labeling of radioactive wastes) are incorporated by reference. The official version can be accessed at http://www.nrc.gov/. The official version is also available in hard copy**.**

DRAFT

Part C: Vermont Yankee Nuclear Power Station (VYNPS)

1.0 Purpose and Scope

Part C of this Rule establishes requirements for the protection of public health and safety as related to the site-boundary of the Vermont Yankee Nuclear Power Station (VYNPS).

2.0 Criteria Applicable to VYNPS Relating to Members of the Public

2.1 The maximum permissible total effective dose equivalent of members of the public in unrestricted areas from all regulated uses of ionizing radiation shall be kept as low as reasonably achievable (ALARA) and shall not exceed the values specified below:

2.1.1 Discharges of radioactive materials and direct gamma radiation to unrestricted areas shall be controlled as follows:

2.1.1.1 Gaseous Effluents

The annual committed effective dose equivalent limit for an individual in an unrestricted area due to plant emissions of radioactive noble gases is 5 millirem. The committed effective dose equivalent from noble gases is calculated using noble gas concentrations in air samples obtained by the Department and as reported by VYNPS.

2.1.1.2 Liquid Effluents

The annual committed effective dose equivalent limit for an individual in an unrestricted area, due to plant discharges of liquid effluents is 5 millirem. The committed effective dose equivalent from liquid effluents is calculated using liquid effluent concentrations in water samples obtained by the Department and as reported by VYNPS.

2.1.1.3 Radioiodine

The annual committed effective dose equivalent limit of an individual in an unrestricted area due to plant emissions of radioiodine is 5 millirem. The committed effective dose equivalent from radioiodines is calculated using radioiodine concentrations in air samples obtained by the Department and as reported by VYNPS.

2.1.1.4 Radioactive Particulates

The annual committed effective dose equivalent limit for an

DRAFT

individual in an unrestricted area due to plant emissions of radioactive particulates is 5 millirem. The committed effective dose equivalent from radioactive particulates is calculated using radioactive particulate concentrations in air samples obtained by the Department and as reported by VYNPS.

2.1.1.5 Direct Gamma Radiation

2.1.1.5.1 The annual effective dose equivalent limit for a member of the public in an unrestricted area due to plant emanations of direct gamma radiation is 5 millirem. For the purpose of this subsection, a measured exposure value of 20 milliroentgen per year above background radiation at any point on the site boundary bordered by land shall be considered equivalent to a 5 millirem effective dose equivalent for a member of the public in an unrestricted area.

2.1.1.5.2 If any site boundary, bordered by land, quarterly measured-exposure value exceeds 10 milliroentgen above background radiation, VYNPS shall take the actions described in **Section 4.0**

3.0 Compliance with Dose Limits for Members of the Public

3.1 VYNPS shall submit an annual report to the Department detailing the surveys and calculations of discharges of all radioactive materials and direct gamma radiation from all operations and activities at the plant and specifically addressing each of the applicable criteria specified in this Rule. The annual report shall be due no later than May 15 for the prior calendar year.

3.2 VYNPS shall submit monthly reports to the Department detailing the surveys and calculations of direct gamma radiation from all operations and activities at the plant and specifically addressing the quarterly and annual direct gamma radiation exposure limits specified in this Rule. The monthly reports shall include copies of all records of all instruments used to monitor public exposure, including all records of calibration of the main steam line radiation monitors and all reports relevant to the off-site dose calculation manual issued or created during the report period. The monthly reports shall be due no later than the 15th of the month for the prior calendar month.

3.3 For purposes of the annual and monthly reports, VYNPS shall calculate the committed effective dose equivalent of discharges of radioactive materials and shall report the measured exposure values of direct gamma radiation to unrestricted areas as provided in the most current VYNPS Off-Site Dose Calculation Manual as approved by the Nuclear Regulatory Commission, and shall report all measured exposure values from all other instruments used by VYNPS to monitor public exposure.

3.4 VYNPS shall provide any other information requested by the Department relating to the information and underlying data and calculations in the annual and monthly reports.

4.0 Required Actions Regarding Dose Limit Exceedances

4.1 VYNPS shall take the following actions as soon as it becomes evident that the quarterly or annual committed effective dose equivalents or measured exposure values exceed, or may exceed, the limits specified in this Rule, but in no event later than the last day of the calendar quarter in which the discharge exceeds these values:

4.1.1 Immediately report the discharge or direct gamma radiation exceedance to the Department.

4.1.2 Immediately make an investigation to identify the causes of the exceedance, or anticipated exceedance, of maximum limits for committed effective dose equivalent or measured exposure values, including an evaluation of all discharges of radioactive materials or direct gamma radiation that contributed to the exceedance, and initiate a program designed to ensure that future discharges will be maintained at or below values not likely to cause exceedance of the maximum limits for committed effective dose equivalent or measured exposure values specified in this Rule. As soon as possible, VYNPS shall report to the Department the action taken or proposed to be taken to achieve immediate reduction of the discharges for the Department's approval; and

4.1.3 VYNPS shall implement the plan approved by the Department with all reasonable speed.

DRAFT

4.1.4 Within 14 days, but in no event later than 10 days after the end of the calendar quarter, submit a report to the Department detailing the actions described above and providing verification of the completion of the implementation of the plan approved by the Department.

5.0 Independent Compliance Monitoring by the Department

5.1 The Department shall conduct environmental surveys and sampling and shall deploy appropriate instruments to measure discharges of radioactive materials and direct gamma radiation emanations from VYNPS. The Department shall use that information to determine compliance with the requirements established in this Rule.

6.0 Inspections

6.1 All regulated entities who receive, possess, use or transfer sources of ionizing radiation shall:

6.1.1 Provide the Commissioner with copies of all reports furnished to the NRC related to radioactive effluent discharges and gamma radiation emanations under normal or abnormal operating conditions.

6.1.2 Permit the Commissioner at all times the opportunity to inspect and evaluate sources of radiation and the premises and facilities wherein such sources of radiation are used or stored, and shall make available pertinent data, as well as records and reports as may be required by the Department.

6.1.3 Grant to the Commissioner access to all records pertaining to the radiological health and safety of employees, to discharges of radioactive material and gamma radiation emanations to the environment, and to any effect of the operation of the facility upon the environment.

6.1.4 Provide the same notice to the Commissioner of any radiological incident and reports thereof and in the same manner as provided to the NRC.

DRAFT

6.1.5 Permit the Commissioner to make unscheduled visits to the regulated facility for the purpose of obtaining samples and surveys for analysis.

6.1.6 Upon request by the Commissioner, VYNPS shall furnish advance notification of each scheduled calibration of effluent monitors and shall permit the Commissioner to be present during such calibration.

6.1.7 Upon request by the Commissioner, VYNPS shall share samples of environmental media for purposes of data correlation.

7.0 Notice, Corrective Actions and Enforcement

7.1 Whenever the Department has reasonable grounds to believe that there has been a violation of any of the provisions of this Rule, the Department shall take appropriate action as provided in this subsection or otherwise provided in law, in order to protect the public health and safety.

7.2 If an inspection, including the Department's independent compliance monitoring of VYNPS, indicates that the regulated entity is not in compliance with the requirements of this Rule, the Department shall notify the regulated entity in writing, with full particulars regarding any deficiencies.

7.2.1 The notice shall include specific required corrective actions necessary for the regulated entity to take to regain compliance with this Rule and may include interim corrective actions, such as requiring further investigation of the circumstances giving rise to the notice, or ceasing use of the source of radiation until such time as full compliance is restored, or such other action deemed necessary by the Department to protect the public health and safety is completed.

7.2.2 A regulated entity shall respond to the Department within the time specified in the notice, which shall be determined by the risk associated with the alleged non-compliance.

7.2.3 If the regulated entity fails to timely and satisfactorily comply with the requirements of the notice, the Department shall initiate an enforcement action.

7.3 If the Department determines that an enforcement action is appropriate, or if timely and satisfactory compliance with a notice issued pursuant to subsection (B) of this subsection has not been achieved, the Department shall issue a notice of violation in writing. The notice shall specify the nature of the violation and required action to restore full compliance. If the Department determines that enforcement action is required, the Department shall:

7.3.1 refer the matter to the Attorney General for injunction proceedings consistent with 18 V.S.A. §1656, or

7.3.2 in the event of an emergency, take immediate action consistent with 18 V.S.A. §1655 (b), or

7.3.3 initiate a proceeding before the Board by issuing a written notice of the alleged violation to the regulated entity and filing the notice with the Board. The Board shall convene a contested case proceeding pursuant to 3 V.S.A. § 809 and 18 V.S.A. § 1655. On the basis of the evidence produced at the hearing the Board shall make findings of fact and conclusions of law and enter such order as in its opinion will best further the purposes of this Rule and applicable law and shall give written notice of such order to the alleged violator, the Department and to any other parties to the proceeding, or

7.3.4 take such other action in the discretion of the Commissioner as authorized by law.

7.4 An appeal of any order issued by the Board pursuant to this subsection shall be to the superior court as provided in 18 V.S.A. § 1655(c)

8.0 Transportation

8.1 Persons transporting or shipping radioactive materials into, out of, through, or within the state shall provide notification to the Commissioner prior to such shipment or transport if such shipment or transport meets any of the following criteria:

8.1.1 Any shipment or package containing a large quantity of radioactive material regulated by the NRC or US Department of Transportation (DOT).

8.1.2 Fuel elements which have been utilized in a nuclear reactor.

8.1.3 Any Fissile Class I, Class II, or Class III package regulated by the DOT.

8.1.4 Any road, rail, air or sea transport of radioactive waste material for disposal.

8.2 The shipper shall supply the following information in writing or by telephone to the Commissioner at least two working days prior to shipment. Schedule changes or additional information must be provided no later than two hours prior to shipment. To avoid undue hardship the Commissioner may approve other reporting schedules requested by the shipper.

8.2.1 Name of shipper;
8.2.2 Name of carrier;
8.2.3 Type and quantity of radioactive material;
8.2.4 Date and time of shipment;
8.2.5 Starting point, scheduled route, and destination; and
8.2.6 Other information required by the Commissioner.

8.3 Shipments shall be made throughout the state with due regard to public health and safety. The Commissioner may require 'changes in dates, routes or time of shipment if necessary to maximize protection to public health and safety. Where possible, the Commissioner shall coordinate such changes with his or her counterparts in adjoining political jurisdictions.

DRAFT