CABINET FOR HEALTH AND FAMILY SERVICES

Department for Public Health

Division of

(Amendment)

902 KAR 100:017. Special requirements for teletherapy licensees.

RELATES TO: KRS 211.842-211.852, 211.990(4)

STATUTORY AUTHORITY: KRS 194.050, 211.090, 211.844

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Human Resources is empowered by KRS 211.844 to provide by regulation for the registration and licensing of the possession or use of any source of ionizing or electronic product radiation and to regulate the handling and disposal of radioactive waste. The purpose of this administrative regulation is to specify special requirements for teletherapy licensees.

Section 1. Applicability. This administrative regulation establishes special requirements for all teletherapy licensees.

Section 2. Use of a Sealed Source in a Teletherapy Unit. A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use only:

(1) In accordance with the manufacturer's radiation safety and operating instructions.

(2) Teletherapy sources manufactured and distributed in accordance with a license issued by the cabinet, the U.S. Nuclear Regulatory Commission or another agreement state.

Section 3. Maintenance and Repair Restrictions. Only a person specifically licensed by the cabinet, the U.S. Nuclear Regulatory Commission, or an agreement state to perform

teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

Section 4. Amendments. In addition to the requirements specified in 902 KAR 100:073, Section 3, a licensee shall apply for and receive a license amendment before:

(1) Making any change in the treatment room shielding;

(2) Making any change in the location of the teletherapy unit within the treatment room;

(3) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(4) Relocating the teletherapy unit; or

(5) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

Section 5. Safety Instruction. (1) A licensee shall post written instructions at the teletherapy unit console. These instructions shall inform the operator of:

(a) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;

(b) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and

(c) The names and telephone numbers of the authorized users and radiation safety

officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(2) A licensee shall provide instruction in the topics identified in this section to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one (1) year.

(3) A licensee shall maintain a record of individuals receiving instruction including, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three (3) years.

Section 6. Doors, Interlocks, Warning Systems, and Survey Instruments. (1) A licensee shall control access to the teletherapy room by a door at each entrance.

(2) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(a) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

(b) Turn the beam of radiation "off" immediately when an entrance door is opened; and

(c) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(3) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(4) A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range one-tenth (0.1) millirem per hour to fifty (50) millirems per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range

one (1) millirem per hour to 1000 millirems per hour. The instruments shall be operable and calibrated in accordance with 902 KAR 100:073, Section 16.

Section 7. Radiation Monitoring Device. (1) A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(2) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

(3) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(4) A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

(5) A licensee shall maintain a record of the check required by this section for three (3) years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

(6) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in this section.

(7) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

Section 8. Viewing System. A licensee shall construct or equip each teletherapy room

to permit continuous observation of the patient from the teletherapy unit console during irradiation.

Section 9. Dosimetry Equipment. (1) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one (1) of the following two (2) conditions shall be met:

(a) The system shall have been calibrated by the National Bureau of Standards or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous two (2) years and after any servicing that may have affected system calibration; or

(b) The system shall have been calibrated within the previous four (4) years; eighteen (18) to thirty (30) months after that calibration the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four (24) months by the National Bureau of Standards or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than two (2) percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(2) The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with this section. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in this section.

(3) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared or compared as required by this section, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

Section 10. Requirements for Full Calibration Measurements of Teletherapy Units. Any licensee authorized under these administrative regulations to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit:

(1) Prior to the first medical use of the unit;

(2) Prior to medical uses under the following conditions:

(a) Whenever spot-check measurements indicate that the output value differs by more than five (5) percent from the value obtained at the last full calibration corrected mathematically for physical decay;

(b) Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location;

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one (1) year.

(4) Full calibration measurements required by this section shall include determination of:

(a) The output to an accuracy within plus or minus three (3) percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) The congruence between the radiation field and the field indicated by the light beam localizing device;

(c) The uniformity of the radiation field and its dependence upon the orientation of the useful beam;

(d) Timer constancy and linearity over the range of use;

(e) The accuracy of all distance measuring devices used for medical use; and

(f) "On-off" error.

(5) A licensee shall use the dosimetry system described in Section 9 of this administrative regulation to measure the output for one (1) set of exposure conditions. The remaining radiation measurements required in this section may then be made using a dosimetry system that indicates relative dose rates.

(6) Full calibration measurements shall be made in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine, "Physics in Medicine and Biology," Volume

16, No. 3, 1971, pp. 379-396, filed herein by reference, or by task group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Volume 10, No. 6, 1983, pp. 741-771 and Volume 11, No. 2, 1984, p. 213, filed herein by reference.

(7) The output values determined in this section shall be corrected mathematically for physical decay for intervals not exceeding one (1) month for cobalt-60 and intervals not exceeding six (6) months for cesium-137.

(8) Full calibration measurements and physical decay corrections required by this section shall be performed by a teletherapy physicist qualified by training and experience in accordance with Section 17 of this administrative regulation and named on the licensee's license.

(9) A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

Section 11. Periodic Spot-checks. (1) Any licensee authorized to use teletherapy units for medical use shall perform output spot-check measurements on each teletherapy unit at intervals not exceeding one (1) month.

(2) Spot-check measurements shall include determination of:

(a) Timer constancy and timer linearity over the range of use;

(b) "On-off" error;

(c) The congruence between the radiation field and the field indicated by the light beam localizing device;

(d) The accuracy of all distance measuring devices and localization devices used for medical use;

(e) The output for one (1) typical set of operating conditions; and

(f) The difference between the measurement made in this section and the anticipated output, expressed as a percentage of the anticipated output expressed as a percentage of the anticipated output which is the value obtained at last full calibration corrected mathematically for physical decay.

(3) Spot-check measurements shall be performed in accordance with procedures established by a teletherapy physicist qualified by training and experience in accordance with Section 16 of this administrative regulation. That individual need not actually perform the spot-check measurements.

(4) A licensee shall have the teletherapy physicist review the results of each output spot-check within fifteen (15) days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification for three (3) years.

(5) A licensee shall use the dosimetry system described in Section 9 of this administrative regulation to make the output spot-check required in this section.

(6) A licensee authorized to use a teletherapy unit for medical use shall perform safety

spot-checks of each teletherapy facility at intervals not to exceed one (1) month.

(7) To satisfy the requirement of this section, safety spot- checks shall assure proper operation of:

(a) Electrical interlocks at each teletherapy room entrance;

(b) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;

(c) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(d) Viewing systems;

(e) Treatment room doors from inside and outside the treatment room; and

(f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(8) A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the cabinet.

(9) A licensee shall promptly repair any system identified during safety spot-checks that is not operating properly.

(10) A licensee shall maintain a record of each spot-check required by this section for three (3) years. The record shall include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated "on-off"

error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

Section 12. Radiation Surveys for Teletherapy Facilities. (1) Before medical use, after each installation of a teletherapy source and after making any change for which an amendment is required by Section 4 of this administrative regulation, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 902 KAR 100:073, Section 16 to verify that:

(a) The maximum and average radiation levels at one (1) meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed ten (10) millirems per hour and two (2) millirems per hour, respectively; and

(b) With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 902 KAR 100:020, Section 2 of this administrative regulations; and

2. Radiation levels in unrestricted areas do not exceed the limits specified in 902 KAR 100:020, Section 7(1) of these administrative regulations.

(2) If the results of the surveys required in this section indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:

(a) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

(b) Until the licensee has received a specific exemption from the cabinet.

(3) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit and the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems per hour, the calculated maximum level of radiation over a period of one (1) week for each restricted and unrestricted area, and the signature of the radiation safety officer.

Section 13. Safety Spot-checks for Teletherapy Facilities. (1) A licensee shall promptly spot-check all systems listed in Section 11(7) of this administrative regulation for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by Section 4 of this administrative regulation.

(2) If the results of the spot-checks required in this section indicate the malfunction of any system specified in Section 11 of this administrative regulation, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to

repair, replace, or check the malfunctioning system.

(3) A licensee shall maintain a record of the facility checks following installation of a source for three (3) years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

Section 14. Modification of Teletherapy Unit or Room Before Beginning a Treatment Program. If the survey required by Section 12 of this administrative regulation indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 902 KAR 100:020, Section 7(1) of these administrative regulations before beginning the treatment program the licensee shall:

(1) Either equip the unit with stops or add additional radiation shielding to ensure compliance with 902 KAR 100:020, Section 7(1) of these administrative regulations;

(2) Perform the survey required by Section 12 of this administrative regulation again; and

(3) Include in the report required by Section 15 of this administrative regulation the results of the initial survey, a description of the modification made to comply with this section, and the results of the second survey; or

(4) Request and receive a license amendment under 902 KAR 100:020, Section 7(2) of these administrative regulations that authorizes radiation levels in unrestricted areas greater than those permitted by 902 KAR 100:020, Section 7(1) of these administrative regulations.

Section 15. Reports of Teletherapy Surveys, Checks, Tests, and Measurements. A licensee shall furnish a copy of the records required in Sections 12, 13, and 14 of this

administrative regulation and the output from the teletherapy source expressed as roentgens or rads per hour at one (1) meter from the source and determined during the full calibration required in Section 10 of this administrative regulation to the cabinet within thirty (30) days following completion of the action that initiated the record requirement.

Section 16. Five (5) Year Inspection. (1) The licensee shall cause each teletherapy unit used for medical use to be fully inspected and serviced during source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) Inspection and servicing of the teletherapy unit shall be performed by persons specifically licensed to do so by the cabinet, the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

Section 17. Training for Teletherapy Physicist. The licensee shall require the teletherapy physicist to:

(1) Be certified by the American Board of Radiology in:

(a) Therapeutic radiological physics;

(b) Roentgen-ray and gamma-ray physics;

(c) X-ray and radium physics; or

(d) Radiological physics; or

(2) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one (1) year of full-time training in therapeutic radiological physics and also one (1) year of full-time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 902 KAR 100:073, Section 19 and Sections 10, 11 and 12 of this administrative regulation under the supervision of a teletherapy physicist during the year of work experience.

902 KAR 100:017

REVIEWED:

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Jeffrey D. Howard, Jr., M.D. Date

Acting Commissioner, Department for Public Health

APPROVED:

_____

Scott W. Brinkman, Date

Acting Secretary, Cabinet for Health and Family Services

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall, if requested, be held on ____, 2018, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky, 40621. Individuals interested in attending this hearing shall notify this agency in writing by ____, 2018, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until_____ , 2018. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Laura Begin, Legislative and Regulatory Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621, Phone: 502-564-6746, Fax: 502-564-2767; Laura.Begin@ky.gov.

Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 902 KAR 100:017
Agency Contact:
Phone Number: (502) 564-
Email:

Contact Person: Julie Brooks
Phone Number: (502) 564-3970
Email: julied.brooks@ky.gov

Provide a brief summary of:

(a) What this administrative regulation does:

(b) The necessity of this administrative regulation:

(c) How this administrative regulation conforms to the content of the authorizing statutes:

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

(b) The necessity of the amendment to this administrative regulation:

(c) How the amendment conforms to the content of the authorizing statutes:

(d) How the amendment will assist in the effective administration of the statutes:

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment:

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3):

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

(b) On a continuing basis:

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment:

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees.

(9) TIERING: Is tiering applied? (Explain why or why not.)

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation: 902 KAR 100:017
Agency Contact:
Phone Number: (502) 564-
Email:

Contact Person: Julie Brooks
Phone Number: (502) 564-3970
Email: julied.brooks@ky.gov

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

(c) How much will it cost to administer this program for the first year?

(d) How much will it cost to administer this program for subsequent years?

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: