

STATE OF COLORADO

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Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

INTERPRETIVE GUIDANCE

Hazardous Materials and Waste Management Division
Radiation Control Program, X-Ray Certification Unit

SUBJECT: Image Guided Radiation Therapy

Basis and Purpose:

Image Guided Radiation Therapy (IGRT) can involve the use of kilovoltage imaging systems for radiotherapy patient setup and target localization. Regulations in Part 24 for use of particle accelerators and therapeutic radiation machines in the healing arts do not address machine performance for these kilovoltage imaging systems. Machine performance and facility requirements in Part 6, X-Ray Imaging in the Healing Arts are not always appropriate for these systems when used in radiation therapy.

The purpose of this guidance is to list the regulatory requirements in Part 24 and Part 6 that are not appropriate for IGRT systems and what alternate means can achieve an equivalent level of patient safety and treatment plan quality. The Department expects that facilities will use current professional standards and guidance such as AAPM Report 104 "The Role of In-Room kV X-Ray Imaging for Patient Setup and Target Localization,

Scope:

At this time, this guidance applies to the on-board imaging options offered by Elekta's Synergy Model and the Varian Trilogy Model and the orthogonal planar imagers used by Accuray's CyberKnife.

Regulations:

Section 24.3.1.3 states, "The registrant or the registrant's agent shall ensure that all applicable requirements of Part 24 are met in the operation of the therapeutic radiation machine."

Section 24.3.1.4 states, "A therapeutic radiation machine that does not meet the requirements of Part 24 shall not be used to treat a patient."

Section 24.8.18.4 states, "When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field."

Section 24.8.1.5 (1) states, "Room Entrances - Each treatment room entrance shall be provided with a warning light, in a readily observable position near the outside of each access door or entrance, that will indicate when the useful beam is "ON" and when it is "OFF"."

Part 6 contains many requirements intended for facilities and x-ray machines that perform diagnostic imaging in the healing arts. For example, there are requirements for stepless adjustment of the radiation field (Section 6.6.2.1), visually defining the radiation field (Section 6.6.2.2), x-ray control location (Section 6.4.2.9(1)), and audible indication of exposure (Section 6.4.2.9 (2)).

Interpretation:

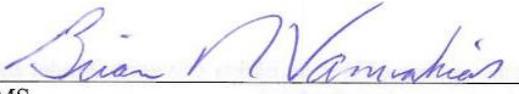
Requirements of Sections 24.3.1.3 and 24.3.1.4 should be waived only as those sections pertain to Section 24.8.18.4 and Section 24.8.1.5 (1) mentioned below. Radiation Therapy facilities are expected to follow all other applicable requirements in Part 24 of the Regulations.

Section 24.8.18.4 – Kilovoltage imaging systems typically does not use a light field because the placement of the useful beam is done automatically by the image guided system. The Department agrees that a light field to show where the radiation field is placed is not necessary with these systems. This requirement should be waived under the condition that the manufacturer's quality assurance program is followed with respect to the target location, tracking and beam alignment systems.

Section 24.8.1.5(1) – These radiation therapy systems produce the useful beam many times during the course of the treatment of a particular patient. The Department agrees that it is unnecessary to have the warning light turn on and off each time the useful beam is turned on and off. The purpose of the warning light is to indicate when the treatment room is in use and that no one should enter. It is acceptable for the warning light to be on throughout the treatment session, regardless of the actual beam condition. This requirement should be waived under the condition that the warning light will indicate when the high voltage potential is applied to the accelerator.

Section 6.6 in Part 6 of the Regulations refers to requirements for stationary x-ray systems. Many of these requirements pertain to machine performance for x-ray machines designed to take radiographs at variable SID's and multiple image receptor sizes. The kilovoltage imaging systems of the CyberKnife, Varian or Elekta systems mentioned above do not fall under the scope of Part 6 requirements. The requirements for stepless adjustment of the radiation field, visually defining the radiation field, x-ray control location, and audible indication of exposure are not applicable for these target locating systems. However, the Department recognizes that some machine performance criteria listed in Part 6 may apply and should be used to ensure accurate target location or reduce patient exposure. The requirements in Section 6.6 should be waived at the Registered Medical Physicist's discretion for those that are not applicable to the target locating systems.

This Guidance may be revoked pending any changes to the Regulations by this Department. Any questions or comments regarding this document should be addressed to the X-Ray Certification Unit at 303-692-3427, by fax at 303-759-5355 or by sending an email to Brian.Vamvakias@state.co.us.

Authorized by:  Date: October 6, 2010
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