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Dockets Management Branch (HFA-305)
Food and Drug Administration
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Rockville, MD
20852



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Subject: Application for Variance

Dear FDA Staff:

In accordance with 21 CFR §1010.4, the following information is provided in support of this application for variance from meeting 21 CFR Sec. 1020.33, Computed tomography (CT) equipment (CT Standard) and from annual reporting as a CT system in accordance with 21 CFR Sec. 1010.4(b)(1).

(i) A description of the product and its intended use.

Varian has two imaging systems that meet the 21 CFR §1020.30 definition of a Radiation Therapy Simulation System. These are Acuity, K033339, and the On Board Imaging (OBI) option to its medical linear accelerators, K042720.

The Radiation Therapy Simulation System definition in 21 CFR §1020.30 is; "a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field". However, both Acuity and OBI have the capability to produce volume computed tomography (CT) images known as Cone Beam CT. Neither device will be used for diagnostic purposes. All patients imaged by either, or both, device(s) will have received diagnostic CT imaging prior to being referred for radiation therapy. All patients on whom either or both devices are used will receive therapeutic irradiation. Ultimately the definition of a Radiation Therapy Simulation System will need to be expanded to include CT imaging and the regulations revised to allow exceptions for Radiation Therapy Simulation Systems using CT imaging.

(ii) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

The CT regulations are intended for protecting the public from unnecessary diagnostic radiation. Neither device will be used for diagnostic purposes and all patients on whom either or both devices are used will have been diagnosed with a lesion treatable with ionizing radiation. All patients will receive therapeutic irradiation. The additional dose from CT imaging, used as a replacement for some of the radiographic and fluoroscopic imaging by the Radiation Therapy Simulation System, will be inconsequential to the total patient dose.

2004V-0553

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(iii) A description of the manner in which it is proposed to deviate from the requirements of the applicable standard.

Both systems comply with the Diagnostic X-ray Standard 21 CFR sections 1020.30, 1020.31 and 1020.32 as applicable to a Radiation Therapy Simulation System. There is no alteration of the physical equipment in order to produce cone beam CT images whose use is to verify the treatment planned from diagnostic CT images.

(iv) A description of the advantages to be derived from such deviation.

Since the devices are not used for diagnostic purposes, the Radiation Therapy Simulation Systems would not have to be measured and certified according to the CT Standard or be subject to annual reporting in addition to that required by the Diagnostic X-ray Standard.

(v) An explanation of how alternate or suitable means of radiation protection will be provided.

Compliance with the sections of the Diagnostic X-ray Standard applicable to Radiation Therapy Simulation Systems is sufficient to protect patients that are undergoing therapeutic irradiation.

(vi) The period of time it is desired that the variance be in effect, and, if appropriate, the number of units the applicant wishes to manufacture.

It is desired that the variance remain in effect until the CT X-ray Standard is revised to exempt Radiation Therapy Simulation Systems.

Should you have any additional questions, please contact me at (650) 424-5731.

Sincerely,



Vy Tran

Corporate Director of Regulatory Affairs