Federal Register: Device Improvements to Reduce the Number of Under-Doses, Over-Doses, and Misaligned Exposures From Therapeutic Radiation; Public Meeting; Request for Comment...

U.S. Food & Drug Administration

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[Notices]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0217]

Device Improvements to Reduce the Number of Under-Doses, Over-Doses, and Misaligned Exposures From Therapeutic Radiation; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; requests for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled ``Device Improvements to Reduce the Number of Under-doses, Over-doses, and Misaligned Exposures from Therapeutic Radiation.'' The purpose of this meeting is to discuss steps that could be taken by manufacturers of linear accelerators, radiation therapy treatment planning systems, and radiation therapy simulators to help reduce misadministration and misaligned exposures. FDA is seeking input on this topic and requests comments on a number of related questions.
Date and Time: The public meeting will be held on June 9 and 10, 2010, from 8 a.m. to 5 p.m.
Location: The public meeting will be held at the Hilton Hotel Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD

20877.
Contact Person: Simon Choi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5400, Silver Spring, MD 20993, 301-796-5426; e-mail: simon.choi@fda.hhs.gov [1].
Registration and Requests for Oral Presentations: Persons interested in attending the public meeting must register by May 15, 2010. If you wish to attend the public meeting, you must register by e-mail at CDRHRadiationTherapy@fda.hhs.gov [2] or by contacting Simon Choi (see Contact Person). Provide complete contact information for each attendee, including name, title, company or organization,

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address, telephone number, and e-mail (if appropriate).
Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m.
If you wish to make an oral presentation during any of the sessions at the meeting (see section I of this document, Public Meeting), you must indicate this at the time of registration. FDA has included specific questions for comment in section II of this document, Questions for Comment. You should also identify the session(s) during which you would like to present, as well as the question(s) you would like to address in each session. In order to keep each session focused on the topic at hand, presentations given during each session should address only the topic specified for that session. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.
If you would like to participate in any of the four planned round-table discussions (see section I of this document, Public Meeting), you must indicate this interest at the time of registration, and also submit a brief statement that describes your experience with radiation therapy devices. FDA is seeking participants interested in engaging in one of four round-table discussions related to the presentations given during each of the earlier sessions of the meeting. Each round-table discussion will include no more than 10 non-FDA participants. Only one participant from an organization or company will be assigned to each discussion group. FDA will attempt to have a range of constituencies represented in each discussion group. Others in attendance at the public meeting will have an opportunity to listen to each round-table discussion.
If you need special accommodations due to a disability, please

contact Simon Choi (see Contact Person) at least 7 days in advance of the meeting.
Comments: FDA is holding this public meeting to obtain information on a number of questions regarding steps manufacturers of radiation therapy devices could take to help reduce over-doses, under-doses, or misaligned exposures from therapeutic radiation. The deadline for submitting comments related to this public meeting is May 15, 2010, by 5 p.m. EST.
Regardless of attendance at the public meeting, interested persons may submit written or electronic comments. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov [4]. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Public Meeting

The objective of this public meeting is to discuss steps that could be taken by manufacturers of linear accelerators, radiation therapy treatment planning systems, and radiation therapy simulators to help reduce misadministration and misaligned exposures. FDA is seeking input on this topic and requests comments on a number of related questions. The public meeting will be held over the course of 2 days. Each day will be divided into two sessions. Day 1 will focus on equipment features that manufacturers should incorporate into radiation therapy devices (morning session) and software (afternoon session). Day 2 will focus on steps manufacturers should take to improve training of individuals who use these devices (morning session) and steps to improve quality assurance (QA) at medical facilities (afternoon session). During each session, members of the public may present oral comments related to the topic of that session. Specific questions for comment are listed in section II of this document, Questions for Comment. Individuals who are interested in giving an oral presentation during any of the sessions must indicate this interest at the time of registration and must also identify the session(s) at which they would like to present (see Registration and Requests for Oral Presentations). In order to keep each session focused on the topic at hand, each oral presentation should address only the topic specified for that session. Commentators are free to submit written comments on any topic(s) to the open docket (see Comments). FDA will schedule speakers for each session

as time permits.
To close each of the four sessions, FDA will hold a round-table discussion between FDA staff and selected participants representing a range of constituencies (for more information about participating in the round-table discussion, see Registration and Requests for Oral Presentations). The participants in each round-table discussion will remark on the presentations given during the session, engage in a dialogue with each other and FDA staff, and provide closing thoughts on the session. Round-table participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. Others in attendance at the meeting will have an opportunity to listen to each round-table discussion.
In advance of the public meeting, additional information, including a meeting agenda with a speakers' schedule for each session, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at http://www.regulations.gov [4]. This information will also be available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm [5] (select the appropriate meeting from the list).

II. Questions for Comment

A. Device Improvements and Reporting

1. Describe issues with misadministrations and your suggestions to address the safety issues.
2. Are there any hardware and software features that manufacturers can build into radiation therapy devices to reduce underexposures, overexposures, or misaligned exposures to ionizing radiation during radiation therapy?
3. What techniques do you recommend for improving therapists attention (e.g. a dead-man switch to assure operator attention). Should efforts to improve device safety features include: incorporation of access controls and audit capabilities into equipment to identify the specific user(s) of the device during any particular treatment? If so, why, and what access controls and audit

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capabilities should be incorporated? If not, why not?
4. If certain changes are desirable as additional safeguards for the devices, how feasible is it to retrofit existing units in the field?
5. Should manufacturers standardize their display format to ensure that treatment settings, protocols, and collimator positions are displayed taking human factors into consideration and are recorded for physician review?
6. Should manufacturers submit more data to FDA as part of their

premarket submissions for approval or clearance of devices, related to the safety of these devices? If so, why, and what data should be submitted? If not, why not?
7. Should there be a mandatory ``time-out'' built into the equipment, similar to what already has been implemented for surgical procedures, to confirm that all settings for the equipment are correct and allow adequate time for QA? If not, why not?
8. Should manufacturers provide better instructions and specifics (i.e. QA methodology) for acceptance testing and/or commissioning due to new and/or unique features/capabilities? If so, why and what should be included?
9. Other than requiring a facility to report to FDA, how can FDA ensure that facilities report to FDA significant under-doses and over-doses? Should there be a quantitative metric used to define a medical event similar to that used by the Nuclear Regulatory Commission (e.g. +[sol]- 20% variation from intended dose)?
10. What prevents users from participating in voluntary reporting?
11. How can FDA encourage reporting and prevent workarounds even when no clinically significant adverse event occurs?

B. User Training

1. Should manufacturers provide training to ensure equipment users have adequate understanding of equipment capabilities, operating principles for the technology, general information about patient dose, and specific dose-related equipment features? If so, why, and what training should be provided? If not, why not?
2. If manufacturers provide such training, which personnel should receive it? In your response, please consider dosimetrists, physicists, radiation therapists or technologists in other specialties and departmental administrators as well as physicians in all medical specialties who may operate radiation therapeutic equipment.
3. If manufacturers provide such training, what is the most effective timing for a new installation and how frequently should it be repeated for optimum implementation? Should manufacturers recommend an internal training program for use by the facility to insure continued staff competence?
4. For software patches and upgrades, how is the software tested for hazard analysis, verification and validation? Should manufacturers perform additional testing to adequately test software patches?
5. Would standardizing terminology and standardizing design of control panels facilitate safe use of the equipment?
6. Should custom-tailored educational material, such as pamphlets, pocket cards, videos etc. that highlight unique features of the equipment, be provided with new equipment?

C. Quality Assurance Measures

1. Is there a model QA program that exists which is widely

accepted? If so, please describe.
2. What types of QA should be the responsibility of the facility, the physicist, the operator, others?
3. Should manufacturers provide QA procedures to medical facilities and users of radiation therapy devices? If so, why, and what instructions should be provided? If not, why not? How extensive should they be?
4. Should manufacturers provide training on QA practices? If so, why, what type of training should be provided, and to which personnel? If not, why not and who should?

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov [4]. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: May 3, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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SOURCE [7]

Source URL (retrieved on *02/01/2015 - 8:16am*):
http://www.mdtmag.com/news/2010/05/federal-register-device-improvements-reduce-number-under-doses-over-doses-and-misaligned-exposures-therapeutic-radiation-public-meeting-request-comment?qt-recent_content=0

Links:
[1] mailto://edocket.access.gpo.gov/2010/simon.choi@fda.hhs.gov
[2] mailto://edocket.access.gpo.gov/2010/CDRHRadiationTherapy@fda.hhs.gov
[3] http://www.mdtmag.com/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=8159
[4] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regulations.gov
[5] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm
[6] http://www.mdtmag.com/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=8160

[7] http://edocket.access.gpo.gov/2010/2010-10754.htm