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. +/- 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*. 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.

[FR Doc. 2010–10754 Filed 5–6–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, May 28, 2010, 12 p.m. to May 28, 2010, 2:30 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on April 28, 2010, 75 FR 22412.

The meeting has been changed to an Internet assisted meeting. The meeting time has been changed to 8 a.m. to 7 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: April 29, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–10873 Filed 5–6–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, May 19, 2010, 12 p.m. to May 19, 2010, 5 p.m., Tata Communications, 2355 Dulles Corner Boulevard, 7th Floor, Herndon, VA 20171 which was published in the **Federal Register** on April 26, 2010, 75 FR 21641.

The meeting has been changed to a Hybrid meeting. The meeting date, time and location remain the same. The meeting is closed to the public.

Dated: April 29, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–10871 Filed 5–6–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Food Protection Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.