

before commencement of the proceeding. For example, the network pool representatives might agree to record a portion of the proceeding up to a break in the proceeding, at which time, while the network representative is disassembling equipment, another media representative might set up to continue recording. If an agreement cannot be reached before the proceeding, the agency will use the time of receipt of any advance notice to determine the representation for each category of media, e.g., one network reporter, one independent reporter. The agency recommends that parties intending to videotape provide as much advance notice as possible, so that the agency may best respond to the needs of the electronic media.

(g) To ensure the timely conduct of agency hearings and to prevent disruptions, equipment is to be stationary during a proceeding and should be set up and taken down when the proceeding is not in progress. As noted previously, the presiding officer may, at his or her discretion, be less restrictive if appropriate.

(h) The agency recognizes that electronic media representatives may desire only short footage of a proceeding, a facsimile of the proceeding, and/or interview opportunities and may be unnecessarily restricted by requirements for setting up before a proceeding and then waiting until a break in the proceeding before being permitted to take down their equipment. To accommodate this possibility, FDA's Press Relations Staff will attempt to make arrangements to respond to such needs by, for example, requesting that the presiding officer provide a break shortly after commencement of the proceeding to permit take down of equipment.

(i) The agency is making a full commitment to allowing, whenever possible, electronic coverage of its public administrative proceedings subject to the limited restrictions established in this guideline.

§ 10.205 Electronic media coverage of public administrative proceedings.

(a) A person may record electronically any open public administrative proceeding, subject to the procedures

specified in this guideline. The procedures include a presumption that agency public proceedings are open to the electronic media. Whenever possible, FDA will permit all interested persons access to record agency public administrative proceedings. Restrictions other than those listed in § 10.206 will be imposed only under exceptional circumstances.

(b) A videotape recording of an FDA public administrative proceeding is not an official record of the proceeding. The only official record is the written transcript of the proceeding, which is taken by the official reporter.

§ 10.206 Procedures for electronic media coverage of agency public administrative proceedings.

(a) To facilitate the agency's response to media needs, a person intending to videotape an FDA public administrative proceeding should, whenever possible, provide advance notice to the Press Relations Staff (HFI-20), Office of Public Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, in writing or by telephone (telephone 301-443-4177), at least 48 hours in advance of the proceeding. The Press Relations Staff will inform the presiding officer that the proceeding will be attended by representatives of the electronic media, and ascertain whether any special provisions in addition to those set forth in this subpart are required by the presiding officer. If so, the Press Relations Staff will function as a liaison between the presiding officer and the person intending to record the proceeding in facilitating any procedures in addition to those outlined in this subpart. The presiding officer will not deny access for failure to provide a 48-hour advance notice. Any advance notice may describe the intended length of recording if known, the amount and type of equipment to be used, and any special needs such as interviews.

(b) Cameras should be completely set up before a proceeding is scheduled to begin or during a break in the proceeding and should remain standing in the area designated for electronic media equipment. Cameras may be taken down only during breaks or after the hearing is over. Roving cameras

will not be permitted during the proceeding. Any artificial lighting should be unobtrusive. Microphones, like cameras, should be in place before the start of a proceeding and may be taken down as indicated in this paragraph.

(c) When space in the hearing room is limited, the presiding officer may restrict the number of cameras or the equipment present. Should such a restriction become necessary, the pool arrangements are the responsibility of the participating media. The agency encourages the network pool to make copies of the tape, film, or other product available at cost to nonpool participants. However, if this is not possible, the agency may need to use the time of receipt of any advance notice to determine the representation for each category, e.g., one network reporter, one independent reporter, etc.

(d) *Off the record* portions of a proceeding may not be videotaped.

(e) Before or during the proceeding, the presiding officer may establish other conditions specific to the proceeding for which the request is being made. These conditions may be more or less restrictive than those stated in this guideline, except that the presiding officer shall observe the agency's presumption of openness of its public proceedings to the electronic media. Only a substantial and clear threat to the agency's interests in order, fairness, and timeliness authorizes the presiding officer to impose additional restrictions. This threat must outweigh the public interest in electronic media coverage of agency proceedings. Additional restrictions shall be narrowly drawn to the particular circumstances. The following factors are listed to assist presiding officers in determining whether the agency's interest is sufficiently compelling to call for the unusual step of imposing additional restrictions. Generally this step is justified when one of the following factors is met:

(1) Electronic recording would result in a substantial likelihood of disruption that clearly cannot be contained by the procedures established in paragraphs (a) through (d) of this section.

(2) Electronic recording would result in a substantial likelihood of prejudicial impact on the fairness of the pro-

ceeding or the substantive discussion in a proceeding.

(3) There is a substantial likelihood that a witness' ability to testify may be impaired due to unique personal circumstances such as the age or psychological state of the witness or the particularly personal or private nature of the witness' testimony, if the witness' testimony were electronically recorded.

(f) Before the proceeding, the Press Relations Staff will, upon request, provide written copies of any additional conditions imposed by the presiding officer (as described in paragraph (e) of this section) to requesting members of the media. Any appeals should be made in accordance with paragraph (h) of this section.

(g) The presiding officer retains authority to restrict or discontinue videotaping or other recording of a proceeding, or parts of a proceeding, should such a decision become necessary. The presiding officer's responsibility to conduct the hearing includes the right and duty to remove a source of substantial disruption. In exercising his or her authority, the presiding officer shall observe the presumption that agency public proceedings are open to the electronic media. The presiding officer shall exercise his or her discretion to restrict or discontinue electronic coverage of a public proceeding, or portions of a public proceeding, only if he or she determines that the agency's interest in the fair and orderly administrative process is substantially threatened. A clear and substantial threat to the integrity of agency proceedings must clearly outweigh the public interest in electronic media coverage of the proceedings before additional restrictions are imposed on the electronic media during the course of the proceedings. The factors noted in paragraph (e) of this section indicate the kind of substantial threat to the agency interests that may require imposing additional restrictions during the course of the proceedings. If additional requirements are established during the hearing, the presiding officer shall notify immediately the Deputy Commissioner of Food and Drugs of that fact by telephone and submit a written explanation of the circumstances that

necessitated such an action within 24 hours or sooner if requested by the Deputy Commissioner. In the absence or unavailability of the Deputy Commissioner, the presiding officer shall notify the Associate Commissioner for Regulatory Affairs.

(h) A decision by a presiding officer, made either before the proceeding or during the course of a proceeding, to establish requirements in addition to the minimum standards set forth in this guideline may be appealed by any adversely affected person who intends to record the proceeding electronically. Appeals may be made in writing or by phone to the Deputy Commissioner or, in his or her absence, to the Associate Commissioner for Regulatory Affairs. The filing of an appeal, whether before or during a proceeding, does not require the presiding officer to interrupt the proceeding. However, the Deputy Commissioner or, in his or her absence, the Associate Commissioner for Regulatory Affairs will resolve an appeal as expeditiously as possible so as to preserve, to the extent possible, the reporters' opportunity to record the proceedings.

[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

Subpart A—General Provisions

Sec.

- 11.1 Scope.
- 11.2 Implementation.
- 11.3 Definitions.

Subpart B—Electronic Records

- 11.10 Controls for closed systems.
- 11.30 Controls for open systems.
- 11.50 Signature manifestations.
- 11.70 Signature/record linking.

Subpart C—Electronic Signatures

- 11.100 General requirements.
- 11.200 Electronic signature components and controls.
- 11.300 Controls for identification codes/passwords.

AUTHORITY: 21 U.S.C. 321-393; 42 U.S.C. 262.

SOURCE: 62 FR 13464, Mar. 20, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 11.1 Scope.

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.

(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by agency regulations, unless specifically excepted by regulation(s) effective on or after August 20, 1997.

(d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with § 11.2, unless paper records are specifically required.

(e) Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

[62 FR 13464, Mar. 20, 1997, as amended at 69 FR 71655, Dec. 9, 2004]