

§ 898.14

21 CFR Ch. I (4-1-01 Edition)

§ 898.14 Exemptions and variances.

(a) A request for an exemption or variance shall be submitted in the form of a petition under §10.30 of this chapter and shall comply with the requirements set out therein. The petition shall also contain the following:

(1) The name of the device, the class in which the device has been classified, and representative labeling showing the intended uses(s) of the device;

(2) The reasons why compliance with the performance standard is unnecessary or unfeasible;

(3) A complete description of alternative steps that are available, or that

the petitioner has already taken, to ensure that a patient will not be inadvertently connected to hazardous voltages via an unprotected patient cable or electrode lead wire for intended use with the device; and

(4) Other information justifying the exemption or variance.

(b) An exemption or variance is not effective until the agency approves the request under §10.30(e)(2)(i) of this chapter.

EFFECTIVE DATE NOTE: At 62 FR 25477, May 9, 1997, §898.14 was stayed pending Office of Management and Budget clearance for information collection.