Changes to QSR

The table below provides a history of changes to FDA's Quality System Regulation (QSR)

The citation is to the Federal R: the first number is the volume, FR indicates the Federal Register, and the last number is the page. You can download the pages from www.gpo.gov.

Change	820.1	820.198	820.200	Change
61 FR 52654, Oct. 7, 1996	--	--	--	This is the initial publication of QSR
65 FR 17136, Mar. 31, 2000	Yes			7. The authority citation for 21 CFR part 820 continues to read as follows: Authority: 351, 352, 360, 360c, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383. 8. Amend § 820.1 by removing paragraphs (e) and (f).

Change	820.1	820.198	820.200	Change
65 FR 66636, Nov. 7, 2000	Yes			5. The authority citation for 21 CFR part 820 continues to read as follows: Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383. 6. Section 820.1 is amended by adding paragraph (e) to read as follows: § 820.1 Scope. * * * * * (e) Exemptions or variances. (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1–800–638–2041 or 1–301–443–6597, FAX 301–443–8818. (2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

Change	820.1	820.198	820.200	Change
69 FR 11313, Mar. 10, 2004		Yes	Yes	14. The authority citation for 21 CFR part 820 continues to read as follows: Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l 371, 374, 381, 383. 15. Section 820.198(d) is revised to read as follows § 820.198 Complaint files. * * * * * (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by § 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. * * * * * 16. Section 820.200(c) is revised to read as follows: § 820.200 Servicing. * * * * * (c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 820.198.

Change	820.1	820.198	820.200	Change
69 FR 29829, May 25, 2005	Yes			6. The authority citation for 21 CFR part 820 is revised to read as follows: Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264. 7. Section 820.1 is amended by adding two sentences to the end of paragraph (a)(1), and by revising paragraph (b) to read as follows: § 820.1 Scope. (a) Applicability. (1) * * * Manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in § 1271.3(d) of this chapter, that are medical devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions of the act or under a biological product license application under section 351 of the Public Health Service Act) are subject to this part and are also subject to the donor-eligibility procedures set forth in part 1271 subpart C of this chapter and applicable current good tissue practice procedures in part 1271 subpart D of this chapter. In the event of a conflict between applicable regulations in part 1271 and in other parts of this chapter, the regulation specifically applicable to the device in question shall supersede the more general. * * * * * (b) The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.

Change	820.1	820.198	820.200	Change
71 FR 16228, Mar. 31, 2006		Yes		3. The authority citation for 21 CFR part 820 continues to read as follows: Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383. 4. Amend paragraph (a)(3) of § 820.198 by removing ‘‘or 804’’.
72 FR 17399, Apr. 9, 2007	Yes			6. The authority section for part 820 continues to read as follows: Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383. 7. In § 820.1, paragraph (e)(1) is revised to read as follows: § 820.1 Scope. * * * * * (e) Exemptions or variances. (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA’s administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1–800–638–2041 or 240–276–3150, FAX 240–276–3151.

Change	820.1	820.198	820.200	Change
75 FR 20915, Apr. 22, 2010	Yes			17. The authority citation for 21 CFR part 820 continues to read as follows: Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264. 18. Section 820.1 is amended by revising paragraph (e)(1) to read as follows: § 820.1 Scope. * * * * * (e) * * * (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002, 1–800–638–2041 or 301–796–7100, FAX: 301–847–8149.