

FDA Guidances Related to Telemedicine

The following references documents on the U.S. Food and Drug Administration's web site related to telemedicine.

1. Telemetry Guidance:

"Wireless Medical Telemetry Risks and Recommendations" (September 27, 2000)
www.fda.gov/cdrh/comp/guidance/1173.html

"Letter: Notice of Proposed Rule Making Regarding Allocating Spectrum For Wireless Medical Telemetry" (July 29, 2000): <http://www.fda.gov/cdrh/ode/fcc.pdf>

2. Medical Image Management:

"Guidance for the Submission of Premarket Notifications for Medical Image Management Devices" (July 27, 2000) www.fda.gov/cdrh/ode/guidance/416.pdf

3. Electromagnetic Compatibility:

"Medical Devices and EMI: the FDA Perspective" (September 9, 1996):
<http://www.fda.gov/cdrh/emc/persp.html>

"CDRH Medical Device Electromagnetic Compatibility Program":
<http://www.fda.gov/cdrh/EMC/index.html>

4. Software Guidance:

"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 29, 1998): www.fda.gov/cdrh/ode/software.pdf

"FDA Policy for the Regulation of Computer Products" (November 13, 1989):
<http://www.fda.gov/cdrh/ode/351.pdf>

"Off-The-Shelf Software Use in Medical Devices" (September 9, 1999):
<http://www.fda.gov/cdrh/ode/otssguid.pdf>

Medical Devices: General Principles of Software Validation; Final Guidance for Industry and FDA Staff; Availability

<http://www.fda.gov/OHRMS/DOCKETS/98fr/011102a.htm>
<http://www.fda.gov/OHRMS/DOCKETS/98fr/011102a.pdf>

"General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (January 11, 2002):
<http://www.fda.gov/cdrh/comp/guidance/938.html> and
<http://www.fda.gov/cdrh/comp/guidance/938.pdf>

5. Hazards Analysis and Risk Management:

"Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management--Identifying, Understanding, and Addressing Use-Related Hazards" (July 18, 2000):

<http://www.fda.gov/cdrh/humfac/1497.pdf>

"Do It By Design: An Introduction to Human Factors in Medical Devices" (December, 1996):

<http://www.fda.gov/cdrh/humfac/doi.pdf>

"Reducing Use Error": <http://www.fda.gov/cdrh/useerror/>

6. General Guidances:

Division of Small Manufacturers, International and Consumer Assistance (DSMICA) can be contacted at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address

<http://www.fda.gov/cdrh/dsma/dsmamain.html>. See also, "DSMA Device Advice":

<http://www.fda.gov/cdrh/devadvice/>

"Use of Standards in Substantial Equivalence Determinations" (March 12, 2000):

www.fda.gov/cdrh/ode/guidance/1131.pdf

'de novo' classification: "New Section 513(f)(2) - Evaluation of Automatic Class III Designation" (February 19, 1998): <http://www.fda.gov/cdrh/modact/clasiii.pdf>

"Deciding When to Submit a New 510(k) for a Change to an Existing Device" (January 10, 1997):

<http://www.fda.gov/cdrh/ode/510kmod.pdf>

Digital mammography and tele-mammography. MQSA Regulations relevant to new mammography modalities are in 21 CFR 900: "Quality Mammography Standards (as amended)":

<http://www.fda.gov/cdrh/mammography/frmamcom2.html#12>.

CLIA (Clinical Laboratory Improvement Amendments of 1988):

"Guidance for Administrative Procedures for CLIA Categorization" (Draft-August 14, 2000):

<http://www.fda.gov/cdrh/ode/guidance/1143.pdf>