Draft Guidance for Industry and Food and Drug Administration Staff - Pediatric Information for X-ray Imaging Device Premarket Notifications

U.S. Food & Drug Administration

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Preface

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Compliance testing for required performance characteristics is specified in 21 CFR 1020.30-1020.33 ("Diagnostic x-ray systems and their major components;" "Radiographic equipment;" "Fluoroscopic equipment;" and "Computed tomography (CT) equipment"). In addition to this required testing, recognized standards specify additional methods for assessment of image quality and dose that should be consulted.

This appendix lists common laboratory tests and the applicable standard for each modality; it is included for reference and is not intended to be exhaustive. The tests listed focus on ensuring the imaging device is capable of producing acceptable quality images at a reasonable dose. The information may also be included in device-specific guidance, which should also be consulted. Inclusion of this list does not imply that all of these standards must be followed for every device or that every applicable test and associated standard has been listed. For additional standards applicable to specific devices, please refer to the Recognized Consensus Standards Database.[38] [4]

The guidance entitled "Recognition and Use of Consensus Standards"[39] [5] describes how the agency will use information on conformance with recognized standards to satisfy premarket review requirements. In the case of 510(k)s, information on conformance with recognized standards may help establish the substantial equivalence of a new device to a legally marketed predicate in the areas covered by the standards. If a 510(k) contains declarations of conformity, this will, in most cases, eliminate the need to review the actual test data for those aspects of the device addressed by the standards. Instead of following a recognized standard, a firm may choose to submit alternative equivalent information demonstrating safety and effectiveness.

Some, but not all, of these tests and standards specifically address pediatric use issues. Therefore, in the design of a new device, it is recommended that a manufacturer consult an expert in pediatric imaging.

Table 2. Physical Laboratory Tests and Applicable Standards

Test and brief description	Modality	Relevant standard or more detailed instructions
Sensitometric Response: The output digital signal value versus the radiation exposure curve provides the sensitometric response of the image acquisition system.	General radiography (excludes dynamic imaging/fluoroscopy and CT)	IEC 62220-1 ed1.0 (2003-10) *Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1: Determination of the detective quantum efficiency*
	Dynamic imaging x-ray devices (e.g., fluoroscopic or cardiac imaging)	IEC 62220-1-3 ed1.0 (2008-06) *Medical electrical equipment - Characteristics of digital X-ray imaging*

		devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging
Modulation Transfer Function (MTF): Provides a quantitative measure of the spatial resolution properties of the image acquisition system.	CT	IEC 61223-3-5 ed1.0 (2004-08) *Evaluation and routine testing in medical imaging departments–Part 3-5: Acceptance tests–Imaging performance of computed tomography X-ray equipment*; Corrigendum 1 (2006-03) and IEC 61223-2-6 ed2.0 (2006-11) *Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment*
	General radiography (excludes dynamic imaging/fluoroscopy and CT)	IEC 62220-1 ed1.0 (2003-10) *Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1: Determination of the detective quantum efficiency*
	Dynamic imaging x-ray devices (e.g., fluoroscopic or cardiac imaging)	IEC 62220-1-3 ed1.0 (2008-06) *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*
Noise Power Spectrum (NPS): As a function of spatial frequency and exposure level, this test provides a quantitative measure of the noise properties of the image acquisition system.	General radiography (excludes dynamic imaging/fluoroscopy and CT)	IEC 62220-1 ed1.0 (2003-10) *Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1: Determination of the detective quantum efficiency*

	Dynamic imaging x-ray devices (e.g., fluoroscopic or cardiac imaging)	IEC 62220-1-3 ed1.0 (2008-06) *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*
Detective Quantum Efficiency (DQE): This test provides a quantitative measure of the efficiency of signal-to-noise ratio (SNR) transfer of the image acquisition system. This measure is obtained by calculating the detective quantum efficiency (DQE) as a function of spatial frequency. SNR analysis should be performed using exposure levels covering the range normally encountered using your system to provide the dynamic range of the system.	General radiography (excludes dynamic imaging/fluoroscopy and CT)	IEC 62220-1 ed1.0 (2003-10) *Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1: Determination of the detective quantum efficiency*
	Dynamic imaging x-ray devices (e.g., fluoroscopic or cardiac imaging)	IEC 62220-1-3 ed1.0 (2008-06)*Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*
Image Erasure and Fading: For systems using a delayed readout of image data, such as a photostimulable phosphor, tests should include image decay as a function of time and temperature and signal retention as a function of the number of erasures and exposures.	General radiography and fluoroscopy	For testing recommendations also appropriate for radiographic and fluoroscopic systems, please see section 8 of the guidance entitled “Class II Special Controls Guidance Document: Full-Field Digital Mammography System.”[40] [6]
Repeated Exposure test for ghosting: Tests for quantitatively assessing residual images/ghosts are described in IEC standards as "lag effect" tests.	General radiography	IEC 62220-1 ed1.0 (2003-10) *Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1: Determination of the detective quantum efficiency*
	Dynamic imaging x-ray	IEC 62220-1-3 ed1.0

	devices (e.g., fluoroscopic or cardiac imaging)	(2008-06) *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*
Automatic exposure control (AEC) performance: A demonstration of the degree of control intended with respect to tube current modulation on non-uniform phantoms or with respect to temporal gating should be performed for a range of exam conditions (phantom sizes or time sequences).	CT: Specifies that CT scanners provide an AEC feature, but does not specify any test of AEC performance.	IEC 60601-2-44 ed3.0 (2009-02) *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*; Corrigendum 1 (2010-05)
	Radiography and fluoroscopy	The following standard also applies to interventional fluoroscopy (with exceptions and additions noted in IEC 60601-2-43): IEC 60601-2-54 ed1.0 (2009-06) *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*[41] [7]
Dose or exposure index measurement, display, automatic reporting of values, and documentation	CT: Dose indices based on Computed Tomography Dose Index 100 (CTDI 100) and radiation dose structured reporting standards	IEC 60601-2-44 ed3.0 (2009-02) *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*; Corrigendum 1 (2010-05)
	Radiography and fluoroscopy: defines reference air kerma and reference air kerma rate	IEC 60601-2-54 ed1.0 (2009-06) *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and*

		radioscopy
	Interventional fluoroscopy: defines reference air kerma, reference air kerma rate, dose-area product; specifies range of operating conditions for dose measurements; defines skin dose as air kerma for display purposes	IEC 60601-2-43 ed2.0 (2010-03) *Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*
	Exposure index standard for general radiography	IEC 62494-1 ed1.0 (2008-08) *Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography*
	Radiation dose structured reporting for radiography and fluoroscopy	IEC/PAS 61910-1 ed1.0 (2007-07) *Medical electrical equipment - Radiation dose documentation - Part 1: Equipment for radiography and radioscopy*
	Reproducibility of radiation output for dental x-ray devices	IEC 61223-3-4 ed1.0 (2000-03) *Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment*
Modality-specific tests not specified in above categories (examples included for reference; not exhaustive)	Dental x-ray imaging: Line pair resolution; Low contrast resolution; Image homogeneity	IEC 61223-3-4 ed1.0 (2000-03) *Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment*
	CT: Sensitivity Profile; Patient-Support Positioning and Accuracy; Tomographic Section Thickness; Noise; Uniformity; Mean CT Numbers	IEC 61223-3-5 ed1.0 (2004-08) *Evaluation and routine testing in medical imaging departments–Part 3-5: Acceptance tests–Imaging performance of computed tomography X-ray equipment*; Corrigendum 1 (2006-03) and

		IEC 61223-2-6 ed2.0 (2006-11) *Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment* and IEC 60601-2-44 ed3.0 (2009-02) *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*; Corrigendum 1 (2010-05)
	Fluoroscopy and radiography: Additional tests are specified in the standards on the right (some of these tests are also included in the FDA performance standards).	IEC 60601-2-54 ed1.0 (2009-06) *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy* and IEC 60601-2-43 ed2.0 (2010-03) *Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*

Pediatric issues that are specifically addressed by the standards referenced in Table 2 are listed in Table 3. (Note that the items below are design features, not tests, but the list is included here for completeness.)

Table 3. Specific pediatric issues addressed by applicable standards

Standard	Modality	Pediatric issues specified
IEC 60601-2-43 ed2.0 (2010-03) *Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential*	Interventional fluoroscopy	• The anti-scatter grid should be removable without tools for interventional x-ray equipment

performance of X-ray equipment for interventional procedures		specified for pediatric applications (subclause 203.6.6; p. 30). • The last image-hold feature is especially important for pediatric applications (Annex AA, p. 42).
IEC 60601-2-54 ed1.0 (2009-06) *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*	Radiography and fluoroscopy	• The anti-scatter grid should be removable for x-ray equipment specified for pediatric applications (subclause 203.6.6; p. 39). • X-ray equipment specified for pediatric applications should have a means of placing an added filter not less than 0.1 mm Cu or 3.5 mm Al (subclause 203.7.1; p. 40).
IEC/PAS 61910-1 ed1.0 (2007-07) *Medical electrical equipment - Radiation dose documentation - Part 1: Equipment for radiography and radioscopy*	Radiation dose structured reporting for radiography and fluoroscopy	Recommends a higher level of conformance (level 2) to the radiation dose structured report for dedicated pediatric equipment (p. 8).

[1] Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s [8]

[2] Device Advice: Premarket Notification (510k) [9]

[3] Laws and Regulations (Radiation-Emitting Products) [10]

[4] See the guidance entitled "General/Specific Intended Use [11]". See also the draft guidance entitled "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device [12]" (issued July 27, 2011). When finalized, this

guidance will represent the Center's current thinking on this topic.

[5] NAS National Research Council Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation. 2006. *Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2*. Washington, D.C.: National Academy of Sciences, National Academies Press.

[6] Larson, D.B. *et al*., “Rising Use of CT in Child Visits to the Emergency Department in the United States, 1995-2008,” *Radiology* , vol. 259(3), pp. 793-801, 2011.

[7] Premarket Assessment of Pediatric Medical Devices [13]

[8] Full Text of FDAAA Law [14]

[9] Title III, the Pediatric Medical Device Safety and Improvement Act (PMDSIA) [15]

[10] FDA's white paper entitled "Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging [16]"

[11] Agenda and transcripts are available at: Public Meeting: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging, March 30-31, 2010 [17]. Public docket submissions are available at: Device Improvements to Reduce Unnecessary Radiation Exposure From Medical Imaging; Public Meeting; Request for Comments [18].

[12] See 75 FR 8375, 8376 (Feb. 24, 2010) [19]

[13] The federal register notice lists all the questions asked at the meeting (See 75 FR 8375-8377 (2010) [20];).

[14] Public Meeting: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging, March 30-31, 2010 [17] (see transcripts links)

[15] The principles of radiation protection in medicine, including "optimization" are described in: International Commission on Radiological Protection. 2007. ICRP Publication 105: Radiological Protection in Medicine. *Ann. ICRP*, *37*(6). Optimization of radiation exposure for x-ray imaging means the following: Examinations should use techniques that are adjusted to administer the lowest radiation dose that yields an image quality adequate for diagnosis or intervention (i.e., radiation doses should be "As Low as Reasonably Achievable" (ALARA)).

[16] http://www.pedrad.org/associations/5364/ig/ [21]

[17] Under section 513(i)(1)(E)(i) of the FD&C Act, when determining that a device is substantially equivalent to a predicate device, FDA may require limitations in the device labeling about off-label use of the device when “there is a reasonable likelihood” of such use and if “such use could cause harm.” FDA believes these conditions generally apply to use of x-ray imaging devices with general indications for use on pediatric populations. Such determinations are made on a case by case

basis and other requirements must be met, including a consultation between FDA and the 510(k) submitter, before such limitations can be required. FDA's policy on when a device may be found "substantially equivalent with limitations" is discussed further in the guidance entitled "Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98-1) [22]."

[18] See the guidance entitled "Premarket Assessment of Pediatric Medical Devices [13]"

[19] Size measurements are based on approximate mean values (averaged across males and females) from: McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal. 2008. Anthropomorphic Reference Data for Children and Adults, United States, 2003-2006. *National Health Statistics Reports*, *10*, 1-48. Available for download at: http://www.cdc.gov/nchs/data/nhsr/nhsr010.pdf [23]. The weight given for the neonate subgroup is lower than the average to ensure that a broad range of sizes is adequately covered.

[20] These suggested subgroups fall within the age groups identified in the guidance entitled "Premarket Assessment of Pediatric Medical Devices [13]": neonate (birth-1 month), infant (1 month-2 yrs.), child (2-12 yrs.), adolescent (12-21 yrs.). For design and evaluation of radiological devices, patient size (i.e. height, weight, thickness) is a better indicator.

[21] Based on reports of the lifetime incidence of cancer vs. age of exposure data, these pediatric subgroups defined by the Agency cover the region where the largest age dependence is expected for cancer risk. Risk decreases much less steeply as a function of age for individuals over 21 years old. [See NAS National Research Council Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation. 2006. *Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2*. Washington, D.C.: National Academy of Sciences, National Academies Press.]

[22] The following reference gives current data for anteroposterior and transverse body diameter for pediatric patients ranging in age from 0.5 to 20 years: Kleinman, P. L., K. J. Strauss, D. Zurakowski, K. S. Buckley, and G. A. Taylor. 2010. Patient size measured as a function of age at a tertiary care children's hospital. *American Journal of Roentgenology*, *194*, 1611-1619.

[23] The following reference used cylindrical phantoms with diameters of 8, 16, 24, and 32 cm to represent a neonate, 5 year old, 12 year old, and adult patient respectively: Siegel, M. J., et al. 2004. Radiation dose and image quality in pediatric CT: effect of technical factors and phantom size and shape. *Radiology, 233*(2), 515-522.

[24] McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal. 2008. Anthropomorphic Reference Data for Children and Adults, United States, 2003-2006. *National Health Statistics Reports*, *10*, 1-48. Available for download at: http://www.cdc.gov/nchs/data/nhsr/nhsr010.pdf [23].

[25] See the FDA guidance entitled "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management [24]." and the standard AAMI /ANSI HE75:2009, *Human factors engineering - Design of medical devices.* See also the draft guidance entitled "Applying Human Factors and Usability Engineering to Optimize Medical Device Design [25]" (issued June 22, 2011). When finalized, this guidance will represent the Center's current thinking on this topic.

[26] Appendix, Table 2 entry "dose measurement, display, and documentation" includes relevant dose metrics and FDA-recognized standards for different modalities.

[27] Although the focus of this guidance is on pediatrics, the Agency recommends that devices be designed and tested to enable optimized imaging for a broad range of adult sizes. The adult range includes small females (5th percentile U.S. female is ~51 kg, 151 cm standing height) up to large males (95th percentile U.S. adult male is ~123 kg, 189 cm standing height). A small adult female is similar in size to an average 12 year old pediatric patient. [Data source: McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal. 2008. Anthropomorphic Reference Data for Children and Adults, United States, 2003-2006. *National Health Statistics Reports*, *10*, 1-48. Available for download at: http://www.cdc.gov/nchs/data/nhsr/nhsr010.pdf [23].]

[28] For more on the appropriate protections for pediatric populations, see the guidance entitled "Premarket Assessment of Pediatric Medical Devices [13]" (2004)

[28] The premarket notification must include labeling in sufficient detail to satisfy the submission requirements of 21 CFR 807.87(e). Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

[30] See the guidance entitled "Premarket Assessment of Pediatric Medical Devices [13]" (2004);

[31] The content, placement, and format (size, color, etc.) of this caution statement should follow the recommendations in the standard: ANSI Z535.4-2007 *American National Standard for Product Safety Signs and Labels*.

[32] McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal. 2008. Anthropomorphic Reference Data for Children and Adults, United States, 2003-2006. *National Health Statistics Reports*, *10*, 1-48. Available for download at: http://www.cdc.gov/nchs/data/nhsr/nhsr010.pdf [23].

[33] NAS National Research Council Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation. 2006. *Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2*. Washington, D.C.: National Academy of Sciences, National Academies Press.

[34] An example is the Image Gently/FDA "Digital Radiography Safety Checklist [26]"

[35] Appendix, Table 2 entry "dose measurement, display, and documentation" includes relevant dose metrics and FDA-recognized standards for different modalities.

[36] A model for such a training program for ultrasound devices (not covered by this guidance) is: *Medical Ultrasound Safety*, 2nd ed. (2009) published by the American Institute of Ultrasound in Medicine (http://www.aium.org/ [27]).

[37] Examples of training materials emphasizing pediatric dose reduction are available at the Alliance for Radiation Safety in Pediatric Imaging website [28].

[38] Recognized Consensus Standards Search [29]

[39] Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards [30]

[40] Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Full Field Digital Mammography System [31]

[41] Subclause 203.6.3.2.102 of IEC 60601-2-54 does not mention pediatrics specifically but it does specify a range of different-sized phantoms (10, 15, 20 cm thickness) for testing of automatic exposure control for direct radiography.

SOURCE [32]

Source URL (retrieved on *08/31/2014 - 4:55am*):
http://www.mdtmag.com/news/2012/05/draft-guidance-industry-and-food-and-drug-administration-staff-pediatric-information-x-ray-imaging-device-premarket-notifications?qt-most_popular=0

Links:
[1] http://www.regulations.gov
[2] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/mailto:thalia.mills@fda.hhs.gov
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[4] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments#ft38
[5] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments#ft39
[6] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments#ft40
[7] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments#ft41
[8] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

[9] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm
[10] http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/LawsandRegulations/default.htm
[11] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073945.pdf
[12] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm265274.htm
[13] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm
[14] http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw/default.htm
[15] http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110
[16] http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199994.htm
[17] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm201448.htm
[18] http://www.regulations.gov/#!docketDetail;rpp=10;po=0;D=FDA-2010-N-0080
[19] http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0080-0001
[20] http://edocket.access.gpo.gov/2010/2010-3674.htm
[21] http://www.pedrad.org/associations/5364/ig/
[22] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082162.htm
[23] http://www.cdc.gov/nchs/data/nhsr/nhsr010.pdf
[24] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm
[25] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm
[26] http://www.pedrad.org/associations/5364/files/Attachment%20D.CR.DR%20%20checklist.pdf
[27] http://www.aium.org/
[28] http://spr.affiniscape.com/associations/5364/ig/
[29] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[30] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm
[31] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107552.htm
[32] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm300850.htm