Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Full-Field Digital Mammography System

Document issued on: March 27, 2012.

This document supersedes "Class II Special Controls Guidance Document: Full-Field Digital Mammography System," issued November 5, 2010.

On April 4, 2012 this document was edited to correct formatting, and to clarify that equivalent mammography reader qualifications are also acceptable in Appendix A.

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Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107552.htm. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (**1616**) to identify the guidance you are requesting.

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Guidance for Industry and FDA Staff

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1. Introduction

The Food and Drug Administration (FDA) has developed this guidance as the special control to support the classification of full-field digital mammographic devices (FFDM) into class II (special controls). Full-field digital mammographic devices are either integrated systems that include both the x-ray delivery system and integrated (non-removable) detector, or detector-only (removable) systems intended to be used on existing x-ray systems where the removable detector, such as a computed radiography cassette replaces the film/screen detector. This guidance does not cover tomosynthesis or computed tomography breast imaging devices. FDA is issuing this guidance in conjunction with a Federal Register (FR) notice announcing the final rule classifying FFDM devices into class II (special controls). The classification regulation designates this guidance document as the special control for these devices.

Designation of this document as a special control means that, following the effective date of a final rule, any firm intending to market a new FFDM device will need to address the issues covered in this special controls guidance. The firm will need to show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness.

2. Background

FDA believes that special controls, when combined with the general controls of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), will be sufficient to provide reasonable assurance of the safety and effectiveness of full-field digital mammography devices. Thus a manufacturer who intends to market a device of this generic type must:

- conform to the general controls of the FD&C Act, including the premarket notification requirements described in 21 CFR 807 Subpart E,
- address the specific risks to health associated with full-field digital mammography devices identified in this guidance, and
- obtain a substantial equivalence determination from FDA prior to marketing the device. (See 21 CFR 807 Subpart E, including 21 CFR 807.81 and 807.87).

This special control guidance identifies the classification regulation and product codes for full-field digital mammography devices (Please refer to Section 3, Scope). In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with full-field digital mammography devices and lead to a timely 510(k) review.

This document supplements other FDA documents regarding the specific content requirements of a premarket notification (510(k)) submission. You should also refer to 21 CFR 807.87, the guidance entitled *Format for Traditional and Abbreviated 510(k)s,*[1] and the Premarket Notification 510(k) section of CDRH's Device Advice web page.[2]

3. Scope

The scope of this document is limited to FFDM systems[3] in the proposed new regulation 21 CFR 892.1715, product code MUE.

21 CFR 892.1715 – Full-Field Digital Mammography System.

> (a) *Identification*. A full-field digital mammography system is a device intended to produce planar digital x-ray images of the entire breast. This generic type of device may include digital mammography acquisition software, full field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories.
>
> (b) ***Classification***. Class II (special controls). The special control for the device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Full-Field Digital Mammography System."[4] See §892.1(e) for the availability of this document.

A mammography system usually consists of an x-ray generator, x-ray control, x-ray tube, collimator, beam filter, breast compression system, grid, image receptor system, and accessories. In the case of integrated FFDM systems, the image receptor system consists of a built-in full-field solid state detector, acquisition software, acquisition work station, and accessories. In the case of detector-only type FFDM systems, the image receptor system

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1 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084396.pdf

2 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm

3 While not a requirement for a determination of substantial equivalence under sections 510(k) and 513(i) of the FD&CAct, FFDM systems must meet the applicable requirements of 21 CFR Part 900, including 21 CFR 900.12(b) and 21 CFR 900.12(e) to be legally used to perform screening or diagnostic mammography in the United States.

4 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107552.htm

consists of a removable solid state detector, detector readout device, acquisition and readout software, acquisition work station, and accessories.

This guidance does not cover display accessories to an FFDM System, i.e., softcopy output devices (monitors), hardcopy output devices (printers), and review workstations. These devices are classified as class II; see 21 CFR 892.2040 and 21 CFR 892.2050. For softcopy (monitors) and hardcopy (printers) output devices, image review manipulation software, and review workstations, please refer to the FDA guidance entitled *"Display Accessories for Full-Field Digital Mammography Systems - Premarket Notification [510(k)] Submissions*."[5]

4. Describing Your Device in a 510(k) Premarket Notification

When submitting a 510(k) premarket notification, you should identify your device by regulation and product code as described in Section 3 and include the information discussed below. You must provide information to show how your device is similar to and/or different from the legally marketed predicate device ("predicate device"). 21 CFR 807.87(f). Side by side comparisons, whenever possible, are desirable. We also recommend that you describe how any differences may affect the comparative safety or effectiveness of your new device.

Indications for Use

You should compare your device's indications for use (IFU) statements to the IFU of the predicate device, including any specific intended uses.

The usual IFU for a FFDM system is:

> The (*device name*) is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The (*device name*) is intended to be used in the same clinical applications as traditional film/screen systems.

An FFDM system can be indicated for screening use only or for both screening and diagnostic uses. If you choose to include the diagnostic use, the descriptions and testing described in this document should incorporate diagnostic examples.

Device Description

You should compare the descriptions of all components of the FFDM system and the predicate device using tables, associated pictorial representations of the layout, interconnection of the different components, and geometric characteristics.

[5] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107551.pdf

Descriptions Common to Integrated Detector and Detector-Only Systems

Detector

For the x-ray detector, you should describe the:

- type, such as amorphous selenium (a-Se) layer coated on a thin-film transistor (TFT) array, or amorphous silicon with deposit of cesium iodide, or array of charge coupled devices (CCDs) optically coupled to thallium activated cesium iodide (CsI:Tl) scintillator plate, or other type (describe);
- size of active area, pixel dimensions and fill factor, and matrix size;
- x-ray interaction material and thickness or areal mass density (in mg/cm^2 or equivalent) of the materials;
- interaction efficiency for a typical clinical mammographic x-ray spectrum;
- scanning rate (for systems using a slot scanning system);
- relevant temporal characteristics, such as decay rate of the phosphor afterglow for indirect detectors, latent image decay, and ghosting; and
- image read-out mechanism.

Flat Field Correction and Pixel Defects

For systems that perform flat-field and/or pixel defect corrections, you should describe the following:

- typical pixel-to-pixel variations in sensitivity and offset;
- the flat-field correction procedure;
- the number, spatial distribution (single pixels, lines, blocks), and types (dead pixel, sensitivity or offset out of acceptable range) of pixel defects allowed and the rationale for selecting these criteria; and
- the methods of compensation for these defects.

Image Acquisition

For the image acquisition components, you should describe the analog to digital conversion (ADC), if appropriate, including bit depth, matrix size, and pixel width.

For image processing algorithms, you should provide:

- the methods for assessing and choosing among the available image processing algorithms (i.e., suitability and selection);
- a description of the algorithm(s) including detailed flowcharts indicating at which point raw image is processed into a DICOM For Presentation image; and
- the name and characteristics of the platform for the software.

Descriptions Specific to Integrated Systems

X-ray Unit

For the x-ray unit, you should describe the following:

- source to image receptor distance (SID);
- source to patient support device distance; and
- the design and testing methods used to assure complete coverage of the breast and alignment of the x-ray tube focal spot, chest-wall edge of the patient support device, and the chest-wall edge of the image receptor.

X-ray Tube

For the x-ray tube, you should describe the following:

- target materials;
- all available x-ray filters (material and thickness);
- window material and thickness; and
- focal spot sizes.

X-ray Generator

For the x-ray generator, you should:

- provide the trade name and model if manufactured by a third party;
- describe the type, range, and accuracy of technique factors (x-ray tube voltage, x-ray tube current, exposure time and mAs) for all combinations of anode materials and focal spot sizes, as appropriate; and
- describe the method of implementing automatic exposure control (AEC) if provided as part of the system (for example, low level pre-exposure using the image receptor as the AEC detector).

X-ray Anti-Scatter Grid

For the x-ray anti-scatter grid, you should describe the following:

- grid ratio;
- primary transmission;
- selectivity; and
- contrast improvement factor.

You may use the methods described in International Standard IEC 60626 (2001-08) *Diagnostic x-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids* to perform and report these measurements. If any of the measurement conditions described in the standard is not appropriate for your device, you may substitute an alternative that corresponds to the clinical use of your device. The alternative should be documented. Alternative methods for assessing grid performance are also acceptable. If an alternative method is chosen, it should be described completely. If the method has been described in the literature, a reference and justification is sufficient.

Breast Compression System

For the breast compression system, you should describe the following:

- paddle types, sizes, geometries, and materials;
- power-driven, hands-free compression control system;
- fine adjustment compression control system;
- compression override capability; and
- manual or automatic emergency compression release features.

Principles of Operation

The principles of operation should discuss the general sequence of events in a patient examination procedure and the flow of image data from the detector to the final image.

Software

In addition to the above, you should submit the information described in the guidances entitled "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"[6] and "*Guidance for Off-the-Shelf Software Use in Medical Devices*.[7]" The information you should submit is determined by the "level of concern," which is related to the risks associated with software failure. The level of concern for an FFDM system is moderate.

Descriptions Specific to Detector-Only Systems

For detectors intended to be used with conventional mammographic x-ray systems, as direct replacements for the film/screen cassettes [such as computed radiography (CR) plate/reader/display systems], you should list the x-ray system specifications and performance requirements necessary to assure the proper function of the mammographic system using your detector-only system. Given the range of mammographic x-ray systems that can be used with your detector, describe in as much detail as possible the procedure to be used for calibrating the AEC function. Describe the tests and target values for radiation dose as a function of breast thickness and composition that are to be used to verify proper AEC performance.
Also indicate whether the user needs to do anything other than follow the x-ray device's instructions to calibrate the AEC for your detector.

5. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the device addressed in this document. The measures recommended to mitigate these identified risks are described in this guidance document, as shown in the table below. We recommend that you also conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device and include the results of this analysis in your 510(k). If you elect to use an alternative approach to address a particular risk identified in this document, or if you have identified risks additional to those in this document, then you should provide sufficient detail to support the approach you have used to address those risks.

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[6] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf

[7] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf

Table 1 – Risks to Health and Mitigation Measures

Identified risk	Recommended Mitigation Measures
Electrical hazards	6. Electrical Safety
Corrupted or non-diagnostic image	8. Physical Laboratory Testing 9. Clinical Image Evaluation
Inadequate breast coverage	8. Physical Laboratory Testing 9. Clinical Image Evaluation
Excessive x-ray exposure	8. Physical Laboratory Testing
Inappropriate breast compression	8. Physical Laboratory Testing
Infection, skin irritation	7. Biocompatibility Testing 10. Labeling

6. Electrical Safety

You should evaluate the electrical safety of your device according to the following standards or use equivalent methods:

- International Electrotechnical Commission (IEC) 60601-1-1 *General requirements for safety - Collateral standard: Safety requirements for medical electrical systems*

The features and design of your device will determine whether other standards are appropriate in addition to or in place of these. You should provide either the results of your electrical safety testing or a declaration of conformity to the standard(s) applicable to your device.

7. Biocompatibility

You should evaluate the biocompatibility of all patient tissue contacting surfaces of your device following ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing methods*[8] or provide equivalent testing information.

8. Physical Laboratory Testing

You should assess the imaging characteristics of your system as described below. Please provide quantitative data from your testing in tabular or graphical form, as appropriate, and also a comparison of your test results to the imaging characteristics of an FFDM predicate device to

[8] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm

establish that, in terms of the risks identified in Table 1, they are substantially equivalent in terms of safety and effectiveness.

As general guidance for these tests, you should describe the following:

- all phantoms;
- test protocols;
- FFDM system settings used to determine the imaging performance; and
- characteristics and settings of the x-ray system(s) used for testing (detector-only systems).

For test objects (phantoms) that are readily available in the imaging community (e.g., American College of Radiology (ACR) Mammography Accreditation Program (MAP) phantom, CDMAM phantom), a simple reference is generally appropriate. Otherwise, provide a complete description of the phantom.

A number of the tests listed below can be performed in conformance with the International Standard IEC 62220-1-2 (2007-06) *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography*. Wherever possible, you should follow this standard and the related standards referenced in it. Where the standard is not completely appropriate for your system, for example, if an x-ray condition (spectrum) not available with your system is specified for a test, describe the alternative procedure used for the test. In general, testing should be performed under conditions that match the intended clinical use of the system.

You should report all relevant exposure parameters, i.e., AEC mode, if AEC was used, x-ray anode type and filtration, actual kVp, and mAs values along with the half-value layer and the exposure at the appropriate location (e.g., detector surface, phantom entrance surface, or both) used in your imaging performance testing.

You should provide the uncertainty (standard deviation or 95% confidence intervals) on each measure used to assess imaging performance. If applicable, you should report the trade name, characteristics, and accuracy of the measuring instruments used for performing the quantitative tests.

Sensitometric Response

You should provide quantitative data on the sensitometric response of the image acquisition system (i.e., the digital value versus radiation exposure curve).

Spatial Resolution

You should provide a quantitative measure of the spatial resolution properties of the image acquisition system (i.e., the modulation transfer function (MTF)).

Noise Analysis

You should provide a quantitative measure of the noise properties of the image acquisition system, as described by the noise power spectrum (NPS) as a function of spatial frequency

and exposure level. You may report either 1- or 2- dimensional NPS. If you use the 1-dimensional NPS, it should be determined from the 2-dimensional NPS according to IEC 62220-1-2, section 6.3.2. You should provide measurements at seven exposure levels: 1/8, 1/4, 1/2, 1, 2, 4, and 8 times the "reference" level, selected according to section 4.6.1 of IEC 62220-1-2. All of the measurements should be done without recalibration of the image receptor, except that offset calibrations may be repeated in clinical practice.

Signal-to-Noise Ratio Transfer - DQE

You should provide 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. For systems using flat-field correction, we recommend that the correction as applied in normal clinical use of the device also be applied for the determination of DQE and noise equivalent quanta (NEQ). You should perform SNR analysis using exposure levels covering the range normally encountered in mammography. IEC 62220-1-2 specifies that measurements be made at an exposure level chosen from those used when the detector is operated for the intended use in clinical practice, which is designated as the "reference" level, and at exposure levels 2 times the "reference" level and 1/2 of the "reference" level. We request that you provide DQE calculations made using the NPS curves determined for each of the seven exposure levels described above.

Dynamic Range

You should provide a quantitative measure of the dynamic range of the image acquisition system. This measure is measured by using the NEQ, DQE, or both, as a function of spatial frequency and radiation exposure level. Please present these measurements at the exposure levels specified in the section on DQE and at a very low spatial frequency and a frequency that is 1/2 of the Nyquist frequency of your detector.

Image Erasure and Fading

For systems using a delayed readout of image data, such as a photostimulable phosphor, you should provide a description for and results of:

- image erasure and fading tests as a function of time and temperature;
- tests of image retention as a function of the number of erasures and exposures;
- information on fogging and depletion of charge after exposure to room light; and
- fading test at 50˚C if the system is intended for batch processing in a mobile facility.

Repeated Exposure Test

You should provide results of 100 or more repeated exposures and erasures showing that there are no residual or ghost images. Tests for assessing image ghosting are described in international and European standards IEC 62220-1-2, FDIS IEC 61223-3-2), or *Addendum on Digital Mammography: The European Protocol for the Quality Control of the physical and technical aspects of mammography screening*, version 1.0, November 2003.

Automatic Exposure Control Performance

For integrated systems, you should provide evaluation results of each AEC mode available in your system. We recommend that AEC performance be evaluated by acquiring data sets for a range of thicknesses from 2 to 6 cm of a homogeneous material at standard mode and magnification mode if available. Tests should include SNR, CNR, the exposure conditions selected by the AEC system (anode, filter, kVp, mAs), and dose for each thickness. The method of estimating the dose should be described. If the method has been described in the literature, a reference may be satisfactory.

Phantom Testing

Please provide soft-copy and hard-copy display test results for imaging of the ACR MAP phantom and for the wax target plate of the phantom with thicknesses of attenuation material selected so that the combinations of attenuation material and plate match 2 and 6 cm of 50/50 breast tissue. Images should be acquired using AEC, if the system is so-equipped. If the system is not equipped with AEC, images should be acquired using clinically appropriate manual techniques. If the AEC system has more than one mode of operation (for example, maximum image quality and minimum patient dose), images should be acquired using all AEC modes. Exposure conditions and dose for each image should be included in the results.

You should provide the protocol and soft-copy and hard-copy display test results for a contrast-detail (CD) phantom.[9] We recommend that the observers participating in the rating experiment have experience (please describe) in evaluating images of the phantom selected. We also recommend that you provide a description of the soft-copy and hard-copy display systems used in the phantom image evaluation.

Test results may be presented in the form of a C-D diagram or using the image quality factor (IQF) method described in Thomas, et al.,[10] or both. A C-D diagram is a plot of the minimum detectable target thickness or contrast as a function of target size. If you use the IQF evaluation method, calculate the IQF at a diameter no larger than 1.8 mm and a thickness no larger than 0.25 μm. According to Thomas et al., the k factor is the product of the thickness and the diameter of the smallest correctly identified disks in the phantom. If you follow this methodology, we recommend using a k factor of 60 μm^2 but not greater than 80 μm^2. We recommend that multiple readers examine multiple images of the phantom and score each of them. We also recommend that you estimate the error bars on your results. In addition, you should perform these scoring tests at multiple exposure levels typical for mammography.

In accordance with 21 CFR 807.87(l), we may request that you provide representative phantom images acquired with your FFDM device.

[9] A radiographic anthropomorphic phantom that meets the requirements of 21 CFR 892.1950.

[10] Thomas, J. A., Chakrabarti, K., Kaczmarek, R., and Romanyukha, A., "Contrast Detail Phantom Scoring Methodology," **Med. Phys.** Vol 32 (3), pp 807-814, 2005.

Patient Radiation Dose

You should provide a quantitative estimate of the patient radiation dose. This estimate should be expressed as the average glandular dose delivered during a single cranio-caudal view of appropriate phantoms. Your testing should simulate 2, 4.2, and 6 cm thick compressed breasts consisting of 30, 50, and 70 percent glandular and 70, 50, and 30 percent adipose tissue, as illustrated in Table 2 below. Please describe the phantom and specify all the conditions of operation of the FFDM system during your testing, including kVp, mAs, anode material, x-ray filtration, exposure level at the entrance surface of the phantom along with the resulting patient radiation dose. X-ray exposure conditions should be selected by the AEC system if the system is so-equipped. If the system does not have an AEC system, you should use a manual technique that would be appropriate for clinical examination of a patient simulated by the phantom.

Table 2: Estimated Patient Radiation Dose (mGy) for Different Phantoms

Percent Glandular / Adipose Tissue	Simulated Breast Thickness (cm)		
	2.0	4.2	6.0
30 / 70			
50 / 50			
70 / 30			

Sponsors are reminded that in order for the device to be used in a facility certified under the Mammography Quality Standards Act (MQSA), the average glandular dose delivered during a single craniocaudal view of a phantom simulating a standard breast must not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. (See 21 CFR 900.12(e)(5)(vi)).

Breast Compression System

For the breast compression system, provide the minimum and maximum powered compression pressures for your device. Describe how you measured these and the reasons for selecting these levels. FDA recommends that the maximum compression force for the initial power drive be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

9. Clinical Image Evaluation

The purpose of this evaluation is to determine if the FFDM images, when reviewed by expert radiologists, are judged to be of sufficiently acceptable quality for mammographic usage that they are substantially equivalent in safety and effectiveness to those from a predicate device. If the physical laboratory testing comparison shows the new device to be substantially equivalent in safety and effectiveness to the laboratory performance of the predicate device, for all characteristics, you should submit the following image evaluation.

The results of an image attribute review of the image sets and associated information from screening examinations of six patients with a final BI-RADS® Assessment Categories of 1 or 2. The screening image sets should consist of four images: craniocaudal (CC) and mediolateral oblique (MLO) views of each breast At least two of the six sets of images should be from patients having almost entirely fatty breasts and two from patients having primarily dense breasts, as described in the BI-RADS® Atlas. If your indications for use include diagnostic use, then at least three of the six patient image sets should also contain spot and spot/magnification diagnostic images. These diagnostic patient image sets could have had initial BI-RADS® 0, 3, 4, or 5 assessments, but the spot and spot/magnification image should lead to a final BI-RADS assessment of 1 or 2. These image sets should be reviewed in the same manner as clinical images submitted by a mammography facility for MQSA accreditation by two expert mammographic radiologists, with a third to resolve disagreements, that meet the qualifications described in Appendix A. The reviewers should evaluate the following mammographic attributes[11] for each case, in order to provide an overall assessment of whether these image sets collectively are of sufficiently acceptable quality for use in clinical mammography and to allow determination of substantial equivalence to a predicate device.

- breast positioning, assessing coverage of the breast on craniocaudal and mediolateral oblique views, separately;
- exposure, assessing visualization of the adipose and fibroglandular tissues and visualization of breast tissue underlying the pectoralis muscle, separately;
- breast compression, assessing overlapping breast structures, uniformity of exposure of fibroglandular tissues, adequacy of penetration of thicker portions of the breast, exposure of thinner areas, and motion unsharpness;
- image contrast for differentiation of subtle tissue density differences;[12]
- sharpness, assessing the edges of fine linear structures, tissue borders, and benign calcifications;
- tissue visibility at the skin line;
- noise, i.e., noise obscuring breast structures or suggestive of structures not actually present;
- artifacts due to image processing, detector failure and other factors external to the breast on hard-copy and soft-copy displays; and
- overall clinical image quality.

The associated information provided should include compressed breast thickness, x-ray exposure conditions (anode, filter, kVp, mAs, exposure, half-value layer), and estimated dose, for each image. For detectors-only type FFDM systems, breast positioning and breast compression do not have to be included in the image evaluation.

Any issue with image evaluation should be fully explained by the expert mammographic radiologists.

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[11] Mammography Quality Control Manual, *Clinical Image Quality*, American College of Radiology, 1999, pp. 79-112.

[12] In the case of soft-copy display, image contrast assessment may require adjustment of the window and level settings.

Investigations involving clinical subjects must comply with 21 CFR Parts 50 and 56.

If the physics laboratory testing or clinical image evaluation raise any specific concerns between your device and the predicate device, you should meet with the Division of Radiological Devices, OIVD, to discuss your options.

10. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the submission requirements of 21 CFR 807.87(e). The following suggestions are intended to assist you in preparing labeling that satisfies 21 CFR Part 801.[13]

Your user manual should include the information described below.

Indication for use

We recommend the IFU address how the device will be used, for example:

The device is intended to be used for screening and diagnosis of breast cancer.

Precautions

The precautions should discuss the potential for adverse events associated with the use of the device and mitigation measures. The adverse events should include:

- excessive breast compression;
- excessive x-ray exposure;
- electric shock;
- infection; and
- skin irritation, abrasions or puncture wounds.

Device Description

For integrated systems, we recommend you describe the technical characteristics and specifications of the major components of your system including:

- x-ray system and control;
- detector;
- breast compression system;

[13] 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.

- acquisition workstation; and
- compatible image display and printer.

For detector-only systems, you should list the x-ray system specifications and performance requirements necessary to assure the proper function of the mammographic system using your detector-only system. Given the range of mammographic x-ray systems that can be used with your detector, describe in as much detail as possible the procedure to be used for calibrating the AEC function. Describe the tests and target values, for radiation dose as a function of breast thickness and composition, to be used to verify proper AEC performance. Also indicate whether the user needs to do anything other than follow the x-ray device's instructions to calibrate the AEC for your detector.

Device Information

We recommend you include:

- an overview of the device;
- the principles of operation for the device;
- the technical specifications of the device;
- technique chart for manual exposures; and
- information on exposure factors.

Summary of physical laboratory testing

You should provide brief summaries of your physical laboratory testing results, including graphs or tables as appropriate, for:

- sensitometric response;
- spatial resolution;
- signal-to-noise ratio transfer;
- dynamic range;
- phantom testing;
- image erasure and fading;
- repeated exposure testing;
- defect characteristics;
- noise analysis;
- patient radiation dose; and
- automatic exposure control performance.

Summary of Clinical Image Evaluation

You should include a summary of the clinical image evaluation performed with the device that includes:

- study objectives;
- study design;
- patient population (e.g., age, ethnic origin);
- variables (e.g., breast composition, breast size); and
- description of the methodology used in gathering clinical information.

Directions for use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we recommend submitting clear and concise instructions for use that delineate the technological features of the specific device and how the device is to be used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

Additional Information

We also recommend you include:

- instructions for cleaning and disinfecting equipment surfaces that contact the patient and all equipment surfaces likely to become soiled during use to prevent disease transmission;
- a description of personnel authorized to service the system; and
- a summary of the training program for facility staff.

In addition, instructions for maintenance of the system performance (quality assurance processes) should include:

- instructions on how to calibrate the digital image detector;
- instructions on how to calibrate the Automatic Exposure Control (AEC);
- For integrated systems, a full description of recommended quality assurance testing (with action limits), including detailed procedures for performing these tests, if applicable, and the frequency of testing (for detector-only, any changes to the system manufacturer's recommended QA); and
- a recommended maintenance schedule.

Appendix A - Recommended mammography reader qualifications

We recommend that FFDM clinical image reviewers meet or establish equivalence to the following requirements:

- Be qualified under MQSA to interpret FFDM exams.
- Be certified by the American Board of Radiology, American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada.
- Have at least five years experience following residency in diagnostic radiology with at least 50% of each year's practice in breast imaging and have had training in clinical image quality equivalent to that provided by the FDA-approved accreditation bodies.
- Be currently using an FFDM system at an MQSA or VAH-certified facility.