

1 Question: Is medical outcomes audit data collected during facility inspections used in a
2 national database?

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4 Answer: No. While medical outcomes audit data is reviewed during the inspection to
5 assure the facility is complying with the regulations, it is not routinely collected by FDA.
6 FDA does not maintain nor does it supply information to such a national database.

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8 Question: What type of lay summary should be sent to a patient who has a normal
9 mammogram, but an abnormal physical exam?

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11 Answer: The facility has a great deal of flexibility in the format and substance of the lay
12 summary. The lay summary must inform the patient of the results of the mammographic
13 examination and follow-up actions, if needed. In the example given, the lay summary
14 should say that the mammogram was normal, but the patient should consult with her/his
15 physician because of the abnormal physical exam.

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17 Question: Must the compression paddle be placed in the x-ray beam during half value
18 layer (HVL) measurements?

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20 Answer: If the HVL measurement is being used to calculate patient dose, the
21 compression paddle must be placed in the x-ray beam during the measurement. If the
22 HVL measurement is being used for purposes other than patient dose, the position of the
23 paddle is not specifically stated in the regulations. However, FDA recommends inclusion
24 of the compression paddle in the x-ray beam because most manufacturers have designed
25 their equipment to be tested in this configuration.

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27 Question: I have a Masters/Bachelor's degree specifically in physics. Do I still need to
28 document my number of semester hours in physics?

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30 Answer: If the degree is stated to be specifically in physics (or any of its sub-specialties),
31 it will routinely be accepted during inspections as adequate documentation of the required
32 number of semester hours in physics. Therefore, during routine inspections, you will not
33 need to provide detailed transcripts to all the facilities where you provide physics
34 services.

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36 If the degree was stated to be in the more general term, physical science, or in one of the
37 three non-physics categories of physical science (chemistry, radiation science, or
38 engineering), then you will have to provide additional documentation demonstrating
39 compliance with the appropriate requirement for semester hours in physics.

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41 Question: What are the minimum tests and/or review that the medical physicist must
42 perform for a facility survey, survey of a mammography unit, equipment evaluation of a
43 unit or processor that has been installed or disassembled and reassembled, and an
44 equipment evaluation of a unit or processor that has undergone a major repair?

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46 Answer:

Facility Survey	All tests as described in 900.12(e)(2), (e)(5), and if applicable (e)(6). Evaluate adequacy of the results of all tests conducted by the facility in accordance with 900.12(e)(1) through (e)(7)
Survey of a mammography unit	All tests as described in 900.12(e)(2), (e)(5), and if applicable (e)(6)
Equipment evaluation of a unit or processor that has been installed or disassembled and reassembled	All applicable tests and equipment requirements described in 900.12(b) and (e)
Equipment evaluation of a unit or processor that has undergone a major repair	Only those tests and equipment requirements described in 900.12(b) and (e) that are applicable to the repaired component of the unit or processor. The decision as to what constitutes an applicable test for the repaired component should be made by the medical physicist.

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2 Question: While performing a physics survey, unit survey, or equipment evaluation, the
3 medical physicist determines that the unit fails a required test(s) and needs to be adjusted
4 or repaired. After the adjustment or repair has been completed, does the test(s) have to be
5 repeated and must the medical physicist perform the test(s)?

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7 Answer: After the adjustment or repair has been completed, the test(s) have to be
8 repeated and must show that the unit is within the appropriate action limit before it can be
9 used on patients. As to who must perform the test(s), if the adjustment or repair
10 constitutes a “major repair,” then the medical physicist must repeat the test(s) as part of
11 the required follow-up equipment evaluation. If the adjustment or repair does not
12 constitute a “major repair,” then the test(s) can be performed by any qualified person (e.g.
13 radiologic technologist or repairperson with the appropriate training/experience).
14 However, in this circumstance, FDA recommends, at a minimum, that the medical
15 physicist be consulted during this process.

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17 Question: Our facility has permanently glued the acrylic contrast disk to the phantom at
18 the center of the cover plate. The regulation states that the OD be measured at the center
19 of the phantom which would require our repositioning the disk (which may leave
20 permanent artifacts) or replacement of the phantom cover. Is there another way to leave
21 the disk in place and still fulfill the requirement?

22

23 Answer: For the purpose of making the density measurements, FDA interprets the
24 “center” of the phantom to be equivalent to measurements taken on the center line as
25 described later in this paragraph. As an alternative to repositioning the disk or
26 replacement of the phantom cover, you may choose to keep the disk in place. Facilities
27 may measure the background density at a different location along the center line of the
28 phantom in the direction parallel to the chest wall, as long this location does not intercept
29 any of the phantom objects. In addition, you must measure the background density at the
30 same location each time the test is conducted.

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In the process of removing the disk, permanent defects may be produced in the cover plate. Such defects may produce permanent “artifacts” in the phantom image. As long as they do not obscure the test objects, facilities can continue to use the phantom. The facility should not subtract these permanent “artifacts” from the phantom score.

Question: We use the same locum tenens interpreting physician on a recurring basis throughout the year. Do we need to handle the personnel records for this person differently from our “permanent” interpreting physicians? Which of his/her records will be reviewed at the time of our next inspection?

Answer: If the locum tenens interpreting physician reads for the facility on a recurring basis throughout the year, the facility can treat this person as “permanent” for purposes of the annual inspection. In that event, the facility has to show that this person met all the requirements (including the continuing requirements, when appropriate) on the date of the inspection.

If the facility considered this person “temporary” and not working at the facility at the time of the inspection, the facility has to show that this person met all the requirements (including the continuing requirements, when appropriate) on each of the multiple occasions this person started reading at the facility. For example, if the person worked for a week at a time starting the 15th day of each month, the facility is responsible for documenting that the person was qualified on each of those 12 occasions. This is not as daunting a task as it first appears. The facility has to document that the person was fully qualified the first time he/she started working at the facility. In addition, in each of the calendar quarters the person worked, the facility has to document (before letting the person provide mammography services) that the person met the continuing requirements (when appropriate) and maintained a valid medical license.

Question: We use the same “temporary” radiologic technologist on a recurring basis throughout the year. Do we need to handle the personnel records for this person differently from our “permanent” radiologic technologists? Which of his/her records will be reviewed at the time of our next inspection?

Answer: If the “temporary” radiologic technologist performs mammograms for the facility on a recurring basis throughout the year, the facility can treat this person as “permanent” for purposes of the annual inspection. In that event, the facility has to show that this person met all the requirements (including the continuing requirements, when appropriate) on the date of the inspection.

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1 daunting a task as it first appears. The facility has to document that the person was fully
2 qualified the first time he/she started working at the facility. In addition, in each of the
3 calendar quarters the person worked, the facility has to document (before letting the
4 person provide mammography services) that the person met the continuing requirements
5 (when appropriate) and maintained a valid State license or certification.

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7 Question: Under what situations should facilities establish new processor operating
8 levels?

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10 Answer: The most warranted and common situations for a facility to establish processor
11 operating levels are when processor QC testing is initiated for a new processor or when a
12 significant change is made in the processing system, i.e., different film brand/type,
13 different chemical brand/type, or a change in processing conditions (standard vs.
14 extended).

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16 Facilities should not use the establishment of new operating levels to correct problems in
17 the processing system, but should troubleshoot and solve the problem with appropriate
18 corrective action.

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20 Question: During the time a facility is establishing new operating levels (typically done
21 by performing a five-day data plot average): A) does the facility continue to plot the data
22 on the processor chart? B) Is the facility exempt from having to stay within the old
23 processor action limits during the five-day averaging period?

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25 Answer: While establishing new operating levels (during which time the facility can
26 continue to process mammograms), the facility must continue to perform the daily
27 processor QC tests and should plot the data in the same manner it usually does. This may
28 be done on the same graph as the previous data or on a different graph. In either event,
29 this new data should be clearly identified as being derived during the establishment of the
30 new operating levels, so that both the facility and the inspector are aware of the origins of
31 this data. Because no operating level has yet been established, the facility is exempt from
32 having to stay within any processor action limits during this five-day averaging period.

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34 Question: What constitutes an equipment evaluation (what tests must the medical
35 physicist perform) for a processor that has undergone major repairs or is a new processor
36 to the facility?

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38 Answer: At a minimum, the following tests must be done for a processor that has been
39 replaced, undergone major repairs or is a new processor to the facility: processor testing
40 as described in 900.12(e)(1), phantom testing as described in 900.12(e)(2), and system
41 artifact evaluation as described in 900.12(e)(5)(ix). If the major repairs or the use of the
42 new processor necessitates a change in clinical technique factors (for the standard breast),
43 that could significantly increase patient dose, a determination of dose as described in
44 900.12(e)(5)(vi) must be done.

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46 Question: Must the equipment evaluation report be sent to the facility within 30 days?

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Answer: The regulations do not specify when the equipment evaluation report must be sent to the facility. However, the facility cannot use the equipment until it has documentation (equipment evaluation report) showing that the equipment passes all the appropriate tests.

Question: What assessment category should be used for post lumpectomy patients, whose mammograms are otherwise negative?

Answer: In the case described, the results could be categorized as; "benign." In addition, qualifying statements such as "post surgical changes noted" may be added. The regulations require that each mammography report contain one of the six overall assessment categories. The decision as to which category to assign is left to the interpreting physician.

Question: Our group practice interprets mammograms sent to us by other facilities under a contractual arrangement. This is the only service that we provide in the mammography area. Does my group practice need an FDA certificate to interpret mammograms?

Answer: No. The basic requirement established by MQSA is that any facility that produces, processes, or interprets mammograms after October 1, 1994, must have an MQSA certificate to continue to operate lawfully. Generally, however, where procedures such as processing and interpretation of the films are performed in a location different from where the mammography is performed, the facility performing the mammography will be responsible for obtaining a certificate.

There is no mechanism at the present time for accrediting and certifying an organization such as yours. FDA's policy is that partial providers, that is, groups such as yours that provide only part of the services required for mammography, will be certified as part of a "system" for producing, processing, and interpreting mammograms.

The provider of some component of that system that performs mammography must take the lead in obtaining a certificate. FDA expects that the owner of an X-ray unit or units will apply for accreditation and receive a certificate. The application for accreditation must show that all components of the system used to produce, process, and interpret mammograms meet the MQSA requirements. If one or more of the facilities for which you interpret mammograms is applying for accreditation and certification, your responsibility will be to provide them with the information necessary to prove that the physicians in your group meet the MQSA quality standards requirements for interpreting physicians.

When the facilities performing mammography receive their certificate, you will be included for the purpose of interpreting mammograms for that facility. If you interpret mammograms for several facilities, your group will be included under several certificates. Conversely, if one of the facilities for which you interpret mammograms is not certified, then it would be unlawful for them to continue to produce mammograms.

1 Although, as mentioned, the owner of the X-ray unit(s) will probably take the lead in
2 obtaining the certificate in most cases, any partial provider in a "system" can seek the
3 required certificate.

4
5 Your group practice could apply for accreditation and receive the certificate, as a part of a
6 system. In that case, your practice would be responsible for assuring not only that your
7 practice meets the MQSA quality standards for interpreters, but also that the facilities that
8 produce and process the mammograms for your interpretation meet the quality standards
9 that apply to them. Your practice would also be responsible for passing the review of
10 clinical images from each facility that produces images for your interpretation, and for
11 meeting the other requirements for accreditation. Finally, as a certificate holder, you
12 would be responsible for paying an annual FDA MQSA inspection fee.

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14 Question: The regulations at 900.12(e)(5)(i) require that an x-ray unit pass an annual test
15 for AEC performance over a range of 2 to 6 cm thick absorbers. If a unit is used
16 clinically at combinations of kVp and filtration that include tissue thickness outside the 2
17 to 6 cm range, must it meet the AEC performance requirements at the thickness' where it
18 operates and must it be tested at those technique factors under the annual quality control
19 requirements?
20

21 Answer: No, the unit is not required to meet the AEC performance specification outside
22 the 2 to 6 cm range and the physicist is not required to test the AEC performance
23 requirements for thickness' outside this range during the annual survey. However, we
24 strongly recommend that in addition to the required testing in the 2 to 6 cm range, the
25 unit also be tested at all clinically used thickness' outside this range and that the action
26 limits specified in the regulations be applied to the extended test.
27

28 You should note that under the Equipment Evaluation outlined at 900.12(e)(10), an
29 evaluation of the AEC under all conditions of use is required, not merely recommended.
30 This is because 900.12(e)(10) mandates conformance with all pertinent aspects of
31 900.12(b) and (e). Under 900.12(b)((10) the AEC is required to be "operable" under
32 "configurations provided." In this context, "operable" means that it must meet the
33 density and reproducibility requirements of (e)(5)(i) under all clinical use situations
34 occurring at the facility.
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36 Question: The Bucky assembly is being replaced on our x-ray unit. Is it necessary that
37 the medical physicist test and pass this prior to its use on patients?
38

39 Answer: If the installation does not involve the replacement of the AEC detector(s) on
40 the system, the exchange of Bucky assemblies would not be considered a major repair
41 and would therefore not require the medical physicist to evaluate the assembly prior to
42 use on patients. If however, the replacement does include the AEC detector, the medical
43 physicist must evaluate the assembly prior to use on patients. There are tests that should
44 be performed when the bucky is replaced (table artifacts, grid artifacts, and x-ray
45 field/image receptor alignment), but these can be done under the direction of the physicist
46 and do not require his/her evaluation prior to the next annual survey.

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2 Question: We are a mobile facility with a van that does not have on-board processing.
3 We have a film-changing room on the van where we load and unload cassettes with film
4 during the day. When the van returns to our main office, we batch process the films. Do
5 we have to perform a semiannual test for darkroom fog in this film-changing room?

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7 Answer: Yes. Since you use a room to load and unload cassettes with film, you must test
8 this room for darkroom fog as well as the darkroom for your processor. Both rooms have
9 the potential to fog films and degrade image quality.

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11 Question: I have my ARRT (M) certificate. Will this certificate be sufficient
12 documentation to show that I have received adequate training in breast anatomy and
13 physiology, positioning and compression, quality assurance/quality control techniques
14 and imaging of patients with breast implants as specifically spelled out in
15 900.12(a)(2)(ii)(A)?

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17 Answer: Yes. The ARRT (M) certificate will be accepted as documenting that the areas
18 of training in breast anatomy and physiology, positioning and compression, quality
19 assurance/quality control techniques and imaging of patients with breast implants have
20 been covered.

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**Required QC Tests* for Facilities Using Multiple Units & Screen-Film
Combinations
(11/22/99)**

Test	Units Tested	S-F Combinations Tested With Each Unit
Focal Spot Condition a) System Resolution OR b) Focal Spot Dimensions (up to 10/28/2002)	All units**	For a), all S-F combinations clinically used with the unit in question. For b), one S-F combination or direct exposure film.
Phantom Image	All units used to image the standard*** breast	All S-F combinations clinically used for the standard breast
Phantom Image	All units that are used <u>only</u> for non-standard breasts, and or magnification work	One S-F combination, using clinical techniques that would be used for the standard breast
Dose	All units used to image the standard breast	All S-F combinations clinically used for the standard breast with their corresponding techniques
Dose	All units that are used <u>only</u> for non-standard breasts, and or magnification work	One S-F combination, using clinical techniques that would be used for the standard breast
Darkroom Fog	Any unit (one only)	All film types clinically used
Uniformity of Screen Speed Screen-Film Contact	Any unit (one only)	All clinically used screens (cassettes), one film type
AEC Performance - Reproducibility	All units	One S-F combination (typically used with the unit)
AEC Performance – kVp & Thickness Tracking	All units used clinically in the 2-6 cm thickness range	One S-F combination (typically used with the unit)
Collimation System Artifacts	All units	One S-F combination (typically used with the unit)
KVp Accuracy & Reproducibility Decompression Radiation Output	All units	None

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* This table does not cover other required QC tests that are independent of the x-ray unit or screen-film combination, e.g., the daily processor QC, the fixer retention, and repeat analysis.

** In this table, "All units" refers to those that are used clinically.

*** The standard breast referenced in this table is defined in the regulations as "a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue."

Verification Testing for Items that Fail QC Tests

Question: For repairs made in response to a failure of one of the QC tests, which of the following items on the list below would be considered a “major repair”, and hence must be evaluated by the medical physicist following the repair and prior to clinical use of the equipment?

Answer: The extent to which the medical physicist must be involved in the following repairs is summarized in the table below.

Item	Extent of Involvement by MP
Compression device adjustment:	
a. pressure	Not required*
b. thickness scale inaccuracy	Not required
c. repair of auto decompression aspect.	Not required
Compression paddle adjustment or replacement:	
a. for deflection problem	Not required
b. for extension beyond allowable limit	Oversight**
Collimation adjustment:	
extension beyond allowable limit	Oversight
AEC Adjustment:	
a. thickness compensation	Conduct evaluation in person
b. image mode tracking	Conduct evaluation in person
c. reproducibility	Conduct evaluation in person
d. bring down dose or decrease output	Conduct evaluation in person
Artifacts caused by filter:	
a. filter replacement	Conduct evaluation in person
Processor artifacts:	
a. roller replacement	Not required
b. replenishment adjustment	Not required
KvP adjustment	Conduct evaluation in person
Addition or subtraction of filtration (HVL problem)	Conduct evaluation in person

*not a major repair

**the facility must, at a minimum, consult with the medical physicist to determine whether this represents a major repair for the facility’s specific unit, and how the evaluation is to be performed