# Update on the new 2018 ACR Digital Mammography QC Manual

Eric Berns, PhD, FACR

April 6, 2020

\*No financial disclosures to report

1

# <section-header><section-header><section-header><section-header><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item>







## **MQSA**

# Facilities that continue to operate and have non-compliance citations that are due to circumstances out of their control:

For any circumstance due to coronavirus which the facility cannot control and that could lead to non-compliance citations, the facility should be prepared to provide detailed documentation. Examples may include (1) the failure of mammography personnel to meet the continuing education requirement due to cancellation of courses/meetings due to coronavirus; and (2) the failure to meet certain aspects of EQUIP due to staffing absences related to coronavirus.

DMQS will continue to monitor the situation and will issue other communications should the need arise. For any other inquiries, please contact the MQSA Hotline at 1-800-838-7715 or MQSAhotline@versatechinc.com.







### **Definition**

- An <u>Alternative Standard</u> was issued by the FDA for the ACR DM QC Manual (November 19, 2018).
  - This means it <u>can replace</u> any other Manufacturer QC Manual.
  - Therefore, you have the option to <u>stop using Mfr QC</u> Manuals <u>when you switch</u> to the ACR DM Manual.
  - <u>Facilities are not required to switch</u>. This is an option, and a choice, to switch to the ACR DM QC Progra







|  |   | 10   | NP ID Nos.   |  |  |                                   | MAP ID No                               | <sup>16.</sup>             |
|--|---|--|--|--|--|-----------------------------------|---|----------------------------|
| Each motical physicial who provides modical physics services at this facility must verify that they meet FDA requirements by completing a<br>oncord biology.   |   |  |  |  | New modalities: You must have received at least 8 hours<br>surveying these surfaces before independently performing  | s of modality-specific training   | ng (e.g., full-field<br>Have you receiv | digital or screen-film) in |
| copy of his form.<br>Please print and complete this form. Signature dates must be within one year fram the date of the most recent medical physicial's Annual<br>Server moort. Oxinal, electronic or faund signatures are required and considered legally binding for this document. Stemped signatures are  |   |  |  |  | included in the above formal mammography electedion or obtained espansion) Full-field digital mammography (divect capture digital and/or computed natiography)  [No ]Yes   |                                   |   |                            |
| not acceptable. Complete all sections, an incomplete application will delay your assentitation. PRIVILEGED and CONFIDENTIAL • PEER REVIEW  |   |  |  |  | Screen-film mammography<br>Digital Breast Tomosynthesis (DBT)  |                                   | □'№ [<br>□'№ [                          | ]`Yes<br>]`Yes             |
| PERSONNEL • MEDICAL PHYSICIST  |   |  | Cod  | e of Virginia 8.91-581.17  | CONTINUING EXPERIENCE  |                                   |   |                            |
| No   |   |  |  |  | 5. How many mammography facilities and units have you sur  | veyed over the previous 24-r      | month period?                           |                            |
| Name: LASTNUME F   | FIRST NAME  |  |  | M DEGREE   | # facilities: # units:   |                                   |   |                            |
| ACR Membership ID#: (optional)   |   |  |  |  | If less than 2 facilities and 6 units, are you in the process of   | f requalifying?                   |   |                            |
|  |   |  |  |  | System for acceptable subject areas)   |                                   |   |                            |
| Do you meet FDA requirements for initial qualifications for me   | dical physicists? (   | complete ONLY I  | he column that perta<br>Alternative kriti<br>must have met be  | ins to you)<br>al Qualifications<br>fare April 28, 1999  | System for exceptible subject areas)<br>D'No D'Yes<br>H'you areaseemed 'No', are you in the proceess of requalifying<br>D'No D'Yes   | a?                                |   |                            |
| Do you meet FDA requirements for initial qualifications for mee<br>FDA Requirements<br>Qualified as a medical physicial under FDA's interim regulations and<br>netweed that qualification by maintenance of the active status of   | dical physicists? (<br>Initial Qua<br>(Master's deg<br>Not app  | complete ONLY I<br>lifications<br>rea or higher)<br>sicable  | Alternative Initi<br>Maternative Initi<br>must have met be<br>(Bachelor  | ins to you)<br>al Qualifications<br>fore April 28, 1999<br>'s degree)<br>D <sup>11</sup> Yes   | System for acceptable subject evans)<br> > Yoo  > Vec<br>If you answered "Wo", any you is the process of requalitying<br> > Yoo  > Vec   | a,                                |   |                            |
| De you meet FDA requirements for initial qualifications for me<br>FDA Requirements<br>Gaaffed as a medical physicial under FDA's letterim regulations and<br>manned hat qualitation by mainternance of the active status of<br>letterstructure, sporval, or certification?   | dical physicists? (<br>Initial Qua<br>(Naster's deg<br>Act app<br>Board   | complete ONLY s<br>ifications<br>rea or higher)<br>sicable<br>Year   | he column that perfa<br>Alternative Initi<br>most have not be<br>(Bachelor<br>D'No<br>Board  | ins to you)<br>al Qualifications<br>fore April 28, 1999<br>'s degree)<br>Pres<br>Year  | System for acceptable adject arease) UP to UP tee Wyou assessed "No", any you in the process of requalitying UP to UP tee  | a?                                |   |                            |
| De you meet FDA requirements for initial qualifications for meet FDA Requirements Coaffed as a motion lynkois uner TDA interim regulators and internet that qualifications for an initiation of the test participation of the test tests of learners, approval, or contribution? Exercic Cretificity participation of the test participation for the test participation of the test participation for the test participation of the test participation for test partipation for test participatio   | dical physicists? (<br>Initial Qua<br>(Master's dog<br>Not app<br>Board<br>ABR  | complete ONLY I<br>Iffications<br>nee or higher)<br>sicable<br>Year  | he column that perta Alternative Initi must have met be (Bachelor (Bachelor Board ABR  | ins to you)<br>al Qualifications<br>from April 28, 1599<br>'n degree)<br>'Yes<br>Year  | System for accepted an adjust areas) System for accepted an adjust areas) To Transmitted To Transmitted areas of requalitying To Transmitted To Transmitted areas and connect. Executed on: Doct   | g?<br>SIGNATURE OF MEDICAL INVESS | 061                                     |                            |
| Do you meet FDA requirements for final qualifications for meet<br>FDA requirements<br>FDA requirements<br>Confects as a mode quark confer FDA interesting patients and<br>matters the quark confer for the series may allow and<br>confects of the series of the series of the series of<br>the series of the series of the series of the series of<br>the series of the series of the series of the series of the<br>conference of the series of the series of the series of the<br>patients of the series of the series of the series of the<br>patients of the series of the series of the series of the<br>1. Another the series of the series of the series of the<br>patients of the series of the series of the series of the series of the<br>2. Another series the series of the series o   | dical physicists? (<br>Initial Gua<br>(Master's deg<br>Not app<br>Board<br>ABR<br>ABMP  | ocomplete ONLY s<br>lifeations<br>me or higher)<br>sicable<br>Year   | Atternative heli<br>Atternative heli<br>must have met be<br>(Bacheler<br>No<br>Board<br>ABR<br>ABMP  | ins to yos()<br>al Qualifications<br>fore April 28, 1999<br>a degree<br>Pres<br>Year   | Synthem the exception length of events  <br> \no_\no_\no_\no_\no_\no_\no_\no_\no_\no_  | 9?<br>BOWTURE OF MEDICAL PROSE    | DIST                                    |                            |
| Do you need FOA requirements for initial qualifications for new<br>ISA Boginement<br>Confert as model approximation of a stress<br>moment in qualification by maintenance of the stress test stats<br>and approximation of the stress test stress and<br>the stress of the stress of the stress of the stress<br>in denotes have of the stress of the stress of the stress<br>the stress of the stress of the stress of the stress of the<br>the stress of the stress of the stress of the stress of the<br>the stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the stress<br>of the stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the stress of the<br>stress of the stress of the stress of the stress of the stress of the<br>stress of the stress of the<br>stress of the stress of the<br>stress of the stress of the                      | dical physicists? (<br>Initial Qua<br>(Master's deg<br>Not app<br>Board<br>ABR<br>ABMP  | ifications<br>rea or higher)<br>sicable<br>Year  | Aternative Ividi<br>Aternative Ividi<br>mask have net by<br>(Bachtele<br>No<br>Beard<br>ABR<br>ABMP<br>No  | ins to yos()  al Qualifications fore An1 28, 1599  a degree)  Year  Year  'Year  'Year  'Year  | System threespike length energy in the second secon   | 97                                | 787                                     |                            |
| Do you went FDA requirements for inflat qualifications for main<br>IGA Bequirements<br>Confines an ended projection of PSA team regulations and<br>beams any approximation of PSA team regulations and<br>team of PSA team of PSA team regulations and<br>team of PSA team of PSA team of PSA team of PSA team<br>and the PSA team of PSA team of PSA team of PSA team of PSA team<br>and team of PSA team<br>and team of PSA team<br>and team of PSA tea   | dical physicists? (<br>Initial Qua<br>(Master's deg<br>Nor app<br>Boerd<br>ABR<br>ABMP  | ifications<br>rea or higher)<br>sicable<br>Year<br>Yes<br>Yes  | Aternative Iviliand Aternative Iviliand | int to you)  al Qualifications fore April 31, 1990  a degree)  Tres  Year  year  'res  'res  'res  'res  'res  | Synthem Transcription Legislation Heaves<br>   Non    Non    Non    Heaves Heaves (In Alexandrophysical<br>   You marketed 'No', any pairs in the process of enquality for<br>   You    You    You<br>   Constity that the information provided in true and connect.<br>Executive Cont<br>   | 92<br>BOWTURE OF MEDICAL PROFILE  | 780                                     |                            |
| To you wert 200 requirements for initial qualifications for main<br><b>ICA Experiments</b><br>Conference and the second second second second<br>lowers, approximation of the second second second second<br>lowers, approximation of the second  | dical physicists? (<br>biblid Gua<br>(Master's deg<br>Not ap)<br>Board<br>ABR<br>ABR<br>ABR<br>ABR<br>Board<br>ABR<br>ABR<br>ABR<br>ABR<br>ABR  | Infrastions<br>me or higher)<br>Iscable<br>Year<br>Year<br>Yes<br>Yes<br>Yes<br>Yes  | Atternative holds Atternative holds Atternative holds Atternative holds Atternative holds Atternative holds Board Atternative  | inis bo you) ai doublections fion April 30, 1999 ai doublections ai doublectio | System threespike large days eases)  | BOWURE OF MEDICAL PARTIES         | D61                                     |                            |
| To you were filled increases for initial equilibriums for mer<br>ISA Registrements.<br>Subject on the second se   | dical physicists? (<br>Initial Ceue<br>(Master's deg<br>Alor ap)<br>Board<br>ABR<br>ADMP<br>Divis<br>No<br>Mester's deg<br>29 accessor Aco  | complete CNLY 1  Iffections are or higher  'Year  'Year 'Yeas 'Yea | he column that parts Atternative help miss have met be (Bachelo  | inis to you)  al Quartifications al Quartifications al Quartifications are set of the se | System thr exception large diper senses)           Dive         Two           Processment         Two           Processment         Two           Dive         Dive   Control of the information provided in the and context. Exercised on: Dott   | 97                                | DBT                                     |                            |
| The year service The section of the section of the sec-<br>TRA Represents for static qualifications for sec<br>TRA Representations of the section regulators of the<br>international section of the section regulators of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>international section of the section of the section of the<br>internation of the biology generation in the section of the<br>internation of the internation of the section of the section of the<br>internation of the internation of the section of the section of the<br>internation of the internation of the section of the section of the<br>internation of the internation of the internation of the internation of the<br>internation of the internation of the internation of the internation of the<br>internation of the internation of the intern | dical physicists? (         holial Cua         (Master's seg         Act spy         Board         ABR         ABR         ADVP         Vio         Vio | In the second se | he column that parta Alternative triff miss flow one's (Bachele (Bachele Alter | init So yoo)  al Quartifications al Quartifications al Quartifications are depended  a dep | System threespike length energy in the second secon   | 97                                | 087                                     |                            |
| To you wert TOR negativenists for install qualifications for near<br>ISA Bagainersets<br>Confide as a readed project TOR's being regulations and<br>being an ended project of TOR's being regulations and<br>being and the second second second second second<br>terms and the second second second second second<br>Theory is and the Sign Compared term and the second<br>terms and the second second second second second second<br>terms and terms and terms and the second second second<br>terms and terms and terms and terms and terms and<br>terms and the first terms are second second second second<br>terms and the first terms are second second second<br>terms are the first terms are second second second second<br>terms are the first terms are second second second second<br>terms are the first terms are second second second second<br>terms are the first terms are second second second second<br>terms are the first terms are second second second terms and<br>second second second second second second second terms and<br>second second second second second second terms and<br>second second seco         | deal physicists? (<br>bidial Case<br>(Nation's egg<br>ABR<br>ABR<br>ABR<br>ABR<br>ABR<br>ABR<br>ABR<br>ABR<br>ABR<br>ABR  | tifications<br>rea or higher)<br>iicable<br>Year<br>Year<br>Year<br>Year<br>Year<br>Year<br>Year<br>Year<br>Year<br>Year<br>Year<br>Year<br>Year   | he column that parts Atternative hild At | ins to you!  | System Traception legislations on<br>System Traception legislations on<br>Types assessed 'We' are just the process of negativity on<br>Types are set to be a set of the | 97<br>BORNTURE OF MEDICAL PAYRO   | 130                                     |                            |

























































| Item                                | Component   | Major<br>Repair | Medical Physicist<br>Involvement |
|-------------------------------------|---|-----------------|----------------------------------|
| Automatic Exposure<br>Control (AEC) | AEC replacement   | Y               | On-site                          |
|                                     | AEC recalibration that affects dose   | Ŷ               | On-site                          |
|                                     | AEC sensor replacement  | Y               | On-site                          |
|                                     | AEC circuit board replacement   | Y               | On-site                          |
|                                     | Density control - internal adjustment*  | N               | Oversight                        |
|                                     | Thickness compensation - internal* adjustment                                 | N               | Oversight                        |
| Bucky Replacement                   | AEC sensor also replaced  | Y               | On-site                          |
|                                     | AEC sensor not replaced   | N               | Oversight                        |
|                                     | DM detector also replaced   | Ŷ               | On-site                          |
|                                     | DM detector not replaced  | N               | Oversight                        |
| Collimator                          | Replacement   | Ŷ               | On-site                          |
|                                     | Reassembly with blade replacement   | Ŷ               | On-site                          |
|                                     | Adjustment  | N               | Oversight                        |
| Compression Device                  | Pressure adjustment   | N               | Optional                         |
|                                     | Thickness scale accuracy adjustment but only if it<br>affects AEC performance | N               | Oversight                        |
|                                     | Repair of auto decompression  | N               | Optional                         |
| Compression Paddle                  | Paddle (new to facility)  | N               | Oversight                        |
|                                     | Deflection adjustment   | N               | Oversight                        |
|                                     | Adjustment due to extension beyond allowable<br>limit, or visible on images   | N               | Oversight                        |
| X-ray Unit                          | Installation  | Y               | On-site                          |
|                                     | Reassembly  | Y               | On-site                          |
|                                     | X-ray tube replacement  | Y               | On-site                          |
|                                     | High voltage generator replacement  | Y               | On-site                          |
|                                     | Filter replacement  | Ŷ               | On-site                          |
|                                     | Manufacturer's software upgrade or modifications                              | Ŷ               | On-site                          |
|                                     | DM detector replacement or repair   | Ŷ               | On-site                          |
|                                     | kVp, mA, or time - internal* adjustments                                      | N               | Oversight                        |
| Display Devices                     | New installation or replacement   | Ŷ               | On-site                          |
|                                     | New video card or software upgrade  | Ŷ               | On-site                          |
|                                     | Relocation  | N               | Oversight                        |
| Computed Radiography                | New installation or replacement of CR reader                                  | Ŷ               | On-site                          |
| (CR) and Photostimulable            | Replacement of all PSP plates   | Ŷ               | On-site                          |
| Phosphor (PSP) Plates               | 0 0 000 1   | N               | Ourselake                        |





# Why should we switch?

### Performing the QC Tests are more efficient:

- Fewer QC tests than mfr QC
- · Less total time spent on QC tests
- 2D and Tomo are both included
- Both paper (PDF) and electronic (Excel) forms are provided by the ACR and can downloaded for free.
- ....Yet, QC tests provide a better quality evaluation of the system.







|  | Aspire Cristalle   |
|--|--|
| <ol> <li>Digital Breast Tomo (DBT) QC test have been added.</li> <li>Z-Resolution         <ul> <li>Digital Pixel values are obtained to calculate Full V</li> <li>DBT Volume Control                 <ul></ul></li></ul></li></ol> | Width Half Mass (FWHM) value<br>d with a DBT exposure                |
| How to obtaining digital pixel data for CNR/SNR/Ghostin  | ng Index calculations (2D Testing)                                   |
| The process below may be used for the following 2D QC tests:<br>Image Quality Test<br>Automatic Exposure Control System Performance<br>Ghost Image Evaluation  |  |
| Note: The "MAX 4.0 MAMMOGRAPHY" menu for 2D must be use<br>deviation measurements.<br>1) Register study on the AWS using appropriate demographi  | ed to obtain appropriate standard<br>cs. Once demographics have been |
| entered, select the "NEXT" button. (Refer to Figure 1.)  |  |
| Press         Ber Although           Mathematic         Search Searchard           Mathematic         Search Searchard           Press         Search Searchard  |  |
|  |  |
| Figure 1: Patient Registration   | Page (3)   |
|  |  |

















### Highlights for Medical Physicist tests:

- MEE
  - HVL, kVp, and Collimation are now MEE only
  - However, for DBT system, collimation is annual (using 2D method)
- · Facilities
  - QC program is structured for modern facilities (with multiple **units**, multiple **RW's**, and at multiple **facilities**)













