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MammographyMatters

Fall 2000 Volume 7, Issue 4

Soft Copy Interpretation of Digital Images Approved

On November 13, 2000, FDA approved an application from the General Electric Company (GE) for use of its Review Workstation (RWS) for final interpretation of mammography examinations. This approval allows the commercial distribution of such devices for what is commonly called "soft copy" interpretation (i.e., interpretation of electronic images produced on a monitor). This new FDA action is a supplement to its earlier approval of the commercial distribution of GE's Senographe 2000D Full Field Digital Mammography (FFDM) unit with hard copy final interpretation of mammography images.

FFDM units (like screen-film units) must undergo a two-stage approval process. The first stage allows the manufacturer to sell FFDM units to mammography facilities. Presently, the Senographe 2000D is the only FFDM unit to receive this approval (granted previously for commercial distribution with hard copy interpretation and now also with soft copy interpretation using a RWS). Like the earlier approval, the new approval was subject to a number of conditions, among them that the device must only be sold to screen-film accredited/certified facilities.

Before a facility can use an FFDM unit for patient examinations, it must also complete the second stage of the approval process. The process for applying for approval to use FFDM units in clinical examinations was

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Mammography Today Brochure Now Available in Print

FDA's Mammography Today brochure is now available from the Federal Consumer Information Center in Pueblo, CO (Catalog Item # 643G). Developed by DMQRP staff, this brochure discusses consumer rights that are guaranteed under MQSA. To request the brochure, call 1-888-878-3256 (a toll-free number) or visit www.pueblo.gsa.gov. You also can request this brochure by writing to: Breast Cancer Awareness Package, Federal Consumer Information Center, Pueblo, CO 81009. Note that this package contains additional information from the National Cancer Institute. Multiple copies may be requested.

The electronic version of Mammography Today continues to be available on our website.

What's Inside

From the Director . . .

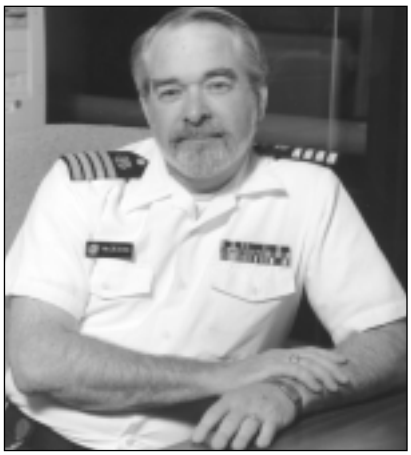
As mentioned in my Summer 2000 column, we have been exploring ways to increase opportunities for more timely communication through effective use of our website. With this issue, we have decided to suspend Mammography Matters *as a newsletter and will instead use this website to present key mammography news as it emerges. When new items are placed on our site, a brief reference will be included under the "What's New" heading with links to any referenced material.*

If you are signed up for our ListServ, you will continue to receive notice of new items on our site. If you have not signed up for FDA's Mammography ListServ, you can do so at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mail/listman.cfm.

Evelyn Wandell will continue to coordinate the writing, oversight of news items, and receipt of any comments on all facets of this news forum. As always, we invite your comments, which should be submitted to Evelyn Wandell at epw@cdrh.fda.gov.

Update on Inspection Results Under the Final Regulations

FDA has been conducting inspections under the Final Regulations for more than one year now. As expected, the number of citations with Level l and Level 2 findings has



decreased in the second half of the year, with a corresponding increase in the number of facilities with no findings. (see Inspection Results Under the Final Regulations: The First Year). Congratulations to facilities and inspectors. We are confident that this trend will continue.

Advisory Committee Chair Completes Term

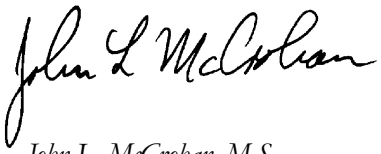
We appreciate the efforts of all members of our National Mammography Quality Advisory Committee (NMQAAC). I especially want to thank Dr. Barbara Monsees, our committee chair. Her leadership has been invaluable to the positive role the committee has served in advising our Division on MQSA issues. (For details of the September 2000 NMQAAC meeting, see NMQAAC Bi-Annual Meeting: Lively Discussion and Fond Farewells.)

Soft Copy Interpretation of Digital Images Approved

In November, FDA approved General Electric's Review Workstation (RWS) for final interpretation of mammography examinations. This allows "soft copy" interpretation of digital images on a monitor (see Soft Copy Interpretation of Digital Images Approved). This new FDA action supplements its January 2000 approval of the Senographe 2000D Full Field Digital ("hard copy") Mammography (FFDM) system (see Winter 2000 issue).

The Agency's approval is a further step to making available a broader range of digital technology, a modality that may enhance a woman's mammography experience by reducing the need for additional exposures.

As with screen-film units, soft copy (and hard copy) are subject to the same two-stage approval process and can only be sold to screen-film accredited/certified facilities. These facilities must wait until they receive a letter of approval from FDA before using any FFDM units and RWS (see Reminder).



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MammographyMatters
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Mammography Matters is a quarterly publication of the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (CDRH), Food and Drug Administration. Its purpose is to help mammography facilities comply with the requirements of the Mammography Quality Standards Act of 1992.

Articles may be reproduced or adapted for other publications. Comments should be addressed to:

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Issues of *Mammography Matters* from Winter 1998 to the present may be viewed on the Internet at **www.fda.gov/cdrh/mammography**

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Facility Hotline

Call the facility telephone hotline **(1-800-838-7715)** or fax **(410-290-6351)** for more information about FDA certification or inspections.

Soft Copy Interpretation of Digital Images Approved

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outlined in the Winter 2000 issue. Complete details on the information to be supplied with the application can be obtained by contacting Ruth Fischer at 301-594-3311.

The facilities with FFDM units previously approved for use with hard copy interpretation have been informed individually of the additional information they must supply for approval to perform soft copy interpretation using an RWS. Purchasers of new FFDM units will provide the necessary information related to soft copy interpretation at the same time as they provide the other required information to FDA.

For the present, facilities relying on soft copy interpretation of FFDM images must also retain the capability of producing hard copy images of primary interpretation quality. Both the final MQSA regulations and the law itself require mammography facilities to provide original mammograms to medical institutions, physicians, health care providers, or to the patient, when requested by the patient or someone acting on her behalf. These original mammograms must be in a form useable by the recipient. For this reason, until digital readout capabilities are generally available in radiological, surgical, and other medical facilities, hard copies of the mammograms must be provided when needed. MM

REMINDER...

Q. My facility has just purchased a full field digital mammography unit and will be applying soon for approval to use it for patient examinations. Can we begin using it for patients as soon as the application is filed or must we wait until receiving a formal approval from FDA?

A. You **must wait** until you receive a letter of approval from FDA before beginning to examine patients. We did permit those facilities who had been involved in the testing of prototype digital units, before the first such unit was approved for commercial sale, to continue examining patients while their application was being reviewed. This was primarily because such facilities had demonstrated adequate performance during the development of the digital units. Facilities wanting to begin the use of digital units now that they are commercially available do not have such a record and so must receive their Letter of Approval before beginning to examine patients. The same approval process holds when facilities add a Review Workstation to begin soft copy interpretation. Facilities interested in purchasing a digital unit should consult the Spring 2000 issue of Mammography Matters for details on how to apply for approval.

Inspection Results Under the Final Regulations: The First Year

In July 1999, when FDA began using the revised inspection software, the distribution of inspection findings, or citations, changed. The number of facilities with the most serious findings (Level 1) and serious findings (Level 2) increased, while the number of facilities with only minor findings (Level 3) and with "No Findings" decreased. FDA had predicted changes in inspection findings with the introduction of the revised software. (See Inspection Results Under the Final Regulations: The First Six Months from the Winter 2000 issue for an analysis of changes in inspection findings.)

% Of Facilities	Q1 10/1-12/31/99	Q2 1/1-3/31/00	Q3 4/1-6/30/00	Q4 7/1-9/30/00	F Y 0 0
% w/L1 as Highest	4.2	4.6	3.8	3.1	3.9
% w/L2 as Highest	34.8	32.8	32.5	30.5	32.6
% w/L3 as Highest	10.8	9.8	10.2	10.4	10.3
% w/ No Findings	49.9	52.6	53.3	55.7	52.9

With the first year of inspections under the final regulations now complete, FDA has released inspection results for Fiscal Year 2000 (10/1/99-9/30/00). As FDA expected, the early rise in Level 1 and Level 2 findings peaked in the first half of Fiscal Year (FY) 2000, but began to decrease in the second half of the year, with the rate of decrease faster for Level 1 findings. Results also showed that most Level 1 findings continue to be for violations of Quality Control tests for the processor and the phantom. The average number of Level 3 citations fluctuated slightly during FY 2000, whereas the number of facilities with "No Findings" increased steadily throughout this period. The table below summarizes these results:

FDA views as positive the decreased number of facilities with Level 1 and Level 2 findings and the corresponding increase in the number of facilities with "No Findings." We are confident that as facilities become more familiar with the requirements of the final regulations, they will continue to improve their performance, with fewer citations and higher quality standards the result.

Where Facilities Should Send Responses to Inspection Findings

Facilities must respond, in writing, to Levels 1, 2, and Repeat Level 3 inspection findings. Facilities should not send their responses, however, to FDA's Division of Mammography Quality & Radiation Programs (DMQRP) in Rockville, MD. This delays the District Office's handling of this important correspondence. Responses should instead be sent to the facility's FDA District Office.

- **For all Level 1 and Repeat Level 2 findings,** a Warning Letter is sent with information as to which FDA District Office should receive the response.
- **With Level 2 and Repeat Level 3 findings,** the inspector indicates in the letter left with the facility which FDA District Office is to receive the response.
- **Level 3 findings do not require a response.** However, correction of this noncompliance is checked during the next inspection.

Recognizing Inspectors' Service

Beginning in Fall 1999, FDA began acknowledging inspectors who had reached their fifth year of service under the MQSA Inspection Program. The following inspectors have now passed that milestone and will be presented with a Certificate of Appreciation in the month following his or her fifth anniversary of service:

Linda Andreis
Dennis Angelo
Gamal Azer
Beverly Jo Carswell
Beverly Clark
Paul Clemons
M. Joe Colemon
Richard Conway
Steven Crawford
Roger Currier
Joseph Dulemba
Tom Dykstra
Terri Eckert
Jack England
Rachel Evans
Karen Farris
Gary Franklin
Andrew Gardosik
Bob Gonsoulin
Manfred Gorisch
Raul Hernandez
Jeanie M. Hudson
Rebecca Hunter
William Kelleher
Terry Kidd
Joseph Koshy
Renee Kugler
Elizabeth Laudig
Viji Mathew
Richard Moreland
Darlene Nalepa-Whitmill
Donald Norton
Dan Oakey
Minh Phan
Daniel Quesada
Ceferina Ramos
Art Saknit
Jeff Sincek
Jeff Tavormina
Tod Van Wieren
James Wormuth
Greg Wos
Mark Zallis

Inspector Info . . .

MQSA-certified inspectors are critical to the success of the mammography program. Since the launch of the MQSA Inspection Program in 1995, inspectors have:

- **Conducted more than 49,000 inspections.**
- **Assisted facilities in increasing their compliance with the national standards.**
- **Achieved a high level of satisfaction among facilities with inspectors technical and professional performance.**

Second Facility Satisfaction Survey Planned

The second FDA-sponsored facility satisfaction survey is planned for Spring 2001. This survey is expected to yield critical information on facilities' experience with the inspection process under the final regulations, in place since April 28, 1999, and what actions, if any, FDA should take to improve the process.

The original facility satisfaction survey was conducted in April 1997. Results from the original survey indicated high levels of satisfaction with inspectors and the inspection process. For the benefit of those who may not have seen the full survey results and the summary of those results, we have restored these two documents to the "Reports" section of our website.

As with the earlier survey, the upcoming survey will be administered by a contractor and will be used to gather data from about 1,000 mammography facilities. To preserve facility anonymity, FDA will receive only survey results. Updates on the survey process will be posted on our website as they are available.

Stay Informed! Sign up for the Mammography ListServ!

Subscribe to the electronic ListServ to receive e-mail alerts and highlights of our website as they become available. You'll also receive notification via e-mail when new articles are published on our website.
To subscribe, visit http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mail/listman.cfm.

Q & A

The following questions and answers come from FDA's Policy Guidance Help System, part of the Mammography Program website (www.fda. gov/cdrh/mammography) to help facilities comply with MQSA regulations. People with questions about MQSA guidance should refer to the Help System for approved FDA answers. FDA welcomes any questions about MQSA or its Mammography Program.

Q I have an employee who completed her 40 hours of mammography training last year. She is going to take the ARRT Mammography exam next month. ARRT will count this as continuing education (CE) if she passes. Does it count toward the 15 CE in a 3-year period for FDA as well? If so, how many credits may she count it as?

A If the technologist has already satisfied his/her initial training requirement, then all 24 credit hours may be applied toward his/her continuing education requirement.

Q Can simulated examinations (person not irradiated) count toward the radiologic technologist initial, continuing, or requalification experience requirement?

A No. Simulated examinations are not acceptable toward meeting the experience requirements. While simulations may be useful, the full experience benefit cannot be achieved without the ability to evaluate and learn from the films obtained during an actual examination.

Q Under the interim regulations, physicians could not count interventional mammographic examinations toward the initial or continuing experience requirements. Has this same policy been extended to radiologic technologists and medical physicists under the final regulations?

A Yes. Because interventional mammography is currently excluded from MQSA regulations, performance of interventional mammographic examinations cannot count toward the initial or continuing experience requirements.

Q I am a medical physicist who earned my degree in physical science at a non-US institution. Is this degree acceptable toward meeting the requirement?

A A degree from a non-US institution is acceptable if the physicist can provide information showing that his/her foreign degree is accepted by an accredited US institution, the Committee on Accreditation of Medical Physicists Education Programs (CAMPEP), World Education Testing, or by one of the professional certifying bodies approved by FDA. In cases where acceptance of a foreign degree by either an accredited US institution or by one of the FDA-approved professional certifying bodies cannot be provided, FDA will evaluate such degrees on a case-by-case basis.

Q If an interpreting physician is the sole owner of a mammography facility or a medical physicist is the sole owner of a physics consulting service (and therefore is considered the most responsible official of the facility), can the interpreting physician or medical physicist document his/her own continuing experience?

A While acting in the capacity of the most responsible official of the mammography facility, an interpreting physician or medical physicist can document his/her own continuing experience. While such documentation will be accepted in routine cases, it is assumed that this documentation is based upon more extensive records, such as facility logs, reports, or survey reports and that these could be examined if need be.

Q If radiologic technologists do not start working directly in mammography after meeting the initial requirements, but decide to start working at a mammography facility later, what must they do to make sure they are in compliance with MQSA? What should facilities do before allowing new personnel, including locum tenens or those personnel who have left the facility but returned later, to provide mammography services?

A Personnel who have not worked in mammography for two years or more after meeting the initial requirements may need to work under direct supervision when they return to mammography, if they do not meet the continuing experience and continuing medical education (CME) requirements. While under direct supervision, these personnel should obtain the necessary continuing

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Q&A

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experience and CME to requalify before resuming independent work in mammography. A facility may be cited during an inspection if such personnel work without supervision prior to obtaining sufficient hours of CME and continuing experience to meet the continuing requirements. Similarly, facilities should check to see that all new personnel meet all the appropriate requirements prior to letting them provide mammographic services independently. If these personnel are working independently and do not have the required continuing experience and CME, the facility may be cited for these problems.

NMQAAC Bi-Annual Meeting: Lively Discussion and Fond Farewells

The National Mammography Quality Assurance Advisory Committee (NMQAAC) held its bi-annual meeting on September 28, 2000, in Gaithersburg, MD. In a forum moderated by Barbara Monsees, M.D., committee chair, members discussed proposed MQSA guidance under the final regulations, FDA's role in evaluating the competency of personnel, small-field digital image receptors, full-field digital mammography certification, the States as Certifiers Program, and the MQRSA Inspection Demonstration Program.

Also noted at this meeting was the upcoming departure of NMQAAC members whose terms have come to a close. The following committee members were thanked for their years of service to NMQAAC: Peter Dempsey, M.D.; Patricia Hawkins; Kendra McCarthy; Ellen Mendelson, M.D.; Barbara Monsees, M.D.; and Robert Pizzutiello, Jr., M.S.E.E. FDA acknowledged these individuals for their expertise and dedication, which have been invaluable in realizing DMQRP's mission.

To review the summary and transcripts of this meeting, go to the Advisory Committee page of the website.

Governmental Entity Program Still Successful

FDA's Center for Devices and Radiological Health completed the third Governmental Entity Audit in 1999, with final results now complete. This audit examines mammography facilities that have declared themselves to be a governmental entity under MQSA. Verifying this declaration is important because facilities that qualify as governmental entities are exempt from paying inspection fees. For the 1999 audit, CDRH audited facilities that had consistently claimed governmental entity status, as well as those that once paid fees but had since declared themselves to be governmental entities and therefore fee-exempt.

The sample size for the 1999 audit was larger than in the first two audits, providing a better indication of compliance with the Governmental Entity Program. As with the first two audits, the most recent audit found that facilities were in compliance with the program. Audit results showed that 100 percent of the inspected mammography facilities declaring governmental entity status had correctly identified themselves as governmental entities. The next Governmental Entity Audit will be completed in Fiscal Year 2001.