DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Dear NMQAAC Committee Member:

Thank you for agreeing to serve at our next meeting of the **National Mammography Quality Assurance Advisory Committee** on November 4, 2011. The committee will meet to provide advice and recommendations on the following issues: (1) proposed changes to the Mammography Quality Standard Act (MQSA) policies and inspection procedures; (2) accreditation body review of soft copy mammography images; and (3) reporting breast density on mammography reports and patient lay summaries. The committee will also receive updates on the MQSA program and the status of the Full Field Digital Mammography universal quality control manual.

Please do not discuss this information with members of the press, public or industry, with financial institutions, or with any other person, including other Panel members. If for any reason you are contacted by anyone seeking to obtain or discuss this information, please refrain from any discussion of it and the meeting and advise me of this immediately. The only publicly available information on the meeting agenda is the meeting purpose described above. Two business days before the meeting, the meeting agenda, the roster, and presentations will be posted on the FDA website.

Enclosed you will find documents and a link to an FDA webpage for the MQSA. Please familiarize yourself with the content of the program and consider how you will respond to the issues and questions that will be presented during the meeting. **The information supplied by FDA is provided in electronic format. If you require additional information or would like a hard copy panel pack, please contact me.** If you believe you may have any conflict of interest for a meeting topic, please refrain from reviewing this information until Committee Management informs you via e-mail that you are cleared for the meeting. After the meeting is adjourned, please leave all confidential material at your place on the Committee table for document tracking. After the meeting, the 24-hour summary, transcript, and summary minutes will be posted at the Committee meeting web site.

In addition, please note that Committee members and consultants who voluntarily submit written analyses, comments, etc. to the agency should be aware that these submissions may be subject to release to the public, by means of the Freedom of Information Act (Ref: CFR 20.80, 20.81, 20.84 and 20.103). Thus, such submissions should only contain material that reflects the technical and scientific content of the subject being reviewed.

If you have any questions or concerns, or if I can be of assistance to you in any way regarding the Committee meeting agenda or logistics, please let me know. Please be mindful that this meeting is scheduled to end at 5 p.m. and you should not plan to leave any earlier than 5 p.m. There will be a FDA representative present at the panel meeting that will be able to adjust your travel arrangements if necessary. If you have any questions or concerns, please contact me by phone at 301-796-6639, via fax at 301-847-8121, or via email at: Shanika.Craig@fda.hhs.gov. Once again, thank you for agreeing to share your expertise with us.

Sincerely,

Shanika Craig, MHA, MBA
Designated Federal Officer
Center for Devices & Radiological Health
U.S. Food and Drug Administration