



Food and Drug Administration
Rockville MD 20857

MEMORANDUM

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

THROUGH: Jenny Slaughter /S/ 9/6/06
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 9/5/06
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: Conflict of Interest Waiver for Carol J. Mount, R.T.

I am writing to request a waiver for Carol J. Mount, R.T., a member on the National Mammography Quality Assurance Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Ms. Mount a waiver under section 208(b)(3). Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee or her employer has a financial interest. Since Ms. Mount is a special Government employee, this individual is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to her or her employer.

Ms. Mount has been asked to participate in the Committee's general issue discussions on (1) amendments to the current Mammography Quality Standards Act (MQSA) regulations; (2) all guidance documents issued since the last meeting; and (3) updates on recently approved alternative standards and the radiological health programs.

Ms. Mount has advised the FDA that she has financial interests which could potentially be affected by her participation in this matter. She reported six mammography related inventions licensed through [-----]
[-----]. She reports that total royalties for all 6 inventions do not exceed [-----] annually.

The function of the Committee, as stated in its Charter, is to provide advice to the Food and Drug Administration on the following tasks: developing appropriate quality standards and regulations for mammography facilities, developing appropriate standards and regulations for bodies accrediting mammography facilities, developing regulations on sanctions, developing procedures to monitor compliance with standards, establishing a mechanism to investigate consumer complaints, reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities, determining whether there is a shortage of mammography facilities in rural and health professional shortage areas, determining whether there will be a sufficient number of medical physicists after October 1, 1999, and determining the costs and benefits of compliance with these requirements. As a member of the National Mammography Quality Assurance Advisory Committee, Ms. Mount potentially could become involved in matters that affect Nuclear Associates. Under section 208, Ms. Mount is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting this individual to participate in such matters, as you deem appropriate.

For the following reasons, I believe it would be appropriate for you to grant a waiver to Ms. Mount allowing her to participate in matters identified below.

First, the Committee discussion is a matter of general applicability, involving an entire class of mammography related products and granting no advantage to any individual manufacturer. Therefore, the potential concern that Ms. Mount's impartiality might be called into question during Committee deliberations should be minimized.

Second, the total annual royalties received are not considered substantial and therefore less likely to affect the integrity of the SGE's services. The Committee's recommendations should have little impact, either negative or positive, on the value of the inventions or on the ability of the licensee to pay royalties.

Third, the Committee's recommendations are advisory only and the Agency officials making the decisions are not bound by the recommendations of the Committee. Therefore, the Agency will take into consideration the involvement of the SGE when making a final decision.

Lastly, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. Presently a radiologic technologist at the Mayo Clinic and an educator at the Mayo Medical School, Ms. Mount has worked in mammography for almost three decades. As the supervisor of breast imaging at the Mayo Clinic, she has extensive experience at a high volume mammography facility and will be able to bring that perspective to the Committee's discussions. In addition, she has developed a number of devices that are used in mammography quality control and has experience in both small and full field digital mammography. Ms. Mount's participation in these Committee deliberations is invaluable and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

