



Conference of Radiation Control Program Directors, Inc.

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July 21, 2000

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Darrell Hocken, Manager
X-Ray Program
Radiation Protection Services
Oregon State Health Division
Department of Human Services
800 NE Oregon Street #21
Portland, OR 97232-2162

Dear Mr. Hocken:

This is in reference to your letter dated December 20, 1999 regarding the Food and Drug Administration's MQSA program. Thank you for your patience in waiting for a response until the CRCPD Board of Directors had an opportunity to discuss your letter at the Board meeting in Tampa. After considering your suggestion, the Board of Directors did not feel that it was an appropriate role for the CRCPD's Committee on Mammography (H-11) to act as a "middleman" between the States and MQSA personnel on contractual issues. However, the Committee has been very active in providing input to the FDA on MQSA issues.

In March of 1996, the Committee on Mammography formed a sub-group called the MQSA Working Group. This Working Group is made up of the members of H-11, several of whom are MQSA inspectors, State MQSA inspectors from each FDA region and several FDA MQSA inspectors. Their charge is "To develop a working group to solicit, discuss and synthesize comments of State participants in the MQSA Inspection Program concerning all aspects of that program [the inspection process, the inspection procedures, the inspection software, etc.] and provide State input to the FDA to assist the Agency in the development of the program as it evolves."

A number of the concerns that you mention in your letter have been previously identified by H-11 and the MQSA Working Group and have been discussed with the FDA. Specifically:

- Differences in inspector training:
 - ▶ The Committee on Mammography is reviewing the current training program for State inspectors. If this initial evaluation determines that a more thorough professional evaluation is needed, the committee will recommend how such a professional evaluation should be conducted. They will also investigate the role of the CRCPD in designing, sponsoring and possibly conducting courses at all levels for individuals to become certified MQSA inspectors.
- The perception that FDA does not value the inspectors' judgement when disputes with facilities arise over inspection results.
 - ▶ The Working Group has advanced this concern of the inspectors to the FDA on several occasions.

A Partnership Dedicated to Radiation Protection

OSP-006 Template
RIDS Distribution SP2

Darrell Hocken

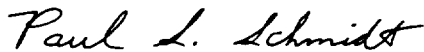
Page 2

July 21, 2000

- The management of policy changes and other e-mail from FDA.
 - The perception that FDA does not value the inspectors' judgement when disputes with facilities arise over inspection results.
- The Working Group has advanced this concern of the inspectors to the FDA on several occasions
 - The Working Group suggested an electronic compilation of current guidance and policy several years ago. The FDA responded with the "Policy Guidance Help System" which is available at the FDA's MQSA web address: <http://www.fda.gov/cdrh/mammography>. Additionally, Lin Carigan of the CRCPD's Office of the Executive Director sends faxes to State Program Directors and/or Mammography Contacts containing the information that is electronically transmitted by the FDA to the State MQSA inspectors.
- Computer software problems.
 - On a limited basis, the Working Group has test-piloted some versions of the inspection software.
- Interpretation of the MQSA rules.
 - H-11 and the Working Group have continually provided comments to the FDA on the rules and guidance documents.

I appreciate this opportunity to respond to your concerns. Please be assured that H-11 will continue to provide the FDA with feedback on the MQSA program and related issues. If you wish to discuss the matter further, please contact Jennifer Elee, Chairperson of H-11, at 381/362-5440.

Sincerely,



Paul S. Schmidt, Chairman
Conference of Radiation Control Program Directors

PSS/JS/ss

cc: Board of Directors/Federal Liaison
Charles Hardin, Executive Director
Ray Paris, Manager Oregon Radiation Protection Services
Jennifer Elee, Chairperson of the Committee on Mammography