

VOLUNTARY VERSUS MANDATORY REGULATORY STANDARDS: EDUCATION, STANDARDIZATION, REGULATION

August, 2, 2011
American Association of Physicists in Medicine
Vancouver, British Columbia, Canada

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VOLUNTARY VS. MANDATORY STANDARDS

- Mammography Experience - MQSA
 - Accreditation
 - BIRADS Reporting
- MIPPA – Mandating Accreditation of Advanced Imaging Modalities for Outpatients
- Interventional Fluoroscopy Radiation Safety
 - Credentialing of non-radiologist Users
 - Follow-up after Significant Dose
- What happens in absence of Standards
 - Independent Health redefines ALARA!
- How do we get from **adoption** to **compliance**?

AMERICAN COLLEGE OF RADIOLOGY MAMMOGRAPHY ACCREDITATION PROGRAM (ACR-MAP)

- 1987 – Voluntary program initiated after reports of quality concerns
 - Gradual, limited adoption
 - Who joined the process? Practices motivated by *quality*.
- Personal experience
 - Encouraged our clients to pursue accreditation
 - Some adopted
 - Others “Where does it say we have to do this?”
- 1992 Law signed by President G. H. Bush
- October 1, 1994 - Effective date (mandatory deadline)

ACR-MAP

- 1991, approximately half of 10,000 facilities had applied for ACR-MAP
 - Half of those had achieved accreditation
- Overall pass rates

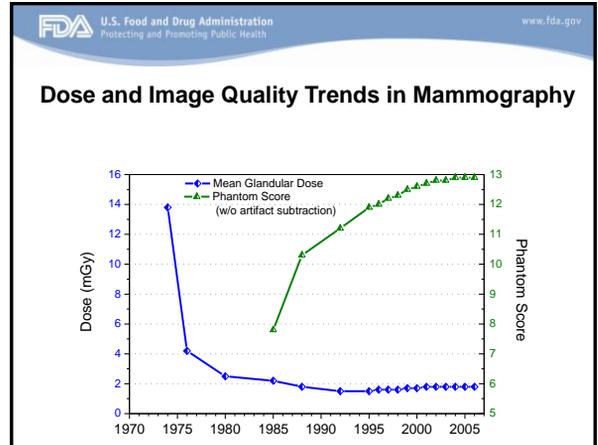
Table 5. ACR Mammography Accreditation Program unit pass rate history

Year of First-Attempt Report	First Attempt			Second Attempt			% Pass Overall
	Total	No.	%	Total	No.	%	
1987 to 1991 [3]	2954	2068	70.0	609	533	87.5	88.1
1994	3929	2751	70.0	917	866	94.4	92.1
1995	5712	4162	72.9	1248	1129	90.5	92.6
1996	4736	4061	85.7	620	545	87.9	97.3
1997	4706	3934	83.6	680	643	94.6	97.3
1998	5428	4275	78.8	949	794	83.7	93.4
1999	5305	4166	78.5	766	632	82.5	90.4
2000	4823	3995	81.1	722	640	88.6	94.1
2001	4563	3771	82.6	590	516	87.5	94.0
2002	5448	4769	87.5	608	538	88.5	97.4
2003	5466	4828	88.3	610	541	88.7	98.2

Destouet et al, J Am Coll Radiol 2005;2:585-594.

DID MQSA IMPROVE QUALITY?

- Qualitative and Anecdotal
- Quantitative



FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

In order to detect change clinically, you need to assure the standard image remains constant.

BREAST IMAGING REPORTING AND DATA SYSTEM BIRADS

- Developed by ACR in 1993
 - to standardize mammographic reporting,
 - to improve communication,
 - to reduce confusion regarding mammographic findings, to aid research, and to facilitate outcomes monitoring.
- As a voluntary standard, met with limited adoption by the most quality focused Radiologists
- Under MQSA (inspection), all interpreting physicians (behavior change) and come into compliance
- Some radiologists still say “Where does it say that I have to do this?”

DOES THIS SEEM ONEROUS? BIRADS ASSESSMENT CATEGORIES

- **Category 0**
 - Need Additional Imaging Evaluation and/or Prior Mammograms For Comparison:
- **Category 1, Negative**
- **Category 2, Benign Finding(s)**
- **Category 3, Probably Benign Finding**
 - Initial Short-Interval Follow-Up Suggested
- **Category 4, Suspicious Abnormality**
 - Biopsy Should Be Considered
- **Category 5, Highly Suggestive of Malignancy**
 - Appropriate Action Should Be Taken

MQSA REGS 21 CFR 900.12(C)

THE MAMMOGRAPHY REPORT SHALL INCLUDE THE FOLLOWING:

- (iv) Overall final assessment of findings, classified in one of the following categories:
 - (A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);
 - (B) "Benign:" Also a negative assessment;
 - (C) "Probably Benign:" Finding(s) has a high probability of being benign;
 - (D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
 - (E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;
- (v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and
- (vi) **Recommendations made to the health care provider about what additional actions, if any, should be taken.** All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

MIPPA

- The Medicare Improvements for Patients and Providers Act (MIPPA)
- Providers of advanced diagnostic imaging services (ADIS) that bill under Part B of the Medicare Physician Fee Schedule must be **accredited by January 1, 2012** to receive payment for the technical component of these services.
- Advanced imaging services include:
 - CT
 - PET
 - Nuclear Medicine
 - MRI

WHAT IS HAPPENING NOW?

- ACR and IAC experiencing significant increase in applications
- Medical Physics consulting groups – greater demand for our accreditation support services
- Some regions, relatively little increase
 - Insurance carriers in many cities have required accreditation for reimbursement for years
- Personal experience
 - After 2001 AAPM Summer School on Accreditation
 - We began encouraging our clients to pursue accreditation
 - Some adopted, over a period of years
 - "Why spend the money when we don't have to?"
- Mandatory Standards needed to assure adoption

RADIATION-INDUCED SKIN INJURIES FROM FLUOROSCOPY

THOMAS B. SHOPE, PH.D.

OFFICE OF SCIENCE AND TECHNOLOGY
CDRH FDA

- presented as Scientific Exhibit 060PH at the 81st Scientific Assembly and Annual Meeting of the Radiological Society of North America, November 26 - December 1, 1995. *Radiology Vol. 197(P) Supplement, P449*
- Subsequently published in *Radiographics (1996)*

1994 AND 1995 FDA FLUOROSCOPY ADVISORIES

- Reported cases of radiation injury from interventional fluoroscopy and Digital Subtraction Angiography (DSA)
- Radiation injuries ranged from temporary erythema to dermal necrosis requiring skin grafts



Institutional Response

- Establish standard operating procedures
 - Record info to estimate skin dose
 - Any procedure approaching (exceeding) some threshold
 - FDA suggested 1 Gy threshold
- Know radiation dose rates
- Modify procedure protocols, as appropriate, to limit cumulative absorbed dose
- Enlist qualified medical physicist to assist in implementing response

OUR EXPERIENCE

- The most quality-focused hospitals adopted, shortly after we introduced concept to them
- Credentialing of fluoroscopy users politically challenging, but important for risk mitigation
- Mandate for behavior change, particularly for cardiologists, created resistance
- The most cost-conscious managers were concerned about cost of the additional work
- “Where does it say that we have to do this?”



NCRP Report #168
 Radiation Dose Management for
 Fluoroscopically-Guided Interventional Medical
 Procedures
 February 14, 2011

.....and we are still talking about this today!

INDEPENDENT HEALTH (INSURANCE COMPANY)
 NIA – NATIONAL IMAGING ASSOCIATES, INC.
 (RBM)

**June 2011, Web Site and provider memo
 Radiation Safety Program Expanding**

Diagnostic imaging is a common tool in the prevention and diagnosis of numerous conditions, injuries and diseases. With the advances in radiology, cumulative radiation exposure is a growing concern among physicians and their patients. However, while there are no safety rules covering the radiation exposure for patients, physicians are asked to follow the principle of **As Little As Reasonably Achievable (ALARA)**.

As a way to raise awareness of radiation exposure that patients receive during diagnostic imaging, Independent Health and National Imaging Associates (NIA) are expanding their radiation safety program.



Beginning on June 27, 2011, physicians will be notified about a patient's exposure to radiation. A special screen will appear on RadMD.com when physicians request preauthorization for diagnostic radiology services if their patients have been exposed to at least 50 milliSieverts (mSv) of radiation.

Because the cumulative effects of radiation exposure increase the risk of serious medical conditions, Independent Health believes it is appropriate to alert physicians when their patients have reached higher-than-normal radiation exposure.

Additional information about radiation safety is available at RadMD.com.

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LESSONS LEARNED

1. Voluntary standards will be adopted by the most quality conscious facilities/professionals
2. Increasing cost pressure in health care
3. "Where does it say we have to do this?"
4. Mandatory Standards, government or reimbursement-based, convert
Adoption to Compliance
5. In the absence of real Standards, those motivated strictly by finances will make up their own rules...
6. Do you want national quality in health care to be
"As Little as Reasonable Achievable"

