CDRH Update

NEMA Diagnostic Imaging and Therapy Systems 24th Annual Meeting

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CDRH and the Imaging Industry

Registration and Listing section of the Office of Compliance:

250 manufacturers of Medical Imaging equipment

Applications in Fiscal Year 1999

Approximately 400 applications submitted for imaging equipment.

- 6 of these were for digital radiographic equipment.
- 2 of these were for digital mammography.
- 4 PMAs for digital imaging have been approved this year.

Standards

Long history of collaboration with NEMA

- The original diagnostic x-ray standard was largely based upon NCRP (National Council on Radiation Protection) report and industry standards.
- Reclassification of magnetic resonance imaging devices derived from collaborative work on NEMA standards.
- The precursor to the abbreviated 510(k) was developed through NEMA/FDA negotiation (1993).

Standards

Current Issues:

- For most standards, it is not feasible for testing to be conducted on a prototype – rather, testing is done on production units against the standard at the time that the declaration is submitted to FDA.
- An abbreviated 510(k) allows a declaration of conformity to the standard with no need for actual review of underlying data.
- During development of the FDA Modernization Act, the idea of "prospective" standard certification was introduced, an approach now under consideration by FDA.

Standards

Long history of collaboration with NEMA

- NEMA perceives the FDAMA use of standards as a direct conflict with its traditional methods but the policy paper being developed will seek to provide a role for standards in multiple regulatory pathways.

Why aren't declarations of conformity to standards (under FDAMA) being used?

Several barriers have been identified:

- Test data is needed before premarket submission ?
- Too few recognized standards exist ?
- Fear of inspections by the Agency ?
- There is no clear incentive to balance risk ?
- The perception remains that reviewers will still request data and not rely on standards ?

Standards: The Issue of Test Data

- FDA will give it further consideration.
- This should be implemented with a minimum of disruption
  - For our reviewers
  - For industry.
  - E.g., "skinny" 510(k)s for imaging devices would be unchanged.
- It is desired that existing policy and procedures be used to accomplish the goal.

Standards

What you can do!

- Get involved to save time, money, effort.
- Tell us what standards need to be recognized.
- Tell standards development organizations what standards need to be developed and participate.
- Tell us how to make the process smoother and more efficient.

Guidance

In 1999, four FDA imaging equipment guidance documents have been issued:

Guidance for Submission of 510(k)s:

- for Solid State X-ray Imaging Devices.
- for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems.
- for Magnetic Resonance Diagnostic Devices.
- for Radionuclide Dose Calibrators.

Digital Mammography

Mammography is a preamendment (Safe Medical Devices Act of 1976) technology which continues to undergo tremendous improvement.

25 million mammograms are performed nationwide annually with significant health consequences for this large population.

Digital Mammography

Therefore, it is imperative to assure that digital mammography is at least equal to analog, which has demonstrated clinical benefit.

A false positive may result in unnecessary biopsy while a false negative may result in delayed cancer diagnosis.

Digital Mammography

Clinical data: How much is needed?

- At the issuance of 1996 guidance on mammography, "agreement studies" were thought feasible
- However, the results of the studies leave open the question of whether digital images will result in more false positive biopsies
- Clinical Screening studies could require as many as 30,000 or more patients.

Digital Mammography

Would a PMA be a more flexible approach than a 510(k)?

- The PMA approach offers an alternative since a small study can be conducted preapproval followed by a large, definitive study postapproval.
- The recently issued letter to manufacturers of digital mammography technology refers to this balance of pre- and postmarket data as mandated by FDAMA.

Digital Mammography

Are there other alternatives ?

- A strategy whereby a joint screening study (ie., multiple manufacturers) could be conducted under the auspices of a third party such as NEMA ?
- Are there opportunities to combine the data collection from the MQSA program to assess the impact of new imaging technology?

- Comments from NEMA are welcomed as the FDA policy on digital mammography is developed.

Fetal Ultrasound Monitors

"Keepsake" videos of the fetus.

- Ultrasound is a Class II prescription medical device.
- A letter to manufacturers in 1994 explained that fetal ultrasound for souvenir purposes is not approved and is an unnecessary exposure to radiation.
- FDA is aware of about 10 locations per year where keepsake ultrasound videotaping occurs.
- One seizure occurred in 1997.
- This is a cottage industry involving registered sonographers and becomes a practice of medicine issue.

People Scanners

People scanners are not medical devices but are handled strictly as radiological products.

- These products screen people for contraband and weapons and are used primarily in prisons and some international airports.
- The issue of exposure to ionizing radiation for nonmedical purposes is monitored by CDRH.
- At the annual meeting of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) recently, recommendations made there in 1998 were further discussed.

People Scanners

TEPRSSC Recommendations:

- registration of the scanners with the state;
- operator training in radiation safety; and
- labeling of scanners as x-ray emitting.

? A letter will be issued by CDRH to manufacturers encouraging implementation of these recommendations.

? Instead of a federal mandatory standard, we convened an ANSI consensus standard work group to include FDA, industry, states, and users.

People Scanners

- CRCPD (the Conference of Radiation Control Program Directors) has passed a resolution that scanners only be used if alternative does not exist.
- The newly formed CDRH Radiological Health Council will have people scanners on its agenda as a crosscutting issue.

HCFA

CDRH will work proactively with the Health Care Financing Administration in meetings with industry.

- More transparent processes
- Attempt to shorten unnecessary delays from a 'serial' instead of 'parallel' evaluation process
- Attempt to avoid redundant requirements

Our Website:

www.fda.gov/cdrh