Digital Mammography and the Mammography Quality Standards Act

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BOTH WIDE and narrow band gap materials are used for x-ray imaging in digital mammography. In computed radiography, those wide band gap materials¹ are selected when x-rays can efficiently produce defect centers as F type centers, which are electron-trapped anion vacancies and hole centers such as H-centers and V_k -centers. Appropriate laser light at a later time stimulates the trapped charges, and their recombination at the luminescence centers results in emission of light producing x-ray imaging. In some materials² double doping by impurity ions also provides stable trapped charges, enabling one to perform read out of the imaging plate at a later time. Efforts are still under way to use the photostimulable phosphors in mammography, in which high detected quantum efficiency (DQE) and resolution and faster decay of the materials are important. Bandyapadhyay and Chakrabarti³ and Chakrabarti⁴ have recently reported photostimulable emission in single crystals of copper doped alkali halides, which seem to possess some of these desirable characteristics. Some rare earth doped wide band gap phosphors that are widely used as screen phosphors in conventional screen-film systems are utilized with CCD arrays in scanning techniques for full breast imaging. Evidently, the choice of materials that have emissions involving parity forbidden f-f transitions has caused huge disadvantages in this attempt; however, efforts are under way to grow these materials in nanocrystalline⁵ form, which may both improve DQE and decrease the decay time because of wave function mixing removing the parity restriction, thus facilitating the use of these materials for slot scanning.

Recently,⁶⁻⁹ several small band gap materials have shown excellent promise as flat-panel detectors providing indirect and direct digital detections. In an indirect process that is essentially a two-step process, flat panel TFT arrays are used with x-ray phosphor coatings on detector arrays made of narrow band gap materials. Input x-ray photons are converted to visible photons by the scintillator, illuminating the arrays that generate a modulated electrical signal. In a direct process, the input x-rays are absorbed directly by the detector matrix and a modulated signal is generated. Both indirect and direct detection have advantages and disadvantages in terms of resolution, cost-effectiveness, and radiation damage¹⁰ of the materials.

As this solid-state imaging technology rapidly advances and several types of digital imaging systems with different solid state materials (imagers) emerge, the FDA is preparing to review a number of premarket submissions and to regulate digital mammography under the Mammography Quality Standards Act (MQSA) of 1992. The Office of Device Evaluation of the Agency has made available to manufacturers a document entitled Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems, intended to provide guidance in the preparation of a regulatory submission. The regulation of digital mammography under MQSA poses unique challenges. The MQSA states that "no facility may conduct an examination or procedure . . . involving mammography after October 1, 1994, unless the facility obtains a certificate . . ." To obtain an FDA-approved certificate, interim regulations effective February 20, 1994 require facilities to meet quality standards in personnel, equipment, dose, quality assurance programs, and medical record keeping and reporting; however, there are inherent problems with applying mammography quality standards, developed primarily to address issues involving film-screen systems, to whole-breast digital systems. Consequently, in July of 1996, the FDA convened a panel of digital mammography researchers and manufacturers to present findings and

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recommendations for quality standards to the FDA's National Mammography Quality Assurance Advisory Committee. The panel, Committee, and FDA agreed that the development of regulatory standards for an evolving technology must proceed cautiously.

The FDA has an established process for allowing new technologies to enter the market once safety and effectiveness are proven. An individual manufacturer submits an application for device approval to the Office of Device Evaluation. With digital

mammography, the manufacturer will also submit an application for approval for alternative standards under MQSA. The FDA anticipates that the reviews will be conducted concurrently, so that no additional delay in marketing is encountered by manufacturers. Scientifically based comprehensive regulations covering all aspects of digital equipment, facility, and personnel performance would not be developed until sufficient experience has been gathered within the medical community with use of digital mammography technologies.

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