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### **NEMA MEDICAL SECTION LAUNCHES PRIVACY AND SECURITY INITIATIVE**

**ROSSLYN, Va, November 8, 2000--** The National Electrical Manufacturers Association's (NEMA) Medical Imaging Informatics (MII) Section has launched a Privacy and Security Initiative to address separate regulations in Japan, Europe, and the United States, that have the potential of introducing incompatibility and unnecessary complexity in product design.

The three particular regulations are the United States' Health Insurance Portability and Accountability Act (HIPAA), Europe's EC 95/46 Directive, and Japan's HPB 517. Healthcare industry vendors have joined this initiative to define a common approach to these new privacy and security regulations.

The NEMA Privacy and Security Initiative was created in response to a cooperation request by the European Coordination Committee of the Radiological and Electromedical Industry (COCIR), which is the NEMA equivalent in Europe. NEMA, in turn, asked its equivalent in Japan, Japan Industries Association of Radiation Apparatus (JIRA), to join the initiative, and is welcoming interested companies and organizations to participate in this endeavor.

NEMA companies are concerned that the wide range of approaches facing healthcare institutions responding to such regulations will result in incompatibilities among institutions, complexity in product design, and a slowing of the implementation of better privacy and security measures. NEMA decided to take a pragmatic approach and to address specific domains, such as remote serviceability of equipment, service access guidelines, and audit trails. These are well understood and the benefits are significant.

Based on market needs, this initiative may be expanded in the future. NEMA's MII Section will meet during RSNA 2000, the annual meeting for the Radiological Society of North America, in late November to hammer out the details of the initiative.

- HIPAA (<http://aspe.os.dhhs.gov/admsimp/index.htm>)

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 was signed into law by President Clinton on August 21, 1996. The goals of HIPAA include improving the efficiency and effectiveness of healthcare delivery through the standardization of shared electronic information, protecting the privacy and security of patient information stored and exchanged electronically, and reducing the cost of exchanging information among healthcare partners.

The Department of Health and Human Services (DHHS) is the regulatory body for HIPAA. There are currently five DHHS regulations at different levels of approval that are related to information privacy and security: Transactions and Code Sets, Security and Electronic Signatures (SES), Privacy, Employer Identifiers, and Healthcare Provider Identifiers. The first DHHS final regulation (Transactions and Code Sets) was published in the Federal Register on August 17, 2000. The other regulations are currently in proposed form and will be published as they are finalized. Each regulation is expected to go into effect two years after final publication.

- EC Data Protection Directive (95/46/EC) - ([http://europa.eu.int/eur-lex/en/lif/dat/1995/en\\_395L0046.html](http://europa.eu.int/eur-lex/en/lif/dat/1995/en_395L0046.html))

The European Community directive 95/46 was adopted on October 24, 1995. This regulation is not specific to the healthcare industry, but it broadly protects personal data to ensure confidentiality and legitimate fair use. Health data is recognized as one of the most sensitive cases of personal data. The transmission of personal data is restricted between complying countries. The U.S. Department of Commerce and the European Commission have adopted seven safe harbor principles, which are detailed at <http://www.export.gov/safeharbor/>. These principles require that organizations provide notice, choice, onward transfer, access, security, data integrity, and enforcement when the disclosure of individual information is involved.

- HPB 517 - ([http://www.medis.or.jp/e\\_mhw01.html](http://www.medis.or.jp/e_mhw01.html))

The Japan HPB 517 regulation was published on April 22, 1999. This regulation is specific to the healthcare industry. It includes specific requirements for electronic storage of clinical records, authenticity and accuracy of data storage and transmission, legibility and irretrievability of stored information, patient privacy, and access control. It also contains organizational management and compliance sections.

NEMA is the leading trade association in the United States representing the interests of electroindustry manufacturers. Founded in 1926 and headquartered near Washington, D.C., its 500 member companies manufacture products used in the generation, transmission and distribution, control, and end-use of electricity. Annual shipments of these products total \$100 billion. NEMA's Diagnostic Imaging and Therapy Systems Division represents more than 95% of U.S. manufacturers of x-ray imaging, computed tomography, diagnostic ultrasound, radiation therapy, magnetic resonance, nuclear medicine imaging and medical informatics equipment.