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NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

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**Andrew Whitman**

Vice President, Medical Products

November 9, 2006

Division of Dockets Management (HFA – 305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket No. 2006N-0292**

Dear Sir/Madam:

We are writing to you in response to your request for comments in the Notice of 71 Federal Register 46233, August 11, 2006, Docket No. 2006N-0292, with respect to the proposed FDA unique device identification (UDI) system for medical devices. NEMA appreciates the opportunity to share our views with you.

NEMA is the largest U.S. trade association representing America's electroindustry. NEMA's Medical Division represents manufacturers of capital equipment which produce over 95% of the market for X-Ray Imaging (including mammography), CT, Radiation Therapy, Magnetic Resonance, Nuclear Medicine Imaging, Diagnostic Ultrasound and Medical Imaging Informatics equipment.

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, diagnostic ultrasound, nuclear medical imaging including positron emission tomography (PET) and magnetic resonance imaging (MRI). Imaging is used both to diagnose and treat patients with disease and offers physicians the ability to view soft tissue and organs, often reducing the need for costly and invasive medical and surgical procedures. With advanced medical imaging, physicians are able to perform a range of less-invasive, highly targeted medical therapies that translate into better and more comfortable care for patients.<sup>1 2</sup> This leads to convenience and easier access for patients increasing the likelihood they will get the tests, treatments and follow-up they need.<sup>3</sup>

Imaging has become a standard of modern care for virtually all major medical conditions and diseases, including cancer, stroke, heart disease, trauma, and abdominal and neurological conditions. That role is reflected in the reliance of physicians upon imaging in everyday

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<sup>1</sup> "Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., *New England Journal of Medicine*, Vol. 352, No. 17; pp 1760-1768, April 28, 2005.

<sup>2</sup> "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." Jelinek, JS, et. al., *Radiology*, 223 (2002): 731-737.

<sup>3</sup> "Travel Distance to Radiation Therapy and Receipt of Radiotherapy Following Breast-Conserving Surgery." Athas WF, et. al. *Journal of the National Cancer Institute*, Vol. 92, No. 3, February 2, 2000; pp. 269-271.

practice, including surgical procedures, and its prominence in physician-developed practice guidelines across a broad range of medical and surgical conditions.

### Executive Summary

NEMA strongly supports the enhancement of patient safety and will partner with FDA in this effort. We also recognize the role of adverse event reporting, product recalls and device tracking as important tools in this regard. However, before proceeding with the development of a UDI system, it must be recognized that there are currently FDA regulatory mechanisms in place which manufacturers employ with respect to adverse event reporting, product recalls and tracking of devices. NEMA believes these mechanisms provide sufficient essential safety-related information to FDA for protecting patient safety.

In addition to being duplicative of current mechanisms, the development of a UDI system for medical devices will be a highly complex undertaking involving reconciliation of competing identification systems and technologies and regulatory requirements in the U.S. and worldwide, and, consequently, will necessarily require significant expenditures of time and resources for all stakeholders. It is critical that FDA, industry and other stakeholders first carefully examine current tools which are available to address these issues to determine if the agency is receiving the information it needs to protect patient safety, before embarking on the creation of a wholly new system. Development of a UDI system should only be considered if necessary patient safety information cannot be provided through existing processes and procedures. NEMA believes that the currently existing adverse event reporting, product recall and device tracking procedures provide the necessary information to adequately protect the safety of patients, thus making the development of a UDI system for medical devices unnecessary. No objective data to the contrary has as yet been presented.

NEMA asks that FDA consider its comments under this proposed rule in the following areas:

1. Problem Definition – What are the problem(s), if any, with respect to patient safety which relate to identification of medical devices before the UDI system should be implemented
2. Addressing FDA’s questions put forth in the August 11, 2006 Federal Register Notice.

### **Problem Definition**

A critical first step must be the definition of the specific patient safety - related problem(s) which currently need to be solved prior to implementing the UDI system. No remedy for these problems can be achieved unless all stakeholders clearly understand what, if anything, is “broken” in the system. NEMA believes that the appropriate course is to first review current processes and determine whether FDA is receiving the information on product identification which it needs to protect patient safety, particularly with regard to adverse event reporting, product recalls and device tracking. If objective evidence of problems are found, stakeholders should then address whether the improvement of currently existing processes and policies will resolve outstanding issues.

It has not been scientifically demonstrated that implementation of a UDI system for medical devices will necessarily lead to improvement of patient safety, thus any potential patient safety benefits of a UDI system are largely unknown at this time. Modification of current

processes which are now established, and which are familiar to stakeholders, will be a more rapid and more efficient means to improve patient safety, than developing an entirely new, costly and complex method of product identification whose benefits are largely unknown.

As stated above, manufacturers of capital medical equipment have established procedures which address product identification requirements for product recalls, adverse events and device tracking. For example, for reporting of adverse events, MEDWATCH Form FDA 3500A requires the manufacturer, or user facility, to provide detailed information on a specific product which is associated with the adverse event, including, among other data:

- Brand name
- Manufacturer Name, City and State
- Model #
- Lot #
- Serial #
- Expiration Date
- Device Manufacture Date

The device manufacturer must also provide information on: the type of reportable event, the type of follow-up, evaluation of the device, including results and conclusions, and the type of remedial action taken.

In addition,, pursuant to the Radiation Control for Health and Safety Act of 1968, 21 C.F.R. §§ 1010 et seq. requires manufacturers of X-Ray equipment to place product identification on their systems and components. This includes the full name and address of the manufacturer of the product and the place, month and year of manufacture.

Currently, manufacturers place identification on their devices, including serial numbers. This identification must be placed on the x-ray generator, table, and beam control device. This achieves the same results and benefits as the proposed UDI system.

Similarly, in its document “Guidance For Industry Product Recalls Including Removals and Corrections,” FDA states that the following information, among other data, should be included in a recall submission from manufacturers:

- Product name
- Model, catalogue, or product order number(s)
- Description of the product
- Intended use or applications
- Product labeling
- Directions for use
- 510(k), IDE or PMA number
- Serial numbers
- Firm name, address, city, state, zip code
- FDA registration number, if applicable
- Health Hazard Analysis

The manufacturer is also required to explain in detail how the product is defective and/or violative, how the problem occurred and the date(s) it occurred. Importantly, the manufacturer must provide date(s) when the product was produced, the quantity which was produced and

distributed, date(s) when the product was distributed, and detailed information on where the product was distributed and identification of the customers who were shipped the device.

Thus, it is clear that processes currently in place provide FDA with the necessary information to protect patient safety and to help locate suspect devices. Revision of existing processes, if needed, to enhance the information provided to FDA would be a more straightforward and efficient way to improve patient safety, than undertaking development of a UDI system which would require very significant expenditures of time and resources. Ensuring patient safety can best be accomplished by having key stakeholders, including FDA, industry and the user community, discuss current processes and how they might be improved. NEMA stands ready to work with FDA on this important effort.

### **Questions put forth by the FDA in the August 11, 2006 Federal Register Notice**

The following reflects NEMA's views on the questions raised by FDA in its August 11, 2006 Notice in the Federal Register.

Question 1. *How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?*

NEMA response:

If a UDI system is needed, as determined by the stakeholders, for enhancement of patient safety, then FDA and the stakeholders should jointly issue and develop such a system through a joint working group. We also support the development of such a system through a similar group sponsored by the Global Harmonization Task Force (GHTF).

More specifically, the process should begin with the formation of an interdisciplinary task force comprised of key stakeholders. Detailed research should be done to resolve critical issues including the advantages and disadvantages of existing UDI technologies, and what the content of the UDI should be. Utmost efforts should be made to investigate the systems now existing in the field and their advantages and disadvantages, to determine if current product identification systems have features which should be incorporated into a UDI system. The goal of such a task force should be to reach consensus on one worldwide system. This will help avoid unnecessary confusion and expense.

With respect to implementation of such a system, NEMA recommends that existing devices in the field be "grandfathered." A process should be developed for regular, ongoing monitoring and evaluation of the UDI system. This process should link the UDI system to performance goals to assess whether the system is in fact reducing medical errors and enhancing patient safety by improvement of the device tracking, adverse event reporting and product recall processes.

Question 2. *What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?*

NEMA response:

FDA should coordinate the development and operation of an interdisciplinary task force as the key stakeholder and moderator of the functions of this body. A task force comprised of the key stakeholders is the best way to help ensure that all parties satisfy their respective needs.

NEMA recommends that a UDI system be voluntary, rather than mandatory. First, a voluntary system is preferable because such a system would be driven by specific customer demand. Customers are more knowledgeable and focused on their own particular clinical environment, and thus can better work with manufacturers to tailor an appropriate solution to their product identification needs.

Question 3. *What are the incentives for establishing a uniform, standardized system of unique device identifiers?*

NEMA response:

Incentives for developing a UDI system for medical devices exist only if after careful investigation it is determined that necessary information relating to patient safety cannot be obtained from existing processes and procedures. The incentives would be to establish a cost-effective mechanism to track and identify devices which are the subject of adverse event reporting or product recalls, and which clearly enhance patient safety. The overall goal should be one worldwide system. In the current proposal, it appears that incentives confer advantages on hospitals with the emphasis on benefiting their inventory management systems.

Question 4. *What are the barriers for establishing device identifiers ? What suggestions would you have for overcoming these barriers?*

NEMA response:

There are a number of formidable barriers for establishing device identifiers. They include:

-Non-uniformity of requirements. Major differences in requirements and regulations exist in the U.S. and worldwide. These include: FDA X-Ray equipment regulations, other identification systems such as GS-1, HIBCC, U.S. Department of Defense identification systems and private “homegrown” systems used by various hospitals. The multiplicity and complexity of existing UDI regulations and requirements in various parts of the world have the potential to create considerable confusion and are contrary to the spirit and intent of global harmonization of regulations.

-Cost Barriers. Costs are another significant barrier to implementation of a UDI system. Costs will be very significant in terms of potential re-design of devices, use of new UDI technologies, efforts to maintain compliance with various worldwide requirements and increases to both manufacturer and user infrastructure in order to develop, maintain and modify UDI systems. Manufacturers will encounter additional barriers in order to maintain appropriate identification of refurbished or updated devices, or revisions in software.

Using one example, if an RFID system is used, it is estimated that there will be a potential cost of \$ .50 to \$ 1.00 for attaching a UDI to each affected device in the field. The cumulative cost could exceed OMB guidelines requiring additional formal reviews. From a

manufacturer's perspective, using this estimate, costs could exceed \$ 100,000 per company depending upon the number of devices in clinical use. This estimate does not include the equipment which will be needed at the hospital to keep track of these devices.

-Hospitals and other user facilities will incur significant costs because hospital staff will need to be trained on bar code or RFID tag readers. Training expenditures will continue to be a significant cost factor as new personnel join hospital staff.

As stated previously, given these very significant costs, NEMA urges FDA to examine current processes to ascertain whether current problems can be remedied prior to development of a new UDI system.

Question 5. *Have you implemented UDI your product line?*

NEMA response:

Most NEMA manufacturers have not implemented UDI in their product lines because they believe current systems for recalls, adverse event reporting and device tracking provide adequate information to FDA to protect patient safety.

Question 6. *Should UDIs be considered for all devices?*

NEMA response:

UDIs should not be considered for all devices.. With respect to capital equipment, UDI should be considered only if it will enhance patient safety, and if existing FDA processes cannot achieve patient safety. Also, as part of the implementation phase, and if FDA does go forward with this proposal, the Agency can limit expenditures by requiring UDI on those devices with the highest risk to patients—for 1-3 years, before concentrating on other less risky devices. For this reason, NEMA recommends that a UDI system be widely recognized worldwide and considered “mature” before implementation.

Question 7. *What level of packaging should be considered for UDI?*

NEMA response:

This is not applicable to capital equipment.

Question 8. *What solutions have you developed or could be developed for addressing the technological, equipment and other problems that might arise in developing and implementing a UDI system?*

NEMA response:

As stated above, manufacturers have not implemented UDI in their product lines due to reliance on current identification systems.

Question 9. *What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the*

*data in the minimum data set improve patient safety? What other data would improve patient safety?*

NEMA response:

A suggested minimum data set for capital equipment could include: manufacturer name, model, date of manufacture, serial number and software version of the device. A minimum data set could differ for different devices, for example, the minimum data set for devices used in conjunction with a drug, or for those devices that would dangerously interact with other drugs or devices, might warrant a larger data set.

*Question 10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?*

NEMA response:

The development of the UDI and its associated data set could be directed by FDA and then maintained by the user facility. User facilities should keep the UDI and make it publicly available

*Question 11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g. laser etched) for certain devices?*

NEMA response:

For capital equipment, the UDI should be placed on the outside of the device itself. While human readable data is beneficial, the permanence of the lettering will raise other questions including the longevity and replacement of the UDI labeling. Industry and FDA should explore the practicality and cost-effectiveness of use of machine readable identification or human readable identification, or both, with respect to placement on devices.

*Question 12. Should a UDI be based on the use of a specific technology (e.g. linear bar code) or be nonspecific? If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be “compatible” with those used for the drug bar code rule? If yes, why? If not, why not?*

NEMA response:

The type of UDI selected should be based on a “mature” technology, which has been established and has few, if any, “bugs.” The system should be universal and allow for use around the world. It should also be a “known” system which is familiar to stakeholders.

*Question 13. From your perspective, what public health and safety benefits could be gained from having a standardized unique device Identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error?*

NEMA response:

As stated above, it is unknown whether a standardized unique identifier system would contribute to meeting device recall and adverse event reporting requirements, or to reducing medical error.

The benefits of UDI at this juncture, in the absence of clearly demonstrated evidence, are speculative. If a system is implemented, FDA and stakeholders will need to determine the system's utility.

Question 14. *From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system?*

NEMA response:

FDA and other healthcare bodies will need to discuss the training and equipment needed in a facility in order to implement a UDI system. Setup costs will have to cover: manufacturer operations and hospital operations, "readers" at all sites to help with label placement, training—manufacturer and hospital. Once the system has been installed in the hospital, the facility will need its own "readers" and training will need to be provided to help staff work with the new system.

Question 15. *If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since institution of UDIs?*

NEMA response:

To the best of our knowledge, most manufacturers of capital equipment have not implemented a form of UDI on their systems. Our comments on the costs and efforts associated with system implementation have been outlined above.

Question 16. *From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?*

NEMA response:

At this point, acceptance of a UDI system among capital equipment manufacturers is expected to be low, given the many unanswered questions about UDI. The rate of acceptance is likely to be low until the many issues pertaining to UDI are resolved and a clear link can be demonstrated between implementation of a UDI system and enhanced patient safety.

Question 17. *From your perspective, what are the obstacles to implementing or using a UDI system in your location?*

NEMA response:

Obstacles to implementing or using a UDI system have been set forth above, and include: the existence of an unclear link between UDI and patient safety, significant costs and time to

develop and implement a UDI system and lack of a worldwide system of harmonized requirements.

### Conclusion

- NEMA strongly recommends that FDA form an interdisciplinary Task Force with all key stakeholders to explore the need to develop a UDI in place of existing regulatory processes and tools. This Task Force should first determine whether any existing problems can be remedied by use of policies and procedures currently in place, instead of implementation of a new identification system.
- GHTF should be a part of this process to assure global acceptance and prevent the use of duplicate and overlapping systems.

NEMA stands ready to work with all key stakeholders and provide its assistance for the enhancement of patient safety.

If you have any questions, or need further information, please do not hesitate to contact Richard Eaton of my staff at (703) 841-3248.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Whitman". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Andrew Whitman  
Vice President Medical Products