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**STATEMENT ON BEHALF OF THE
NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION (NEMA)
AT THE U.S. FOOD AND DRUG ADMINSTRATION'S (FDA)
ANNUAL MEETING ON THE IMPLEMENTATION OF THE MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002 (MDUFMA)**

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**Presented by
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Good morning. I appreciate the opportunity to be here today. I am pleased to provide comments on behalf of the Diagnostic Imaging and Therapy Systems Division of the National Electrical Manufacturers Association (NEMA) on the Third Party Inspections program that was created under Section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). NEMA, the National Electrical Manufacturers Association, is the nation's largest trade association representing the electroindustry. NEMA's Diagnostic Imaging and Therapy Systems Division represents more than ninety-five percent of manufacturers of the nation's manufacturers of X-ray imaging, computed tomography, diagnostic ultrasound, radiation therapy, magnetic resonance imaging, and nuclear imaging equipment. In addition, the division represents manufacturers of extracorporeal lithotripters and picture archiving and communications systems.

Over a year ago, on October 26, 2002, the President Bush signed the Medical Device User Fee and Modernization Act into law. As with many bills passed by Congress, this bill contained many compromises. There were provisions in this bill that were unattractive to many in industry, and I suspect there were similar reservations here at the Agency about some of the bill's provisions, as well. Nonetheless, when all of the provisions of the bill were taken into account, we at NEMA believed that on balance MDUFMA provided constructive new programs for ensuring the ongoing safety of medical devices, providing the Agency with additional resources, and encouraging continued innovation in the medical device industry. Overall, MDUFMA was a carefully balanced piece of legislation

For that reason NEMA is concerned that the failure to implement successfully the programs that were created in MDUFMA could significantly erode the basis for the support the legislation received in industry and possibly in the Congress. In particular, we are here today to discuss the implementation of the new Third Party Inspections program with attention to the possible adverse impact of the FDA guidance issued on April 28, 2003 on the Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002.

We are concerned that the Agency's implementation the Third Party Inspections program, may be flawed, and that significant changes or clarifications may be needed in the Guidance and operation of the program in order to attract companies to sign up to participate. The failure to elicit voluntary company participation could result in a significant waste of Agency resources, and the failure to achieve the programs goals that were outlined in the legislative history. Because of these concerns, we would encourage the Agency to take another look at the Guidance, and the issues we outline below, and conduct a prompt and thorough revision of the document.

Congress authorized the creation of the Third Party Inspections program in order that such a program would succeed, and successfully implemented. So, in addition to raising some of the important issues raised in the April 28th FDA guidance, we would also like to offer some flexible ways of addressing these issues that would enable the Agency to establish, and maintain a program that is consistent with Congressional intent. We believe that the proposed changes, if incorporated into the guidance, would allow FDA to more efficiently utilize an existing Third Party system, and fulfill the legislative intent of MDUFMA Section 201. Moreover, a successful Third Party program will produce Quality System inspection results by third parties for FDA every two years as opposed to the present FDA average inspection frequency of every six years.

Before I get into the substance of our comments, I would like to note that we are aware that Congress has taken some steps to pass a MDUFMA technicals bill this year. The Senate passed S. 1881, Medical Devices Technical Corrections Act, on November 25th, and the House has circulated an internal discussion draft of a bill that they are reviewing. We are hopeful, though time is short, that a bill can gain approval of both Houses when they reconvene next week, and that the corrections contained in this bill will address some of the concerns that we raise here.

I am also aware of several meetings and phone calls between industry and Agency personnel on some of the issues that will be raised in my comments. We are pleased with and appreciative of the Agency for these discussions. We have been encouraged by the direction they appear to be taking. However, as the Agency has not yet issued any formal clarifications on these issues, my comments will include some of the issues that have already been raised and are awaiting a decision. The purpose of raising these concerns now is simply to ensure they are part of the Agency's public record.

The issues we would like to raise, and possible ways of addressing these issues in the April 28th FDA guidance include:

I. **The scheduling and timing requirements in the FDA Guidance must be flexible and clarified or the guidance will nullify the key purpose of the Third Party Inspections Program to permit fewer overall inspections for a manufacturer by allowing the combination of inspectional requirements where they overlap**
[Page 7: The Least Burdensome Approach

**Page 20: (K): What inspections records are to be submitted to FDA?
Page 10, (B) (last sentence): "The intent of these provisions is to focus the use of Third-Party inspections on manufacturers that operate in a global market and are likely to be subject to multiple inspection requirements"]**

We would encourage the FDA to remain flexible in the content and frequency of records to be submitted to FDA. FDA's Quality System regulation is about 90 percent equivalent to ISO 13485 required by the EU and Canada as well as other countries. Third Parties perform audits for ISO 13485 with different frequencies; some perform one audit a year, some two audits a year, but in a two-year period the cycle begins again. We believe that the FDA should allow reports to be submitted on any frequency as long as a complete inspection is accomplished over a two-year period. Third Parties should be allowed to perform one inspection for both FDA quality systems and ISO 13485 requirements and issue reports that will satisfy FDA requirements.

**II. Pre-qualification recognition requirement by foreign governments
[Page 10, B, 5th Bullet: "The establishment submits a statement that the laws of one of the countries in which the device is to be marketed recognizes an inspection of the establishment by FDA."]**

Although this statement tracks the legislation, we understand that no country explicitly recognizes an FDA inspection, nor does FDA recognize an inspection performed by a foreign country. However, we believe that marketing to a country that is covered under the U.S.-EU Mutual Recognition Agreement should be enough to qualify under this provision. If the Agency, cannot agree with that position, we expect the FDA to propose an interpretation that would allow the program to move forward. The inability of the Agency to exercise creativity and flexibility on this issue would effectively kill the program.

**III. Non-MDUFMA-based conflict of interest ban on Third-Party inspectors who had performed contract work with the manufacturer within the last 12 months.
[Page 15; last paragraph, and Page 16 f: Although it is not feasible to identify all of the circumstances that would raise concerns about conflicts of interest in this document, the most common conditions that indicate an actual or a potential conflict of interest are: (f) any personnel of the AP involved in the inspection process participates in an inspection of a firm in which they had performed contract work (e.g., conformity assessment body audit, laboratory testing, or AP inspection) within the last 12 months.]**

Since all work performed by third parties is "contracted work", sometimes performed at a manufacturers facility every 6 months, we believe this part of the guidance is flawed. There is no explicit basis for this guidance in MDUFMA. The thrust of Section 201 is to save resources, to be able to bundle or couple inspections (for FDA, Canada, the EU, etc.,) into one inspection. This interpretation of the conflict of interest provisions in MDUFMA could make it difficult, if not impossible, for a manufacturer to identify a Third

Party with whom they might reasonably and efficiently work. The Third Party Inspections program is a voluntary program. If companies do not sign up to participate in the program, it will fail. This provision undermines the incentives for companies to participate in the program, and therefore we suggest the requirement be dropped.

IV. **Expanded FDA Compliance Authority to Permit Third Parties to Determine Compliance with non-FDA Compliance Requirement**

[Page 6, 5th Bullet: "For purposes of this guidance, an Accredited Person (AP) is a Third Party recognized by FDA to:

- **Assess the quality system of eligible manufacturers of Class II and III devices under 21 CFR Part 820;**
- **Determine compliance with other device requirements in the act and regulations;**

AND

Page 9, III, A, Second Line: "The primary purpose of an inspection by an AP is to evaluate the manufacturer's compliance with the Quality System regulation (21 CFR Part 820) and other FDA regulations."]

During the development of the legislation, Congress intended that Third Party inspections would be focused on GMP/Quality Systems inspections, the type that is required every two years pursuant to 510 (h) of the Act. Stating Third Party inspections "determine compliance with other device requirements" is too open ended. It was never the intent to transform Third Party auditors into FDA investigators. Only those items normally addressed under a 510(h) GMP/QS inspection should be included in a Third Party inspection.

V. **Unfeasible Compliance Data Submission Requirement**

[Page 11, 3rd Bullet and 1st Open Bullet: "A request for additional information concerning: "compliance data showing whether the establishment has consistently complied with QS/GMP requirements and promptly corrected any problems; this data must include complete reports of inspections or other quality control audits made during the preceding two years, as well as other compliance data FDA deems necessary. The establishment is responsible for providing this information to FDA; and / or..."]

This guidance states, "this data must include complete reports...." which we recognize is a direct quote from MDUFMA. However, as the Agency is aware, manufacturers rarely are provided with "complete reports" following an FDA audit, or even following most other national or international regulatory inspections. Generally, companies are provided with findings, or summaries or some other abbreviated reports. The guidance should make a common sense clarification that a "complete report" should require no more than what the

company was provided at the completion of the inspection at issue. In the event the report left with the manufacturer by the AP requires follow-up action, a complete report would then also include a record of the follow-up action.

In addition, we are concerned that the Guidance omits a critical qualification to the supply of data from the manufacturer that is explicitly included in MDUFMA, namely, (underlined words indicate words in MDUFMA that are omitted in the Guidance: "this data must include complete reports of inspections regarding Good Manufacturing Practices or other quality control audits made during the preceding two years that were conducted by persons other than the owner or operator of the establishment, as well as other compliance data FDA deems necessary."

Since this is a Guidance for FDA staff, among others, we also believe it is important that the purpose for requesting this data be included in the Guidance, especially since it is explicitly included in the MDUFMA language. Specifically, MDUFMA reads [see FFDCA Section 704 (g)(6)(B)(iii)], "Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problem identified in such inspections."

VI. Non-MDUFMA-mandated and ambiguous expansion of FDA authority to require information not pertinent to the relationship between the manufacturer and the Third Party

[Page 11, 3rd Bullet and 2nd Open Bullet: "The relationship between the establishment and the AP, including information on previous inspections of the manufacturer or any related manufacturers. FDA may request this information from either the establishment or the AP."]

In the section of the Guidance quoted above, we are concerned that the phrase "...or any related manufacturers " lacks clarity and therefore risks misinterpretation. MDUFMA is clearer stating "...or other establishments owned or operated by the owner or operator of the establishment". We believe the FDA guidance should use the MDUFMA language.

VII. Relationship of the MDUFMA Third Party Inspections Program to the FDA/EU MRA Inspections Program

[Page 5, I: "The Inspection by Accredited Persons Program will be conducted independent of Third Party inspections performed under the U.S. / EC Mutual Recognition Agreement (MRA), currently in progress."]

We believe that this should be clarified so it is understood that the FDA accreditation of third parties under the Accredited Persons Program is separate, and independent from FDA/EU accreditation of third parties under the MRA, but that third parties can be accredited under both programs, and can conduct inspections of manufacturers under

both programs performing independent or combination inspections. This we believe would be consistent with the intent of Congress, and the legislative history.

VIII. Knowledge required of Third Parties beyond that necessary to conduct GMP/QS inspections

[Page 12; 1. Personnel: FDA expects AP's to have sufficient personnel, with the necessary education, training, skills and experience to review records and perform inspections...]

This section of the guidance suggests that the Agency may envision the Third Parties overreaching the authority established by Congress. Under this section of the guidance, the FDA requires knowledge on the part of the Third Parties of 21 CFR Parts 11, 801, 807, 809, 814 and 821, which is beyond what is necessary to perform adequate GMP/QS inspections. We believe that it is important for the Third Parties to operate within the parameters envisioned by Congress.

We are especially concerned that in developing the April 28th Guidance, the Agency may have missed two critical factors that Congress intended as it moved to establish the Third Party Inspections program. First, it appears that the Agency may not appreciate that the Third Party Inspections program is a voluntary program. Companies are not compelled to participate in this program. As it stands now we honestly wonder how many companies would want to participate in the program that appears envisioned in the April 28th Guidance. Currently most domestic device manufacturers are inspected once every five or six years. So, for this program to work it must be user friendly enough to make it attractive for companies to have their operations inspected to FDA standards throughout a two-year cycle. This, we believe, will require flexibility on the Agency's part that is not evident in the Guidance. While we do not expect the Agency to compromise on its inspectional standards themselves, we would expect that the Agency would demonstrate flexibility on the scheduling and format of inspections, on the combination of inspections to FDA standards with other international inspections, and on the bureaucratic and the operational details of the program that could make it unnecessarily complicated, time-consuming, or expensive for companies to participate.

Second, it appears that the Agency may also not appreciate that one of the overriding interests of Congress in creating the Third Party Inspections Program was to facilitate the ability of U.S. device manufacturers to ease their overall regulatory burden by combining various international inspections with the Third Party Inspection to FDA standards under the Third Party Inspections program. There is little or no reflection of this major Congressional interest in the Guidance document. If the Agency does decide to reconsider and perhaps re-craft portions of this Guidance, we would offer the following selections from the MDUFMA legislative history for your consideration:

> "Despite this progress, however, the increase in the total number of inspections is causing the FDA and companies alike to look for new ways to streamline systems

and avoid duplicative inspections. It has become clear that if each country insists on its own individual medical device inspections then harmonization, while important, is not enough." (H. Rpt. 107-728, 33)

"With the establishment of a voluntary Third Party inspection program in the United States the Committee anticipates that at some time in the future, more and more countries would move toward mutual recognition. The Committee believes that at some point a medical device company that markets its products in the European Union, Canada, the United States, China, Brazil, Mexico and other countries should be able to contract with a single independent Third Party which has sought and received accreditation from each of these countries to conduct inspections to each of their national standards. Under these circumstances, the Third Party could perform a single inspection that would cover each nation's medical device quality systems requirements." (H. Rpt. 107-728, p. 34-35)

"In addition, the Third Party inspections program is intended to help qualified firms schedule inspections in a manner that will help them meet the multiple inspection requirements of a global market." (H. Rpt. 107-728, p. 36)

We recognize that this Third Party Inspections program is a new program, and that it may require new ways of thinking in order for it to succeed – not just in the Agency, but in industry, as well. And while we have raised a number of issues and concerns about some of the proposals and processes under consideration, we are encouraged by the constructive engagement that we have seen at the Agency. Moving in new directions can often be difficult, and we want to commend that Agency for its leadership and effort to reach out and to listen to other perspectives as they build what could be a very important program for industry, the Agency, and ultimately, the public health.

Thank you very much for the opportunity to be here and make this presentation today.