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April 4, 2003

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Dockets Management Branch (HFA-305)
Center for Devices and Radiological Health
United States Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0534
Comments on selected provisions in the Third Party Inspections Program of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)

To Whom It May Concern:

On behalf of the Diagnostic Imaging and Therapy Systems Division of the National Electrical Manufacturers Association, I am pleased to submit comments relative to the Third Party Inspections Provision 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 picture archiving and communications systems.

NEMA's comments with regard to a number of provisions in MDUFMA Section 201 are as follows:

1. **MDUFMA Sec. 201** [New provision added to FFDCA (Federal Food, Drug and Cosmetics Act) - **Sec. 704 (g)(6)(A)(iii)(II)**] - This new provision within the FFDCA declares that one of the conditions for a device establishment that wishes to be deemed eligible for inspections by accredited persons under this new program is that "(T)he owner or operator of the establishment submits to the Secretary a statement that the law of a country in which such a device is

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marketed, or is intended to be marketed, recognizes an inspection of the establishment by the Secretary..."

NEMA suggests that this condition could be met when either one of two of the following circumstances exist and the company so notifies the Secretary that: (1) the country recognizes the FDA Export Certificate, "Certificate to Foreign Government", and the last FDA inspection of record resulted in either "no action indicated" or "voluntary action indicated", or (2) the country has entered into an MRA with the U.S. for quality systems inspections of manufacturers of medical devices.

2. **MDUFMA Sec. 201** [New provisions added to FFDCA - **Sec. 704 (g)(6)(B)(i)** and **(B)(ii)(I)**] - Under these new provisions of the FFDCA governing the Secretary's response to a request from an establishment for a Third Party to conduct an inspection, the Secretary has three options for a response: first, he can provide clearance for participation in the program; second, he can fail to respond to the notice within 30 days in which case the establishment is deemed to have clearance; or third, he can make a request to the company for certain additional compliance data.

   NEMA suggests that the regulations governing MDUFMA should clarify the criteria by which the Secretary shall make his decision to provide clearance for inspections subsequent to the first inspection by an FDA accredited Third Party. Specifically, NEMA believes that those criteria should be: (1) whether or not the establishment had previously been accepted in the FDA Third Party Inspections program, and (2) whether or not the previous inspection has a positive outcome. If these criteria are met and unless the Secretary has other specific information that would mitigate against further participation in the program, then NEMA suggests that a positive (1) and (2) be the basis for approval of subsequent approvals.

   In addition, NEMA believes that the request for data under (B)(ii)(I) should be deemed fulfilled if the previous inspection conducted the Secretary or an accredited person resulted in 'no action indicated' or 'voluntary action indicated'.

3. **MDUFMA Sec. 201** [New provision added to FFDCA - **Sec. 704 (g)(6)(A)(iv)(I)**] – This new provision of the FFDCA is one of the four conditions that must be met in order for a device establishment to be eligible

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for inspections by persons accredited under the program. This provision requires that "...persons accredited under paragraph (2) did not conduct the two immediately preceding inspections of the establishment, except that the establishment may petition the Secretary for a waiver of such condition." NEMA's believes, assuming an establishment otherwise complies with the other criterion for participation in the Third Party Inspections program, that this provision permits the establishment to participate in this new FDA Third Party Inspections program for up to four years. After four years, or two inspections by FDA accredited Third Parties, the establishment would have to either have the establishment inspected by the FDA before they could continue in the Third Party Inspections program, or they could seek a waiver. If the company meets the criteria for the waiver, and if the waiver is granted, the company could have one additional inspection by an accredited FDA Third Party. After which point, no further waivers are permitted, and the establishment must be inspected by FDA personnel.

NEMA is concerned that medical device companies may be reluctant to participate in this new program if they believe it could effectively be terminated after as few as four years or two inspections by an accredited FDA Third Party. For this reason NEMA urges that establishments that are participating in the Third Party Inspections program and who have exhausted their opportunities to use accredited Third Parties for their inspections should receive the highest priority of FDA inspectional resources to ensure that the mandatory FDA inspection required to continue within the program is conducted on schedule so that further participation in the FDA Third Party Inspections program by the establishment can continue without interruption. As a result, NEMA believes that the Secretary should direct the FDA to coordinate with the establishment such that the third in a sequence of three inspections (or fourth if a waiver is solicited and granted) is performed by the Secretary following the first of two inspections conducted by accredited persons.

In addition, NEMA urges the Agency as it solicits participation in this program to highlight the benefits to companies such as reducing the company's global regulatory burden by combining an inspection by an FDA accredited Third Party who also has the capability to provide simultaneous inspectional services that comply with other national and international standards (e.g. ISO).

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4. **MDUFMA Sec. 201** [New provision added to FFDCA - **Sec. 704 (g)(6)(B)(iii)**] – This new provision of the FFDCA relates to response of the Secretary to a notice that each company must submit to in order to be eligible to participate in the inspections program. As stated in #2 above, under new Sec. 704 (g)(6)(B)(i) the Secretary has three options for a response: first, he can provide clearance for participation in the program; second, he can fail to respond to the notice within 30 days in which case the establishment is deemed to have clearance; or last, he can make a request to the company for certain additional compliance data.

   Regarding this additional compliance data request, MDUFMA states, "The compliance data to be submitted by a device establishment under clause (ii) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h), and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502 and other applicable provisions of this Act. Such data shall include complete reports of inspections regarding good manufacturing practice or other quality control audits that, during the preceding two-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. 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."

   NEMA suggests that the sentence in the law above, "The compliance data to be submitted by a device establishment under clause (ii) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h), and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502 and other applicable provisions of this Act" make it clear and establishes a context such that the data under discussion bears on Good Manufacturing Practices data alone. NEMA believes that the only data that complies with this provision would be routine FDA Q.S. audits or Q.S. audits required before a PMA is approved.

   However, NEMA would note that in the event that FDA were to recognize ISO 13485 as equivalent of GMS/QSR then these data also would be eligible data under this provision.

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NEMA also notes that this provision says, "(S)uch data shall include complete reports...." As the FDA is aware, manufacturers rarely are provided with "complete reports" following an FDA or most other national or international regulatory inspections. Generally, companies are provided with findings, or summaries or some other abbreviated reports. NEMA believes that a "complete report" should require no more than what the company was provided at the completion of the inspection at issue.

However, NEMA believes that for the sake of completeness where audit systems require interaction with the manufacturer to assure that all findings are addressed a complete report would only be a report in which the manufacturer has been given time to address a finding(s) or where they have been denied approval by the auditor on the basis of failing satisfactorily to address findings.

5. **MDUFMA Sec. 201** [New provision added to FFDCA - **Sec. 704 (g)(7)(E)]** - This new provision of the FFDCA requires an accredited person who "discovers" a condition that "could cause or contribute to an unreasonable risk to the public health" to "immediately" notify the Secretary of the identification of the device establishment subject of inspection and such condition.

   NEMA urges the FDA to recognize that the "discovery" of a condition that "could cause or contribute to an unreasonable risk to the public health" could be a part of a process, and not a single point in time. An FDA accredited Third Party inspector could discover a condition that raises a concern, but not know at that point how serious the problem is. Conceivably it could take hours, or perhaps days to determine whether or not the concern was warranted, and, if so, how serious the problem is. For this reason NEMA suggests an accredited person should have a reasonable amount of time to verify that a potential problem is an actual problem that could cause or contribute to an unreasonable risk to the public health.

   In addition, NEMA suggests that it is reasonable for the FDA to understand the word immediately to be any time from one to no more than five working days from discovery and evaluation of the impact of the problem

Thank you for your consideration. If you have any questions, please do not hesitate to contact me.

Sincerely,

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