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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RE: FDA Docket No. 98N-0331 (CDRH Draft Guidance
for Staff, Industry, and Third Parties Implementation
of Third Party Programs Under the FDA
Modernization Act of 1997)

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 Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997 that was made available by Federal Register notice on July 18, 2000.

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.

98N-0331

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NEMA has been a long and strong supporter of the FDA Third Party Review Program, and many of our member companies have been beneficiaries of the efficiencies created by this system. NEMA member companies have participated in the Third Party Review Program as a significantly greater percentage than our segment of the industry represents in the medical device industry as a whole. We have participated in the program not only for its success in completing pre-market notifications in a timely manner as compared to the traditional FDA process, but also because we believe that this kind of system is a critical component in the eventual creation of a global regulatory regime that will cut through the proliferation of numerous, different national regulatory systems that are hampering the ability of American medical device companies to introduce the life saving and life enhancing benefits of their technology to patients outside the United States. As a result, we are gratified to see that in keeping with the FDA Modernization Act of 1997 (FDAMA) the Agency plans to move forward with expansion of the program to permit the inclusion of Class II products that do not currently have guidance documents. However, we are concerned that key elements of the Guidance Document could undermine the success of this effort by reducing the number of medical device manufacturers who might otherwise be able to participate in the program, and discourage from participating those who might be eligible.

NEMA and NEMA Member Company Support of the FDA Third Party Review Program – NEMA's interest in and support for the use of outside medical technology experts in third parties operating under FDA supervision and performing FDA functions dates back to a NEMA White Paper entitled, "Re-Inventing the Regulation of Medical Devices: A Challenge for the Twenty-First Century" dated January 25, 1995. Subsequently, NEMA worked hard to educate both the Congress and the FDA regarding the benefits of the Third Party Program, and was pleased that Congress chose to include a framework for a meaningful Third Party Review Program in FDAMA.

NEMA shares the Agency's disappointment in the underutilization of the Third Party Review Program, but believes that expansion of the program coupled with an education effort on the part of the industry trade associations and the Agency will remedy this problem. NEMA would also like to point out that following an education effort by the trade association participation by the diagnostic imaging industry increased by 200 % in FY 1999 over FY 1998, and that more than half of all "third party" 510(k)s cleared by the FDA in FY 1999 were for diagnostic imaging devices.

In order to increase industry participation the Third Party Review Program, NEMA has:

1. Raised this issue at each meeting of its Board of Directors in 1999 and 2000.
2. Sent a letter on May 22, 1999 to each member company with pertinent facts regarding the success of the FDA Third Party Review Program in conducting reviews in record time and encouraging the use of Third Parties.
3. Sent a letter on June 17, 1999 to each of the participating third parties describing the NEMA effort to increase participation by its member companies and urging them to be innovative and supportive in order to obtain support from industry.
4. Invited the third parties approved to review diagnostic imaging devices to attend the 1999 NEMA Diagnostic Imaging Annual Meeting as exhibitors to foster interchange between the industry and third parties.
5. Dedicated a portion of the 1999 Annual Meeting to further educating the diagnostic imaging industry on the FDA Third Party Program.
6. Spearheaded a multi-industry effort in 2000 to develop materials that can be used to persuade medical device companies of the benefits of participation in the FDA Third Party Program. This effort was timed to encourage greater participation in the Program following its expansion to include products that do not have guidance documents.

NEMA has a long and consistent history of supporting third party programs at the FDA and has invested considerable time and energy in making the program a success. Moreover, with the exception of digital X-ray equipment, and radiation therapy devices, all of the other diagnostic imaging medical technologies represented by NEMA were included in the original Third Party Review Program because they already had established product specific guidance documents available for use by Third Parties. As a result, most of the medical imaging products manufactured by NEMA member companies are already eligible for the Third Party Review Program, as it stands. Consequently, our comments on this expansion of the Third Party Review Program are aimed at creating what we believe could be a vibrant, healthy Third Party Review Program for the rest of the medical device industry as a whole, and not solely for our membership. We are convinced of the value of this program to the public and the medical device industry, and we want to see it succeed. It is for this reason that we raise the following concerns regarding the draft Guidance Document.

The Draft Guidance Will Limit the Actual Expansion in the Program, and Permit Only a Modest Increase in Overall Participation by Industry in the Third Party Program – While it is clear that the Agency believes that the Draft Guidance will permit a dramatic increase in the Third Party Review Program, we believe that several key elements of the document will de facto significantly limit the expansion of the program and greater industry participation. A number of factors make this so:

- 1. The Unnecessarily Restrictive Criterion for Third Parties to Conduct Reviews of Eligible Medical Devices Under the Draft Guidance** – The Draft Guidance establishes a two-fold test before an FDA Accredited Third Party Organization can participate in the expansion in the program envisioned by this Draft Guidance: first, the Accredited Third Party must have previously completed three (3) successful 510(k) reviews under the existing third party program; and second, one of the three previous 510(k) reviews under the program has to have been in the same or a similar medical specialty area as the device the Third Party now intends to review.

As the FDA moves into an area of Third Party-based regulation for which it has limited experience, we recognize the need for the Agency to be comfortable with the new system, and have assurance that it will work. We also understand and recognize the need for the public to have confidence that this new system will provide effective safeguards for the public health. As a result, we see no problem with the Agency requiring some level of experience with the existing Third Party Review process before allowing an Accredited Third Party to participate in the expanded program. We also agree that the previous successful completion of three 510(k) reviews under the third party program is a reasonable threshold of experience.

However, we do take exception with the additional requirement that one of those three previous successful 510(k)s under the third party program include at least one 510(k) review that was in the same or a similar medical specialty area as the device the Accredited Third Party intends to review. We believe that this requirement is unnecessary, and will provide a significant practical barrier to the expansion of the Third Party Review Program – the very purpose of this Draft Guidance.

We believe this requirement is unnecessary because in order to become an "Accredited Person" under the Third Party Review Program, the third party will already have had to have established its expertise not only to comply with the program requirements, but specific expertise in specific medical specialty areas. In other words, not all Third Parties accredited under the Third Party Program are accredited to review all types of medical devices. Third Parties are accredited because they have established to the Agency's satisfaction that they are competent to review medical devices in specific medical specialty areas. Therefore, if a third party is intending to review a product in a medical specialty area for which they have been accredited by the Agency, and if they have demonstrated successful experience under the Third Party Review Program by having previously successfully completed three (3) reviews under the Program that it seems unnecessary to us to add the additional requirement that at least one of the previous successful 510(k)s have been in the same or a similar medical specialty area as the Third Party now intends to review.

In addition to being unnecessary, we are concerned that this element of the Draft Guidance could prevent the Agency from achieving its intended purpose to "encourage the more widespread use of the third party program..." We understand that at present there are only twelve (12) accredited Third Parties under the FDA Third Party Review Program. We also understand that of these twelve only six (6) currently have met the threshold of having previously completed three successful 510(k) reviews under the third party program.

Although the Draft Guidance offers no estimate on the theoretical number of 510(k)s that would be eligible for review under the expansion of the program, even under the existing program the number of 510(k)s eligible for review were nearly 2,000. This expansion of the program would theoretically increase to some point well beyond this. In which case, there would only be a maximum of six accredited third party organizations qualified to handle this workload.

We also believe it is unlikely that the number of accredited third parties that have meet the threshold of having previously completed three successful 510(k) reviews under the third party program to increase significantly. The reason for this is straightforward: entry into the expanded third party program, is essentially through the existing program, and if a third party has been unable to achieve the necessary three successful reviews of the program in the first eighteen (18) months of its operation, it seems unlikely that many will do so under the requirements and restrictions of the expanded program.

Moreover, section 523(b)(4) of FDAMA says, "...The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least two or more accredited persons from which the regulated person may select one for a specific regulatory function." This means that for the new expanded system to work to its fullest, two of the six qualified accredited third parties will have had to have previously completed at least one successful 510(k) review under the third party program for each medical specialty area. If not, no medical device in that medical specialty area can be reviewed under this program – even if they otherwise qualify.

As a result, we are concerned that while the criterion and procedures in this Draft Guidance may theoretically expand the number of products eligible to participate in the Third Party Review Program, as a practical matter the expansion of the program is likely to be small – at least at first, and it is likely to suffer from a bottleneck in the form of a limited number of accredited Third Party organizations that are qualified to participate in the expanded program under this Guidance and FDAMA.

NEMA Recommendation: On page 6 of the Draft Guidance the second sentence of the first bullet explaining the qualification for an Accredited Person to conduct a review under this Guidance should be stricken as follows: ~~"This should include at least one 510(k) review that was in the same or similar medical specialty area as the device the Accredited Person now intends to review."~~

- 2. Uncertain Time Considerations** – We believe as currently arranged the second and third requirements for an accredited third party to participate in the expanded program will create significant approval time uncertainties for medical device companies. These approval time uncertainties will dampen interest in the program.

The second and third requirements for an accredited third party to participate in the expanded program involve a mandated "contact" with the appropriate CDRH Office of Device Evaluation (ODE) Branch Chief (or designee) to confirm that the third party is eligible to conduct the review in question under this Guidance, and "to identify pertinent issues and review criteria related to this type of device." The third requirement is for the third party to create a summary of the meeting documenting the discussion and submitting the summary to ODE.

The principle concern here regards the ambiguity of the details surrounding the "contact" with ODE, and the subsequent written summary of the discussion. It is certainly reasonable for the FDA to require contact between the Agency and a third party hoping to conduct a 510(k) review of a class II device for which there is no product specific guidance. However, statements in the Draft Guidance such as "(t)he pre-submission discussions and the creation of a record of those discussions will help FDA ensure the consistency and timeliness that can be provided by device-specific guidances," and "the FDA may utilize such documentation to ensure consistency in its own interactions with different Accredited Persons and regular submitters" raise substantial concerns that the purpose of this "contact", and the subsequent written summary of discussions is to require the creation of a written de facto product specific guidance document for each class II product permitted under the program expansion before the product can be reviewed by the third party.

If it is not the purpose or intention of the FDA to require the development of a de facto product specific guidance for each new class II product to be included in the expanded program before it can be reviewed (something the Agency has not done on its own), the Guidance should clarify this ambiguity and clearly state so. In addition, further guidance should be provided as to the type of information that should be included in the written summary. In addition, the Agency should make it clear in the Guidance that "review memos" and other internal, relevant documents that are used by FDA staff to train and prepare for the review of class II products that do not have product specific guidance will be made available to the third party during the "contact" phase before the review begins and should be incorporated in any discussion summary.

Unless these clarifications are made, there is a real risk that industry will view reviews under this expanded program as a risky, uncertain two-fold process: first, the writing of a de facto product specific guidance, and then, the review of the product. The uncertainty surrounding the writing of this de facto guidance – especially in terms of how long it could take – could create a perverse disincentive whereby everyone wants to be the second, third or fourth company to put a specific type of device through the system, but no one wants to bear the cost or uncertainty of being first.

NEMA Recommendations:

3. On page 6, the last paragraph, strike the second sentence as follows:
“~~The pre-submission discussions and the creation of a record of those discussions will help FDA ensure the consistency and timeliness that can be provided by device-specific guidances.~~”
4. On page 6, the last paragraph, strike the third sentence as follows: “~~In addition, the FDA may utilize such documentation to ensure consistency in its own interactions with different Accredited Persons and regular submitters.~~”
5. On page 6, the last paragraph, after the first sentence insert the following sentences as follows: “Before and as preparation for the discussion the FDA will provide the Accredited Person with such internal review memoranda, and any other relevant internal documents used to train or prepare FDA staff for the review of class II products that do not have product specific guidance. These documents can also be incorporated in any discussion summary. The FDA will acknowledge the receipt of the summary from the Accredited Person, and indicate any problems they have with the document in a timely manner. The purpose of the discussion and subsequent summary is not the development of a de facto product specific guidance, but the identification of key areas of concern relating to the review of this type of device based in so far as possible on the internal review memoranda and other documents supplied by the FDA.”
6. **Uncertain Costs** – Related to the uncertainty regarding the timeliness of the approval of products under the program expansion if de facto product specific guidance are required for participation in the program, there are cost uncertainties, as well. If it is unclear how long it will take for a product to get cleared under the expanded program, it will be more difficult for companies to calculate the benefit of the program to their company and to make a decision to participate in the program. Companies are in the business of mitigating risk and controlling uncertainty wherever possible. Consequently, the greater the uncertainty in this program – both in terms of timeliness of approvals and costs – the less likely companies will be to participate.

NEMA Recommendation: See recommendations for number 1 and 2 above.

The Draft Guidance Time Frame for Evaluating the Success of the Program is Too Short – As we stated earlier in our comments, we are concerned that the program expansion envisioned in this Draft Guidance is likely to grow quite slowly, and consequently, we believe that the one year mentioned in the Draft Guidance is too short a time in which to provide a fair evaluation of the program. Unless the Agency adopts some of the recommendations outlined in these comments to make it easier for accredited third parties to qualify to perform 510(k) reviews under this program expansion, and to make it clear that the process envisioned is likely to result in timely, cost-effective clearances – similar to those under the existing Third Party Program, this program will be slow starting and difficult to expand. We believe that the review process envisioned under this Draft Guidance is significantly different from the existing Third Party Review Program and that consequently a two year time period for reviewing the success of the program is more reasonable.

NEMA Recommendation: On page 8 of the Draft Guidance, the last full paragraph on that page strike the number “12” and insert the number “24” so that the complete sentence would read as follows: “The Agency intends to review the pilot program ~~12~~ 24 months after it begins to see if the number of third party 510(k)s has increased significantly...”

In addition, we were surprised to find the following statement in the Draft Guidance: “Any 510(k) for a Class II device for which clinical data are needed to make a determination of substantial equivalence will continue to be subject to primary review by FDA and will not be processed by the FDA under the special procedures for this program” (underlining added).

Section 523(a)(3)(A)(iii) of FDAMA says, in general, an accredited person may not be used to perform a review of – “a class II device which requires clinical data in the report submitted under section 510(k) for the device, except that the number of class II devices to which the Secretary applies this clause for a year, less the number of such reports to which clauses (i) and (ii) apply, may not exceed 6 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.”

We were surprised at the unqualified use of the word "any" with regard to participation by class II devices requiring clinical data in this program expansion for several reasons: first, we were surprised that the Guidance Document failed to recognize or acknowledge this 6 percent threshold; and second, being unaware of any public data on the percentage of class II devices requiring clinical data, we were surprised that the Draft Guidance would categorically prohibit any class II devices requiring clinical data from inclusion from the program without offering a factual basis for the assurance that the number of such 510(k)s was under the 6 percent threshold.

NEMA Recommendation: On page 7 the last paragraph strike the first sentence, and insert a substitute set of sentences as follows: "~~Any 510(k) for a Class II device for which clinical data are needed to make a determination of substantial equivalence will continue to be subject to primary review by the FDA and will not be processed by the FDA under the special procedures of this program.~~ If a Manufacturer or Accredited Person seeks review under the special procedures of this program for a 510(k) for a Class II device for which clinical data are required, the reviewer shall determine whether the 6 percent limit set forth in Section 523 has been met. If the limit has not been met, the reviewer shall notify the Manufacturer or Accredited Person of such and that this review will continue to be subject to primary review by the FDA and will not be processed by the FDA under the special procedures for this program. If the limit has been met, the reviewer shall notify the Manufacturer or Accredited Person that this review can be conducted under the special procedures for this program."

Finally we would note that the results of the Third Party Review Program Expansion under this Draft Guidance may be insufficient to permit the Secretary to notify Congress that the clock has started on FDAMA's sunset provisions for the Third Party Review Program. FDAMA established two criteria to start the clock on the sunset provisions established in the law. Section 523(c) of FDAMA says, "The authority provided by this section terminates – (1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k), or (2) 4 years after the date on which the Secretary notifies Congress that the Secretary has made a determination described in paragraph (2)(B) of subsection (a) for at least 35 percent of the devices that are subject to review under paragraph (1) of such subsection." With the third anniversary of the signing of FDAMA into law rapidly approaching, there is little doubt that Congress viewed these 60 percent and 35 percent thresholds respectively as a basic measure of a good faith effort to establish the kind of Third Party Review Program that they envisioned in the provisions of FDAMA. Consequently we believe that the provisions of this Draft Guidance should be carefully crafted with both of these thresholds in mind – that is, a program crafted not only that expands the number of

products theoretically eligible for review under the program, but also a program that lowers unnecessary obstacles and makes it easy for companies to participate in an effective, well-managed Third Party Review Program.

NEMA is pleased to submit these comments relative to the Agency's Draft Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997 that was made available by Federal Register notice on July 18, 2000. NEMA looks forward to working with the agency to ensure that the Third Party Review Program is a success.

If you have any questions, or need further information, please do not hesitate to contact me at (703) 841-3241.

Sincerely,

A handwritten signature in black ink that reads "Robert G. Britain". The signature is written in a cursive style with a large, prominent initial "R".

Robert G. Britain
Vice President, Medical Products
National Electrical Manufacturers Association