National Electrical Manufacturers Association

The Association of Electrical Equipment and Medical Imaging Manufacturers
www.nema.org

October 22, 2013

Mr. Douglas Bell
Chair, Trade Policy Staff Committee
Office of the U.S. Trade Representative
Washington, DC 20230

Re: Docket USTR-2013-0027 - Non-Standards Measures

Dear Mr. Bell:

The National Electrical Manufacturers Association (NEMA) is pleased to respond to your August 19 *Federal Register* request for public comments to assist the Office of the U.S. Trade Representative and the Trade Policy Staff Committee in preparation of the annual National Trade Estimate Report on Foreign Trade Barriers (NTE). As requested, the following comments will address measures that are not standards-related.

NEMA is the association of electrical equipment and medical imaging manufacturers, founded in 1926 and headquartered in Arlington, Virginia. Its 400-plus member companies manufacture a diverse set of products including power transmission and distribution equipment, lighting systems, factory automation and control systems, medical diagnostic imaging and radiation therapy systems. The U.S. electroindustry accounts for more than 7,000 manufacturing facilities, nearly 400,000 workers, and over $100 billion in total U.S. shipments.

NEMA urges you to take the following into account as you compile the annual NTE report:

I. Worldwide tariff elimination for all NEMA products

The worldwide elimination of tariffs on electrical and medical imaging products is a fundamental NEMA goal. We urge the U.S. to pursue tariff elimination for electrical and medical imaging products in all negotiating forums, including bilateral, regional, plurilateral and multilateral. In this regard, NEMA is fully supportive of the negotiations underway in the Trans-Pacific Partnership, in the Trans-Atlantic Trade and Investment Partnership, and in the World Trade Organization (WTO). The negotiations on expansion the product coverage of the WTO Information Technology Agreement, in particular, hold the potential for broad-based tariff elimination. We would support additional sector-based plurilateral negotiations to negotiate reciprocal tariff reductions and elimination among willing countries.

NEMA also urges the U.S. to leverage the 2012 success of the Environmental Goods tariffs cap commitments within the Asia Pacific Economic Cooperation forum to help reinvigorate efforts to negotiate a broader and deeper Environmental Goods and Services Agreement to liberalize trade in energy efficient goods and energy and environmental services among as many countries as possible, consistent with President Obama's call in his June 2013 Climate Action Plan.

II. Free Trade Agreements

The U.S. government should negotiate and ratify free trade agreements (bilateral, regional and multilateral) that further open commerce for our member companies while upholding the following NEMA principles:

- Immediate reciprocal tariff elimination
- No governmental mutual recognition agreements (MRAs) where product is not U.S. federally regulated
- National treatment
- Adequate legal and administrative infrastructure in place for implementation, transparency and enforcement of agreements
- Protection of intellectual property rights
- Elimination of technical barriers to trade (TBTs)
- Compliance with all World Trade Organization (WTO) TBT Agreement requirements
- Safe conduct of product and persons
- Energy and environmental services liberalization
- Inclusive definition of "International Standards"
- Market-driven development of product standards and conformity assessment
- Conformity attestation methods that include the optional use of the IEC Conformity Assessment Systems – IECEE, IECEx and IECQ, where appropriate

III. Horizontal Cross-Cutting Issues

Remanufacturing

Under the auspices of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, work continues on the extension of export controls and trade prohibitions to cover shipments of used products for repair, refurbishment and reuse. The Convention, an agreement among 175 countries, currently governs trade in hazardous wastes but could be expanded dramatically under pending proposals supported by environmental non-governmental organizations.

The U.S. is participating in the negotiations but is not currently a signatory to the Basel Convention, so U.S. influence is limited. The EU proposals would apply hazardous waste controls and trade bans to exports of most used electrical and electronic equipment resulting in massive costs on manufacturers that rely on transboundary movement of equipment for legitimate service, repair, refurbishing, remanufacturing, and root-cause analysis activities.

While the proposals are intended to address the real issue of illegal shipments of "e-waste", they are overly expansive and would, in effect, seriously impair the broad environmental, economic and social benefits arising from repair, refurbishing, remanufacturing, and reuse of electrical and electronic equipment. The U.S. must continue to work with stakeholders and like-minded parties to the Basel Convention to impress upon all countries the need to preserve the right to move legitimate shipments of used electrical and electronic goods for assessment, repair and refurbishment. In the service industry parts are often considered assets and are shipped back and forth to support the necessary markets. Barriers to trade in parts and remanufactured items can become prohibitive for well-intentioned companies trying to support their operations in another market.

In addition, several countries, including Brazil, China and India, either have or are considering import bans for all remanufactured equipment despite the fact that if such remanufacturing were to be done in-country would be accepted. This clearly is not only a safety issue. Recognizing that some countries may want to prevent importation of products that are headed for their solid waste facilities rather than recycling or reuse, NEMA and the Medical Imaging and Technology Alliance (MITA), a division of NEMA, encourage USTR to continue to work with these countries and others to recognize the value of high-quality remanufactured equipment, especially in the medical imaging industry.

Customs Classification

The U.S., the European Union, China and other major producing countries have been at odds over the proper classification in the Harmonized System for energy-efficient lamps containing light-emitting diodes (LEDs). These issues extend from the LED lamps, which are primarily used to replace other types of lamps in existing lighting fixtures, to LED fixtures themselves as well as parts and components of LED lighting systems such as the power supplies known as "drivers".

Work is underway in the World Customs Organization to develop new classifications for LED lighting products for the 2017 edition of the Harmonized System. This work is expected to conclude in March 2014 with the adoption of a brand new classification for HS2017.

However, the U.S. and its trading partners must expedite implementation of the September 2013 determination by the WCO Harmonized System Committee to classify LED lamps under the

current HS2012 in a way that facilitates trade and allows for competitive and flexible international supply chains. The global lighting industry should not have to bear the current costs of complexity and uncertainty and wait any longer for national customs authorities to harmonize their classifications of efficient and durable LED lighting products that are in increasing demand by customers. USTR, the Department of Commerce, the International Trade Commission and the Department of Energy should encourage Customs and Border Protection to adopt and implement expeditiously and fully the determinations of the World Customs Organization with respect to LED lighting products in HS2012.

IV. Country-Specific Issues

China — Export Quotas, Tariffs and Bans

China continues to impose significant export restrictions on certain rare earth elements (REEs) mined and processed in China. Many of these REEs are used in electroindustry equipment, including energy efficient lighting products, certain electric motors, certain electrical-current-carrying wire and cable products, and certain medical imaging equipment. Dramatic cost increases in recent years, driven in part by the export restrictions, threaten viability of U.S.-based manufacturing of certain products. NEMA views this as part of China's approach to force more manufacturing on the ground in China since final products made within China containing REEs do not face export barriers.

Separately, it has been brought to our attention that China's import tariffs on lighting fixtures all remain above 10 percent ad valorem, with some as much as 17.5 percent. All U.S. tariffs for these products are below 10 percent, as are EU tariffs.

China – Government Procurement

NEMA strongly encourages the U.S. government to work with its international partners to ensure that China's 2011 commitment to de-link its government procurement and "indigenous innovation" policies is fulfilled and that no similar proposals are brought so far forward toward full implementation and potential violation of multiple commitments of China's leadership to resist trade and investment protectionism. In the context of the ongoing negotiations on China's accession to the WTO Government Procurement Agreement (GPA), NEMA is particularly concerned about future purchasing by state-owned enterprises, including the state-owned utilities, since they could also be included under any type of "indigenous innovation" acquisition policy. NEMA has reports from some sectors of the electroindustry citing discriminatory purchasing decisions by state-owned utilities requiring use of local content and intellectual property registered in China.

In the negotiations on China's accession to the WTO GPA, NEMA would like to see China's schedule of commitments include specific disposition for Chinese state-owned enterprises (SOE) as well as sub-national government entities to be included explicitly in the GPA for all procurement, or to be categorically excluded from the GPA for all procurement, so that NEMA members have certainty as to whether an SOE or sub-national government entity is covered by the GPA commitments.

China – Transparency

MITA appreciates that the China Food and Drug Administration (CFDA) is making progress to honor U.S. and WTO commitments to increase transparency, and requests that USTR continue to monitor and offer support to CFDA as steps are taken to centrally publish on-line all regulations and guidances, standardize 60-day comment periods on all proposed legislations, regulations, standards and guidances and provide prior notification to the WTO as required.

China – EMC Testing

China is moving to test equipment for electromagnetic compatibility (EMC) in-country starting January 1, 2014. In other countries, EMC test reports from third party testing labs are accepted, and the burden for global manufacturers is that additional testing is duplicative and costly as shipping large capital equipment such as CT, MRI and X-Ray for testing that has already been done is both unnecessary and burdensome.

Although MITA appreciates CFDA's activity to smooth the transition to these new EMC requirements, we request that USTR provide assistance to ensure that this does not become a barrier to trade as it could significantly increase time and cost to market.

China – Product Inspection and Quarantine

China's requirements for Inspection and Quarantine (AQSIQ) and the Conformity Certification (CCC) registration further impede the ability to import some electrical goods. China should take further steps to rationalize and, if possible, relax these requirements.

China and Brazil – International Regulatory Harmonization

China is a member of the International Medical Device Regulator Forum (IMDRF), however they continue to observe IMDRF activity rather than actively participate. It is incredibly important for manufacturers that China actively participates in, adopts and implements IMDRF work items to ensure increased and continued adoption of internationally harmonized regulations and standards. Our members sell products around the globe, thus deviation of requirements to

market good and services in China, particularly in the case of regulated medical imaging equipment reduces access and increases cost, forcing manufacturers to tailor highly advanced and complex, large capital equipment specifically for one country.

In addition to China we applaud Brazil's active role to date in IMDRF and request that USTR encourage the continued involvement of their Health Surveillance Agency (ANVISA) in this forum. More specifically, ANVISA should not only actively participate in IMDRF, but more importantly adopt and implement IMDRF work items.

Brazil — Tariffs

Brazil continues to charge high electrical equipment external tariffs on non-MERCOSUR imports and inputs. Many NEMA product groups are particularly concerned about high Brazilian duties even as Brazilian products enjoy, by virtue of our Generalized System of Preferences (GSP) program, tariff-free market access in the U.S. that is encroaching upon U.S. manufacturers' market share. In particular, the electric motor industry has raised concerns about high tariffs as a barrier in the Brazilian market.

We were pleased to learn that Brazil let expire the dramatic tariff increases imposed in September 2012 on circuit breakers and surge protection devices and has abandoned its February 2013 proposal to raise tariffs significantly on another tranche of products, including electric motors, motor parts, motor drive controllers and certain electrical relays.

Finally, our membership has also expressed concerns about Brazil's duty-drawback policy, which requires 60% local integration in order to be claimed. In practice, double-duties impact far too many products that are shipped to Brazil and then trans-shipped onwards to third countries.

Brazil – Import Licensing

Brazil requires import licenses for some electrical and electronic equipment on a one-off basis. Importers need to apply for the license and then import specific quantities. This requirement should be relaxed if not eliminated so that foreign companies can compete on a level playing field with domestic producers and not have to wait for two weeks for an import license to be granted.

Brazil – Regulatory Transparency

MITA requests USTR to push for increased transparency in the regulatory process in Brazil as it is difficult for manufacturers to keep up with current and applicable regulations.

Regulations of Brazil's Health Surveillance Agency, ANVISA, are published in several ways and have changed frequently in several years, which makes for a large number of documents. This situation makes it difficult for manufacturers to keep up and comply with all the requirements. This increases uncertainly throughout the medical device industry, particularly for smaller enterprises which lack the resources and capacity to appropriately monitor this information.

MITA's objective is to advocate for more transparency and clarity in the medical device regulatory process, making it easier to keep up with regulations and understand them. This can start with the on-line posting of all mandates as well as draft regulations, standards and guidances in English and Portuguese; standardized 60-day comment periods; transition periods and dates for regulations, standards and guidances to enter into force; and clear delineation of the authority of the regulation.

Brazil – Good Manufacturing Procedures

Brazil has traditionally required Good Manufacturing Procedures (GMP) certification for medical devices, which has been complicated due to the costly, lengthy, and changing process to attain it. Delays can last several years, which leads manufacturers to invest elsewhere, which reduces patient access to the same care that people receive in other countries. As such, industry strongly advocates for full acceptance of ISO 13485, the internationally-accepted standard for GMP.

There has been very positive news recently that ANVISA will no longer require GMP certification as part of their product registration requirements. However, the Agency has said that it will publish a list of medical devices which will continue to require GMP certification. MITA requests that USTR monitor ANVISA to ensure they follow through on their proposal to drop GMP requirements, and that medical imaging equipment is not included in the Agency's list of devices still requiring GMP certification.

India

The Government of India is putting in place a series of trade barriers with the apparent intent to disadvantage foreign firms attempting to do business in the country. These include formal forced localization policies for information and renewable energy technologies, both of which are integral parts of a modern electrical network infrastructure. In addition, the systems of technical standards development and conformity assessment (testing and certification of products to standards) fall far short of transparency and national treatment.

Our manufacturers also report that India's use of a Special Valuation Board (SVB) to approve the declared value of goods in advance imposes an undue effort and delay. The SVB must be courted for related-party importation made for onward domestic sale. Regulations change without notice and custom-manufactured items are nearly impossible to fit within this scheme. Finally, India's failure to provide adequate protection for intellectual property rights is a major barrier to companies seeking to sell on the Subcontinent.

Argentina – Safety Certification

As of July 1, 2012, Argentina began requiring physical samples of equipment be supplied by foreign manufacturers or importers to obtain Argentina's S-Mark safety certificate for electrical and electronic appliances within the scope of application of Resolution 92/98 (50-1000V AC or 50-1500V DC). This requirement does not apply to domestic manufacturers. Prior to that date, policy allowed foreign manufacturers and importers to obtain an S-Mark safety license from a local Certification Body (CB) who has reviewed the test report from a foreign CB operating under the IECEE CB Scheme. There is no safety justification for this policy change.

This measure is the latest in a series that make it extremely difficult to sell products into Argentina. Several NEMA member companies have told us that this policy change is a major issue for them and many others importing product into Argentina, over and above the government's export equalization policy that requires importers to match the value of their imports with an equivalent value of exports.

Thank you for your consideration of these remarks.

Sincerely,

Kyle Pitsor

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National Electrical Manufacturers Association (NEMA)