Setting Standards for Excellence

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Vice President, Government Relations

October 25, 2017

Edward Gresser
Chair, Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Submitted electronically via www.regulations.gov

Re: Docket USTR–2017–0013, Request for Public Comments to Compile the National Trade Estimate Report on Foreign Trade Barriers

Dear Mr. Gresser,

As the leading trade association representing the manufacturers of electrical and medical imaging equipment, the National Electrical Manufacturers Association (NEMA) provides the attached comments in response to the August 2, 2017, solicitation of public input to inform preparation of the annual National Trade Estimate Report on Foreign Trade Barriers.

The National Electrical Manufacturers Association (NEMA) represents 350 electrical and medical imaging manufacturers at the forefront of electrical safety, reliability, and efficiency. Our combined industries account for more than 400,000 American jobs and more than 7,000 facilities across the United States. Domestic production exceeds $114 billion per year and exports top $50 billion.

Attached please find brief comments. They are arranged thematically and are not intended to be comprehensive so when specific countries and measures are mentioned they are to illuminate challenges faced by our Member companies. We are open to discussing these comments further and providing additional details at your request. Our Member companies count on your careful consideration and we look forward to outcomes that meet their expectations.

If you have any questions on these comments, please contact Craig Updyke of NEMA at 703-841-3294 or craig.updyke@nema.org.

Sincerely,

Kyle Pitsor

Kyle Pitsor
Vice President, Government Relations

Attachment

NEMA Comments for the National Trade Estimate Report on Foreign Trade Barriers

Import Policies

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 *fora*, including bilateral, regional, plurilateral and multilateral.

Despite U.S. efforts through bilateral free trade agreements and global efforts to achieve World Trade Organization (WTO) agreements that further liberalize industrial market access, NEMA members continue to face high applied customs duties in specific foreign markets, including advanced developing countries. Most notable among these are India and Brazil, ranked as the 6th and 8th largest economies in the world, respectively, by Gross Domestic Product (GDP). According to U.S. export trade data for 2016, India is the 17th largest market for U.S. exports of NEMA-scope products. In 2017, India applies 12.5 percent tariffs in our areas. In the case of Brazil, which according to U.S. export trade data for 2016 is the 9th largest destination for U.S. exports of electroindustry products, 16-18 percent import tariffs are compounded by cascading federal and state taxes that further raise the costs of imported goods.

While broad, global industrial market access commitments to reduce and eliminate tariffs would be welcome, they are also unlikely. Targeted efforts, however, can bear fruit. NEMA remains a supporter of focused tariff elimination initiatives among willing countries under WTO auspices, including the Information Technology Agreement (as expanded in 2016) and negotiations on an Environmental Goods Agreement (EGA).

Technical Barriers to Trade

Standards and Regulations

Technical standards play a vital part in the design, engineering, production, distribution, installation and use of electrical equipment and medical imaging technology destined for both national and international commerce. Documents developed as voluntary consensus standards often form the basis for national or regional mandatory technical regulations.

Recognizing that international trade facilitates access to the best available technologies, many governments and state-owned companies put in place policies specifying that "international standards" are preferred when developing mandatory standards for their home market. In fact, the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) directs WTO members to use available "relevant international standards…as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or

inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."[1]

In many cases, however, this directive is misinterpreted to connote endorsement of standards developed and published only by organizations that carry "international" in their names, including the International Electrotechnical Commission (IEC), International Organization for Standardization (ISO) or International Telecommunications Union (ITU). This has the effect of excluding standards from other Standards Development Organizations (SDOs) like NEMA. These types of policies have several serious deleterious effects, including distortion of the market through restriction or removal of market access for NEMA Member companies manufacturing and selling products that meet competing (and equally efficacious) standards to satisfy needs of the country's existing and future infrastructure and customer demand. These policies also have negative and costly ramifications for potential buyers whose choices may be limited to products that meet an IEC or ISO standard that may not include essential requirements for their home market and thus presents "fundamental technological problems."

Certain IEC technical committees remain resistant to including North American requirements in their standards, one by-product of the special relationship between the IEC and the European Union's SDO, CENELEC.

As the U.S. and others strive to achieve the promise of emerging technologies, including through an Internet of Things, technical standards are playing an essential part. U.S. government trade agencies have an important role to play in working with foreign governments, NEMA, and others in the private sector to keep markets open and competitive. This should preclude creation of new barriers to trade, while enabling connectivity and interoperability while at the same time safeguarding privacy and cybersecurity in electrotechnical and medical imaging products.

Conformity Assessment and Certification

In-country testing requirements, where the design verification testing must be performed on local soil, continue to act as difficult, costly and time-consuming barriers for NEMA manufacturers of electrical equipment and medical imaging equipment. The burden of testing the same product multiple times to the same or equivalent standard can be a significant barrier to market entry. Our trading partners should make commitments to allow for accreditation of qualified conformity assessment bodies and afford them national treatment in the same spirit as the U.S. Occupational Health and Safety Administration's Nationally Recognized Testing Laboratory (NRTL) program.

[1] See Article 2.4 of the TBT Agreement, available here: https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm#articleII

NEMA continues to receive reports from its manufacturers that face demands for repeated and redundant testing when attempting to gain access to China, Brazil, Argentina, Russia, Saudi Arabia, South Africa, and other countries. In the electrical equipment sector, these demands can conflict with multilateral agreements put in place to facilitate international trade in equipment and services while maintaining required levels of safety (e.g. the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE) and the IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx System)).

For example, Russia's National Certification Body recently withdrew its acceptance of manufacturer data and threw into question use of manufacturer test equipment for products covered by the IECEx System. In South Africa, national authorities are withdrawing the country from the IECEE "CB Scheme" and pursuing construction of a redundant national testing system. In Saudi Arabia, manufacturers of electric motors and other electrical products continue to face unnecessary market access challenges with regard to standards, testing and certification requirements. NEMA will continue to work with USTR and the Saudi Arabian Standards Quality and Metrology Organization (SASO) to reform its regulations and procedures.

NEMA's medical imaging division, the Medical Imaging Technology Alliance (MITA), and MITA members also continue to express concern over regulatory and registration uncertainty within China's medical device market.

Specifically, industry is awaiting adoption by the China market of the 2005 third edition series of IEC 60601-1, Medical Electrical Equipment: General Requirements for Basic Safety and Essential Performance. Transition to the third edition is underway in other major world markets, and manufacturers have already created the next generation of devices in compliance with the updated standard series. Third-party testing laboratories are fully capable to certify these products. Delay in adopting the third edition is an obstacle to market access for U.S. manufacturers and continued improvement in patient access to advanced medical imaging equipment in China.

MITA members remain concerned over two separate and uncoordinated efforts within China to translate and transpose into national regulation the Digital Imaging and Communications in Medicine (DICOM) Standard, for which MITA serves as the Secretariat. These efforts have the potential to impose unwarranted testing and certification requirements, not only disparate from each other, but also from the requirements of the normative DICOM Standard. Moreover, the concerns expressed above about in-country testing requirements also come into play here. Testing and certification in China goes beyond the industry standard self-attestation accepted by other medical device regulators around the world.

In early 2017, Chinese authorities cancelled certification and testing fees in a stated effort to reduce cost and complexity for manufacturers. However, these actions have had the negative effect of depriving test labs of their income. Manufacturers are still required to submit test reports from accredited medical device testing labs in China to the China Food and Drug Administration (CFDA) as part of their applications for product approval, but the labs that test products and issue the reports are unable to pay their employees and support their normal pace of business. As a result, both manufacturers and the testing labs they depend upon are suffering from this lack of resources. A testing backlog has been exacerbated with a surge in demand, duplicative test requests, and loss of incentive to provide prompt and efficient testing services. This situation places a higher burden on foreign companies, especially for large medical devices, which must ship their systems to China for in-lab testing. Chinese authorities should suspend the cancellation of fees for medical equipment testing services for a least one year and work with stakeholders to create a transition plan and a long-term plan for provision of testing services for medical devices in China

Overall, NEMA urges China to further improve its transparency and information-sharing regarding standards development and conformity assessment requirements for electrical equipment and medical imaging products, as well as give greater consideration to North American-based international norms.

In the case of the European Union, the conditions NEMA reported in previous years have not changed. Specifically, all avenues for obtaining required third-party certification for EU market access exclude U.S. testing laboratories from the final stage of product certification—the judgment of test results and approval of the product. U.S. laboratories are not allowed by EU regulators to exercise "engineering judgment" and must therefore perform redundant, additional tests that European laboratories are not required to perform. This is much different than the treatment of EU certification bodies that are permitted to continue to use best engineering practice in their testing protocols to ensure product safety.

This lack of national treatment of U.S. certification bodies in Europe (in sharp contrast to the process employed by OSHA in administering the NRTL program) significantly increases the testing costs for U.S. product manufacturers, adds increased time to market, and has effectively required U.S. certification firms to establish operations in the EU to remain competitive.

<u>Other Regulatory and National Treatment Barriers</u>

MITA and its members have cited and remain concerned about multiple measures taken at the national, provincial and local levels in China that would have the effect of disadvantaging non-Chinese companies that manufacture medical technologies. These measures involve, but are not limited to: differential registration fees set by China’s Food and Drug Administration (CFDA);

policies that promote purchasing quotas and reimbursement for products of Chinese-owned firms but exclude products of foreign-owned companies, even if manufactured in China; and requirements mandating clinical trials be conducted within China prior to registration of proven medical imaging technologies. In addition, requirements for products to be registered in their Country of Origin prior to beginning the regulatory approval process in China represent another trade barrier for non-Chinese manufacturers.

Many, but not all, of these concerns could be addressed by implementation of commitments China has made in recent years in bilateral forums with the U.S.

NEMA and MITA look forward to fruitful cooperation with U.S. and Chinese agencies to bring China's policies and practices into line with international norms and best practices for the benefit of Chinese patients.

In general, local certification, test marks and local language requirements are costly to U.S. manufacturers. To affix the required labels and attestations is often challenging (and often there is insufficient space on the product to contain them). Due to specific regulations that require specific labels/marks for individual countries, a product may be different only because of the required test marks and local language text for functional or safety information (i.e. warnings, control panels, etc.) when alternatively one test mark and international symbols could be used. Companies that manufacture durable equipment, which typically remain in production for 7+ years without a major redesign, report that immediate or one-year implementation dates for new and revised regulations and standards are a major problem for legacy products that have been exported and imported without incident for many years.

We urge USTR to remain active in preventing and removing barriers to international trade in high-quality remanufactured equipment such as medical imaging units.

END COMMENTS