National Electrical Manufacturers Association

Representing Electrical and Medical
Imaging Equipment Manufacturers
www.nema.org

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Office of Management and Budget
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Jean-Luc Demarty
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Dear Administrator Bershteyn, Director General Crespo, Ambassador Shapiro, Director General Demarty,

Thank you for the opportunity to provide the following comments on United States-European Union trade and economic relations on behalf of our more than 400 member companies. At NEMA we believe there is significant potential to strengthen further U.S.-EU trade and investment relations to support mutually beneficial job creation, economic growth and international competitiveness.

NEMA is the U.S. association of electrical equipment and medical imaging manufacturers, founded in 1926 and headquartered in Arlington, Virginia, USA. Our member companies manufacture a diverse set of products including power transmission and distribution equipment, lighting systems, factory automation and control systems, and medical diagnostic imaging systems. Worldwide annual sales of NEMA-scope products exceed $120 billion. The electrical equipment and medical imaging industries together support more than one million U.S. jobs.

NEMA is pleased with the engagement and commitment of U.S. and EU leaders in the High-Level Working Group on Jobs and Growth (HLWG) as well as the High Level Regulatory Cooperation Forum (HLRCF).

Your September 7 solicitation of comments from the public stated your

> *hope to receive detailed input on differences between existing regulation in the United States and Europe that may impose unnecessary costs and burdens on American businesses, and on priority areas where we should cooperate on future regulations affecting new and innovative growth markets and technologies, particularly for small and medium sized businesses.*

Furthermore, your Sept. 7 solicitation invited "views on how to promote greater transatlantic **regulatory compatibility** generally" and in particular economic sectors *(emphasis added)*.

We note that the U.S. and its partners in the Trans-Pacific Partnership negotiations have set a very high goal for a forward-looking agreement. In general, we believe that this level of ambition should be the "floor" from which a new U.S.-EU pact must be built, rather than a "ceiling" that might restrain negotiators.

That said, in general negotiators should make every effort to reduce uncertainty and raise the level of confidence and assurance for electrical manufacturers and associated services providers that want to trade and invest across the Atlantic.

Barriers to trans-Atlantic trade and investment are already relatively low, given low customs duties, high trade volumes and significant levels of cross-investment. According to U.S. government data, the value of U.S.-EU trade in electrical and medical equipment within NEMA's scope in 2011 totaled approximately $15.7 billion; data through August 2012 indicated an expected increase for the full year of 2012.

***New Industries and Technologies***

The U.S. and EU must continue their focus and redouble their efforts to prevent barriers to trade in new and emerging industry sectors. From NEMA's point of view, these industry areas include Smart Grid, electrical vehicle ("e-mobility") supply equipment, and advanced lighting technologies. The U.S. and EU should work closely and collaboratively with their industry stakeholders to define open and compatible standards in these areas to prevent the creation of technical barriers to trade.

As an example, Intelligent Transportation Systems (ITS) technologies are also a growing export sector largely based on voluntary consensus industry standards, including some developed with the support of the U.S. Department of Transportation. Many of these standards have been recognized, adopted and are being used in a growing number of countries, including in the European Union. The EU should recognize and adopt these standards more broadly rather than invest scarce resources in developing EU-only standards.

The Medical Imaging and Technology Alliance (MITA), a division of NEMA, represents manufacturers of medical imaging, radiation therapy, and radiopharmaceutical products that operate in the U.S. and EU. There are several opportunities within the medical imaging industry to boost trade and investment between the U.S. and EU in order to support mutual job and economic growth as well as to increase the international competitiveness of our industries. By joining forces on matters of common interest to better communicate, coordinate and collaborate, the U.S. and EU can work together to reduce unnecessary regulation and improve market access to life-saving medical equipment. This can be done by mutually identifying topics and trends with global industry impact, developing joint positions, leveraging the benefits of international standards, advocating for efficient and reasonable regulation that promotes innovation, supporting harmonization of regulatory frameworks and streamlining clearance processes. By working together, millions of people around the world will benefit from improved access to these life-saving technologies.

Ongoing negotiations under the auspices of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal are nearing a decision to extend 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 proposals from the European Union, with support from environmental non-governmental organizations.

The U.S. is participating in the negotiations but is not currently a full 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 legitimate (non-waste) equipment for authorized 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, eliminate the broad environmental, economic and social benefits arising from repair, refurbishing, remanufacturing, and reuse of electrical and electronic equipment. The U.S. and EU must 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 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 it is 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 MITA encourage the U.S. and EU to continue to work with these countries and others to recognize the value of high-quality remanufactured equipment, especially in the medical imaging industry.

There is a great deal of inequality in healthcare expenditures between more and less developed countries, and as technology advances, costs go up, which makes the inequality worse. Remanufactured medical imaging equipment save lives by improving access to technology that otherwise may not be available; saves money by lowering the cost to purchase advanced medical technologies; and saves resources, which allows for the re-use of products that contain precious metals and keeps those materials out of landfills.

Medical imaging equipment and other advanced medical devices are designed to last for as many as twenty years or even longer. Many doctors in developed countries purchase new products every few years to keep pace with the most recent technological advances, therefore there are a number of safe, advanced, fully-functioning devices that can be used for many more years and at reduced cost.

MITA members have years of experience with remanufactured products, which fall under U.S. Food and Drug Administration supervision to ensure that products are properly certified and meet the necessary specifications. The U.S. and other developed countries have used remanufactured equipment for quite some time and pre-owned products make up a significant percentage of the U.S. market. A white paper on

good remanufacturing practices for medical imaging equipment is also available at http://www.cocir.org/uploads/documents/46-907--39-final_grp_report_2009.pdf. The paper was published in 2009 by the global medical imaging industry, represented by MITA and its European and Japanese counterpart industry organizations COCIR and the Japan Industries Association of Radiological Systems (JIRA). The paper proposes principles for remanufacturing to ensure that only quality remanufactured medical imaging equipment be introduced into markets.

***Regulatory***

U.S. industries and the U.S. Government have frequently complained about the EU propensity to establish regulations lacking in solid technical justification and whose burdens of implementation are not proportionate to intended consumer or environmental benefits. Typically, these regulations are based on the "precautionary principle" and are developed with procedures that are not transparent to all stakeholders, including the U.S. electrical manufacturing industry and other trading partners. Further, stakeholders find they have no way to hold EU authorities accountable for the regulations produced and implemented. The U.S. must refrain from adopting the EU approach to regulatory development and implementation.

Trans-Atlantic harmonization of existing regulations in and of themselves is not the goal NEMA would recommend. That said, the U.S. and EU should work together to minimize the barriers that existing regulations present to trade in safe products in the spirit that regulations should not be trade-distorting. The two partners should share data with each other that enables regulatory comparisons and enables mutual compliance.

Improvements to regulatory compatibility in the medical imaging sector should be achieved via mutual recognition of each other's quality management systems and audits, of a singular standard for a medical device marketing application with electronic submission capabilities, and of a singular standard for a Global Unique Device Identification Database for medical devices. For a detailed discussion of these recommendations on medical imaging equipment, please refer to the recent joint paper of COCIR and MITA provided under separate cover.

In the electrical equipment sector, the two parties should consider launching joint initiatives to improve market surveillance and enforcement of their regulations.

Our industry is committed to working with USTR and OMB to engage with the EU on questions of governance and regulatory disciplines, and to find solutions to its systemic regulatory problems, ensuring justification, transparency and openness in development of directives, as well as "national treatment" and accountability in their application.

***Standards and Conformity Assessment***

The EU has failed to adopt the principles determined by the World Trade Organization (WTO) Technical Barriers to Trade Committee for the development of international standards

- openness
- transparency
- impartiality and consensus
- relevance and effectiveness,
- coherence
- development

and that in these terms an "international standard" is neither automatically nor limited to a standard that is developed by one or more of the three Geneva-based standards development organizations (SDOs) – the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU), and the International Organization for Standardization (ISO). The EU should recognize and adopt the WTO TBT definition formally and in practice.

The EU authorities should recognize and leverage the fact that non-EU, non-Geneva SDOs are capable of developing standards that can enable companies to achieve compliance with the essential requirements of EU directives and regulations. The EU should recognize fully that standards developed by international standardization organizations that meet the requirements of the WTO TBT Agreement should be accorded "presumption of conformance" to relevant EU legislation if the technical committees developing the standards take the essential requirements of the legislation into account when they are developing the standard. This would be a major new idea and significantly benefit the U.S. and EU manufacturing industries.

On a related level, the important standards-setting bodies CEN and CENELEC are lacking in transparency and openness inasmuch as they absolutely deny full participation by any U.S.-interested party despite legitimate business concerns and impacts. This is particularly significant when there is specific knowledge that CEN/CENELEC standards resulting from mandates under EU directives will be developed into *de facto* market access requirements. Moreover, given European predominance as per the one-nation-one-vote schemes employed by the IEC and ISO, CEN/CENELEC standards inevitably have the inside track on becoming the norms adopted by these bodies. As noted above, the U.S.-EU Working Group should engage in a constructive dialogue on achieving greater reliance in both economies on international standards as defined by the WTO TBT Committee.

The U.S. and EU have been at odds for over 10 years on the subject of conformity assessment for electrical and electronic products, with the EU pushing for U.S. regulators to accept Supplier's Declaration of Conformity (SDOC). The Department of Labor (DOL) has resisted this push, with NEMA's support. As an alternative, DOL's Occupational Safety and Health Administration (OSHA) certified an EU lab to do the mandatory third-party testing and certification required by OSHA. This alternative provides market access for EU suppliers in compliance with U.S. laws and regulations to

protect workers but more importantly U.S. workplace market demand for third-party certified electrical equipment.

NEMA does not oppose SDOC. NEMA's view is that efforts to institutionalize SDOC as the only acceptable method of conformity assessment could have serious negative effects on established and successful practices in our sector. These practices have a stellar record in identifying non-compliant and counterfeit products. SDOC should be an option rather than an obligation. Where suitable monitoring institutions are in place, the market should be allowed to determine the appropriate means of conformity assessment. This final point is the key one: The market should be allowed to determine the appropriate means of conformity assessment.

In the EU market, all avenues for obtaining required third-party certification 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 sharp contrast to the fully open, transparent and uniform process employed by OSHA in administering the Nationally Recognized Testing Laboratory (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. Accordingly, the U.S. and EU should provide full national treatment to U.S. and EU conformity assessment (testing and certification) bodies.

***Tariff Barriers***

On tariffs, the U.S. and EU should vigorously pursue and secure an agreement to expand the scope of the World Trade Organization's plurilateral Information Technology Agreement to eliminate tariffs on covered equipment. In addition, the U.S. and EU should build upon their joint proposal to the WTO for an Environmental Goods and Services Agreement (EGSA) by implementing such an agreement on a bilateral basis. This could be taken several steps further in the industrial market access area by an agreement to eliminate tariffs on all U.S.-EU trade within NEMA's product scope. Most remaining tariffs fall into the "nuisance" category and thus do not perform any useful function besides some small revenue to the respective treasuries. Saving time and money not having to pay import duties could provide for notable efficiencies and re-programming of company resources into more productive activities.

Tariffs must be included within the scope of any U.S.-EU negotiations and NEMA supports complete and immediate tariff elimination.

***Services***

Expanding from the issue of access for conformity assessment services providers, the U.S. and EU should also use the opportunity to open to each other their markets for energy and environmental services, technical and engineering services, and maintenance and repair services.

***Trade Facilitation***

The U.S. and the EU should work together to develop and adopt harmonized customs classifications for traded products, especially for products where trade is growing significantly such as solid-state lighting technology. For example, the global lighting industry should not have to bear the costs of complexity and uncertainty maintained by customs authorities who should be facilitating trade of efficient and durable LED lighting products that are in increasing demand by customers.

***Conclusion***

In general, NEMA recommends that all U.S. free trade agreements, including any possible bilateral or regional agreement, adhere to the following 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

Thank you again for the opportunity to share our views and recommendations. As part of this process, we look forward to providing further advice at your request or as conditions warrant.

Respectfully,

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NEMA