



Setting Standards for Excellence

October 1, 2010

Ms. Gloria Blue
Office of the U.S. Trade Representative
Washington, DC 20230

Submitted to: www.regulations.gov, Docket USTR-2010-0021

Re: Standards-Related Measures

Dear Ms. Blue:

The National Electrical Manufacturers Association (NEMA) is pleased to respond to your August 6 *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, NEMA is providing separate sets of comments on standards-related measures and on other measures of concern. This document addresses standards-related measures.

NEMA is the association of electrical and medical imaging equipment manufacturers. Founded in 1926 and headquartered near Washington, D.C., its approximately 450 member companies manufacture products used in the generation, transmission and distribution, control, and end use of electricity. These products are used in utility, industrial, commercial, institutional, and residential applications. The association's Medical Imaging & Technology Alliance (MITA) Division represents manufacturers of cutting-edge medical diagnostic imaging equipment including MRI, CT, x-ray, and ultrasound products. Worldwide sales of NEMA-scope products exceed \$120 billion. In addition to its headquarters in Rosslyn, Virginia, NEMA also has offices in Beijing and Mexico City. (The Association's product scope is attached.)

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

I. Supplier's Declaration of Conformity

While there are some in U.S. industry who maintain that the very fact that many nations do not use Supplier's Declaration of Conformity (SDOC) as the preferred means of conformity assessment for various information technology products is itself a trade barrier, our view is that moves to institutionalize SDOC could have serious negative effects on established successful practices in our sector. 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.

II. European Union — Regulations, Standards, and Conformity Assessment

The EU Commission continues to advance regulatory initiatives, currently a revision of its Restriction on Hazardous Substances (RoHS) Directive, that could have negative impacts on market access. This follows on earlier enacted legislation relating to Energy Using Products (EUP), Chemicals (REACH), Waste in Electrical and Electronic Equipment (WEEE) and RoHS. The REACH Regulation is currently going through an awkward implementation phase and could be undercut further by a revised RoHS Directive now being considered by the Parliament, Member States and Commission.

As we and other industry associations have often noted, the EU is increasingly establishing regulations that lack technical justification and whose burdens of implementation are not proportionate to intended consumer or environmental benefits. Typically, these regulations 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.

The recent EU Regulation 765/2008 on market surveillance and accreditation requires that each member state designate a single national accreditation body. Germany's Central Authority of the Federal States for Safety (ZLS) issued a ruling indicating that for GS certification, a GS certifier cannot accept Certification Body (CB) Test Reports without further testing being done. This is in sharp contrast to previous policies and practices whereby such test reports were readily accepted and GS certification issued. Unlike Germany, OSHA NRTL Program 8 leaves the decision on whether to conduct additional testing with the NCB as it should be. ZLS's ruling significantly adds to the cost of product conformance and the time required to get products into the German market by requiring redundant testing for all electrical products not made and tested in Germany. The new policy by the designated German accreditation body has the potential to balloon to similar requirements across all 27 EU member states.

On a related level, the important standards-setting bodies CEN and CENELEC are even more lacking in transparency and openness inasmuch as they absolutely deny 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 New Approach 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 International Electrotechnical Commission (IEC) and International Standardization Organization (ISO), CEN/CENELEC standards inevitably have the inside track on becoming the norms adopted by these bodies.

All avenues for obtaining required third-party certification for the EU market 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 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.

Separately, the most recent revision of the ISO 9000 standard has resulted in a deviation from the EU approach for CE marking because the new standard, ISO 9001:2000 has introduced major changes to the ISO 9000 system. To an extent, these changes are not compatible with the ways in which the system for conformity assessment is being used in modules D, E and H. The revision did away with the distinction between ISO 9001, 9002 and 9003 which mapped directly onto the module D, E, and H. As such, a firm that has adopted this quality management system is no longer deemed to have its production process in control according to Council Resolution of 21 December 1989 on a Global Approach to Conformity Assessment requirements, requiring it to undertake additional costly and time-consuming steps to obtain approval from the various EU conformity bodies before their products are approved. This development is particularly onerous for small and medium-sized enterprises located outside the EU. For these SMEs, there are no safety or quality benefits in having to completely change their documentation structure and systems to the process model contained in the revised standard. While the EU does not require manufacturers to comply with ISO 9000 in order to obtain the CE mark, the majority have chosen to implement a quality system in accordance to ISO 9000 to meet the basic requirements for modules D, E and H. Unlike small and medium-sized companies located in the EU, which can drop ISO 9000 and implement their own quality system, U.S. small and medium companies will be reluctant to deviate from an approach that has worked effectively in the past placing them at a competitive disadvantage in the EU market place. Within the EU Commission, the Directorate-General for Enterprise (DG Enterprise) was expected to develop a guidance document that would describe how ISO 9000:2000 could be selectively applied to meet the different requirements of the three modules. As of this date, the long-awaited guidelines have not been published.

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Our industry is committed to working with USTR, through engagement with the EU on questions of governance and regulatory disciplines, 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.

III. Saudi Arabia – Standards

Recently, the Saudi Arabia Standards Organization (SASO) announced in an obscure publication a planned major change to its standard for wiring devices while failing to provide WTO TBT Notification. The change amounted to the development of two distinct configurations for socket outlets, neither of which permits the use of currently available devices from U.S. manufacturers, despite decades of safe and reliable use in the Saudi market. The unannounced change and short window for compliance adds significant product development and tooling costs to U.S. manufacturers, reduces the market for U.S. products, and causes unneeded disruption to sales.

IV. China — Standards and Conformity Assessment

Within the International Electrotechnical Commission (IEC) there are systems that are intended to facilitate market access among participating countries by providing accreditation of member certification laboratories so that testing done in one country would be accepted for certification and market access in other countries (IECEE, IECEX, IECQ). NEMA has received reports from a number of manufacturers that have experienced the demand for repeated testing when attempting to gain access to the Chinese market. These demands conflict with the agreements China signed as a member of the conformity assessment systems.

In addition, we note that China is increasingly permitting standards and conformity assessment professionals from outside the Middle Kingdom to participate in the development of new standards, but the current policy still leaves such participation up to the respective technical committee chairs. We urge China to further improve its transparency and information-sharing regarding its standards development and conformity assessment requirements for electrical products, as well as give greater consideration to North-American-based international norms.

We also urge China to revise its mandatory certification procedures regarding the CCC mark to accept test reports from duly accredited testing laboratories located outside China, and to move toward accreditation of one or more non-Chinese certification organizations to give manufacturers of electrical products choice in selecting their third-party testing and certification provider(s).

Multiple and often redundant inspection and certification requirements for medical imaging equipment also remains a problem despite Beijing's pledges under the auspices of the Joint Committee on Commerce and Trade (JCCT), and must be addressed in a meaningful and committed manner.

V. Free Trade Agreements

Washington should negotiate and ratify free trade agreements (bilateral, regional and multilateral) that further open commerce in electrical goods while upholding the following NEMA principles on standards and conformity assessment:

- No Public Sector Mutual Recognition Agreements (MRAs) For Non-Federally-Regulated Products
- National treatment
- Adequate legal and administrative infrastructure in place for implementation, transparency and enforcement of agreements
- Protection of intellectual property rights
- Reduction in technical barriers to trade (TBTs)
- Compliance with all World Trade Organization (WTO) TBT Agreement requirements
- Inclusive definition of “International Standards”
- Market-driven development of product standards and conformity assessment\
- Conformity attestation methods include optional use of the IEC Conformity Assessment Systems – IECEE, IECEX and IECQ, where appropriate

Most directly, NEMA recommends these principles be upheld in any Trans-Pacific Partnership Agreement.

Thailand

Bangkok consistently fails to adhere to the WTO TBT Notification process, resulting in electrical manufacturers becoming aware of new regulatory requirements through unsolicited third-party advertisements long after the requirements have taken effect. Additionally, new regulations consistently fail national treatment, tilting the market to advantage Thai manufacturers and seriously disadvantaging U.S. manufacturers.

APEC MRA — Technical Regulations

Many APEC governments continue to endorse the development of a public-sector Mutual Recognition Arrangement on Conformity Assessment of Electrical and Electronic Equipment (MRA) — an arrangement in which, at NEMA's behest, the U.S. government is not participating. In our view, the International Electrotechnical Commission (IEC)-based conformity assessment schemes for electrical products are designed to be global in applicability, and should be adopted in lieu of regional public sector MRAs. While NEMA supports public-sector Mutual Recognition Arrangements or Agreements for federally-regulated products such as medical devices, it opposes them for non-regulated items such as most other electrical equipment. In the latter instances, MRAs open the door to the creation of unnecessary U.S. federal regulation.

VI. The Americas

Mexico — Standards and Conformity Assessment

NEMA is very involved in the standards and conformity assessment processes in Mexico. At any given time the country is developing or making revisions to 20 to 30 electrical product standards each year. The authorities do accept and take into account public comments on proposed standards; however, a draft regulation that has been substantially revised based on public comments may not be circulated for final public review prior to publication. NEMA would welcome the Mexican standards authority's (DGN) application of consistent procedures in the consideration and adoption of NOM standards, which directly affect market access for many proven commercial products since they are *de facto* technical regulations.

We are pleased with the change in procedures being followed with regards to incorporating voluntary NMX standards into mandatory NOM standards, although experience shows that in the long term we must remain vigilant to ensure proper compliance by the authorities.

Mexico was required under its NAFTA obligations to recognize, starting January 1, 1998, conformity assessment bodies in the U.S. and Canada under terms no less favorable than those applied to Mexican conformity assessment bodies. Mexico indicated its willingness to conform to these obligations late in 2005 via an announcement in the *Official Gazette*. We are aware of two U.S. conformity assessment bodies that have now been accredited by Mexico (EMA) for conducting conformity assessment on electrical products subject to mandatory NOM regulations. Mexico also recently announced acceptance of certain U.S.-certified electrical products as being equivalent to products meeting certain NOM standards, informally known as the "Duarte Plan." We are cautiously optimistic that expansion of this plan will provide continued access of U.S. manufactured products into Mexico at lower costs and fewer delays.

Brazil — Standards and Conformity Assessment

Under great pressure from European manufacturers, Brazil is developing standards for an increasingly broad range of electrical products that are principally based on IEC standards. New INMETRO certification decrees covering electrical products are issued each year.

Moreover, part of the Brazilian electrical sector (increasingly under the influence of European companies) is trying to use the MERCOSUR standardization and certification channels to create barriers to US products in Brazil. The strategy consists in replacing all Brazilian standards that permit the use of American products by MERCOSUR standards, which, in many cases, would not include US technology, because they are based on IEC standards. In addition, European manufacturers in Brazil are more aggressively trying to impede NEMA member companies' participation in the Brazilian standardization process through their large "influence" in the trade association ABINEE and the national standards organization ABNT. NEMA calls on Brazil to ensure consistent application of national and WTO TBT national treatment policies to all manufacturers, both domestic and foreign.

Canada — Standards and Conformity Assessment

Ontario provincial authorities recently suspended implementation of their Regulation 438/07 that authorized the local Electrical Safety Authority (ESA) to regulate the sale of all electrical products in the Province. In addition to the obligations outlined in the regulation, manufacturers of electrical products for sale in Ontario would have been required to register with Ontario's ESA. This includes manufacturers of products currently sold in Ontario as well as any manufacturer who intended on manufacturing and selling new electrical product(s) there. Registration by the manufacturers' authorized representative(s) would also have been required. NEMA urges caution in the further development of this and any other new local regulations that provide no additional safety to consumers but require additional time and resources by manufacturers to meet the requirements. Such developments should be made in consultation with industry and their proven product certification partners.

Thank you for your consideration of these remarks.

Sincerely,

A handwritten signature in blue ink that reads "Gene Eckhart". The signature is written in a cursive, flowing style.

Gene Eckhart
Director, International Trade

Attachment: NEMA Product Scope by HTS Number

NEMA Product Scope by HTS Number

<u>HTS number</u>	<u>Product description</u>
3208.10	Paints/varnishes, dispersed or dissolved in a non-aqueous medium: Based on polyesters
3208.20	Based on acrylic or vinyl polymers
3208.90	Based on other synthetic polymers or chemically modified natural polymers
3907.10	Polyacetals, other polyethers and epoxide rsins, in primary forms: Polyacetals
3907.20	Other polyethers
3907.30	Epoxide resins
3907.40	Polycarbonates
3907.50	Alkyd resins
3907.60	Polyethylene terephthalate (bottle-grade resins and others)
3907.91	Other polyesters: unsaturated, allyl resins: Allyl resins, uncompounded Other allyl resins, compounded Other unsaturated polyesters
3909.10	Urea resins; thiourea resins
3909.20	Melamine resins
3909.30	Other amino-resins
3909.40	Phenolic resins
3909.50	Polyurethanes: Elastomeric, cements and other polyurethanes
3917.21	Tubes, pipes and hoses: Of polymers of ethylene
3917.22	Tubes, pipes and hoses: Of polymers of propylene
3917.23	Tubes, pipes and hoses: Of polymers of vinyl chloride
3917.40	Non-metallic fittings for tubes, pipes and hoses

3919.10	Self-adhesive plates, sheets, film, foil, tape, strip and other flats shapes of plastic: Filament reinforced tape and electrical tape
3919.90	Other electrical tape
3921.90	High pressure paper reinforced decorative and non-decorative (includes industrial) laminates
6814.10	Plates, sheets and strips of agglomerated or reconstituted mica, on a support or not
6814.90	Other mica
7305.31	Longitudinally welded, tapered pipes and tubes of steel, principally used as parts of illuminating articles
7306.30	Tubes/pipes of steel, welded, of circular cross-section Non-insulated metallic conduit
7308.20	Towers and lattice masts
7408.11	Copper wire with a maximum cross-sectional dimension over 9.5 or With a maximum cross-section dimension > 6 mm but < 9.5
7408.19	Copper wire not of refined copper
7408.21	Copper wire of copper-zinc base alloys (brass)
7408.22	Copper wire of copper-nickel or copper-nickel-zinc base alloys, coated/plated w/metal or not coated or plated w/metal
7408.29	Copper wire not of copper-zinc base alloys, coated/plated w/metal or not coated or plated w/metal
7413	Stranded wire, without fittings Other cables, without fittings Stranded wire, cables, plaited bands, with fittings
8501.10	Motors of an output not exceeding 37.5 W
8501.20	Universal AC/DC motors of an output exceeding 37.5 W
8501.31	Other DC motors: DC generators: Of an output not exceeding 750 W
8501.32	Other DC motors: DC generators: Of an output exceeding 750 W but not exceeding 75kW
8501.33	Other DC motors: DC generators: Of an output exceeding 75kW but not exceeding 375 kW

8501.34	Other DC motors: DC generators: Of an output exceeding 375 kW
8501.40	Other AC motors, single-phase
8501.51	Other AC motors, multi-phase: Of an output not exceeding 750 W
8501.52	Other AC motors, multi-phase: Of an output exceeding 750 W but not exceeding 75 kW
8501.53	Other AC motors, multi-phase: Of an output exceeding 75 kW
8501.61	AC generators (alternators): Of an output not exceeding 75 KVA
8501.62	AC generators (alternators): Of an output exceeding 75 kVA but not exceeding 375 kVA
8501.63	AC generators (alternators): Of an output exceeding 375 kVA but not exceeding 750 kVA
8501.64	AC generators (alternators): Of an output exceeding 750 kVA
8503.00	Commutators: Stators and rotors for motors and generators
8504.10	Ballasts for discharge lamps or tubes
8504.21	Liquid dielectric transformers: Having a power handling capacity not exceeding 650 kVA
8504.22	Liquid dielectric transformers: Having a power handling capacity exceeding 650 kVA but not exceeding 10,000 kVA
8504.23	Liquid dielectric transformers: Having a power handling capacity exceeding 10,000 kVA
8504.31	Other transformers: Having a power handling capacity not exceeding 1kVA
8504.32	Other transformers: Having a power handling capacity exceeding 1 kVA but not exceeding 16 kVA
8504.33	Other transformers: Having a power handling capacity exceeding 16 kVA but not exceeding 500 kVA
8504.34	Other transformers: Having a power handling capacity exceeding 500 kVA
8504.40	Static converters (electronic transformers)
8504.50	Other inductors

8504.90	Parts of speed drive controllers
8506.10	Primary cells and primary batteries: Manganese dioxide
8506.30	:Mercuric oxide
8506.40	:Silver oxide
8506.50	:Lithium
8506.60	:Air-zinc
8506.80	Other primary cells and primary batteries
8506.90	Parts of primary cells and batteries
8507.30	Nickel-cadmium storage batteries
8507.40.	Nickel-iron storage batteries
8507.80	Other storage batteries (not including lead-acid)
8507.90.80	Parts
8513.10	Lamps: Flashlights and Other (lanterns)
8513.90	Parts: of flashlights and lanterns
8515.31	Machines and apparatus for arc (including plasma arc) welding of metals: Fully or partly automatic
8515.39	Machines and apparatus for arc (including plasma arc) welding of metals: Other
8515.90	Parts: Of welding machines and apparatus
8530.10	Traffic control equipment
8530.80	Other signaling equipment
8530.90	Parts
8531.10	Burglar or fire alarms or similar apparatus (incl. smoke detectors)
8531.20	Indicator panels incorporating liquid crystal devices (LCDs) or light emitting diodes (LEDs)
8531.80	Paging alert devices and other signaling apparatus

8531.90	Parts of signaling equipment
8532.10	Fixed capacitors used in 50/60 Hz circuits, w/reactive power capacity of not < .5 kvar
8533.	Electrical resistors (including rheostats and potentiometers), other than heating resistors; parts thereof
8533.39	Wirewound variable resistors, including rheostats and potentiometers (incl. dimmers)
8535.10	Electrical apparatus for switching or protecting electrical circuits, voltage > 1,000 V: Fuses for a voltage > 1,000 V
8535.21	Automatic circuit breakers for a voltage > 1kV but < 72.5 kV
8535.29	Other circuit breakers for a voltage > 72.5 kV
8535.30	Isolating switches and make-and-break switches
8535.40	Lightning arresters, voltage limiters and surge suppressors
8535.90	Other electrical apparatus for switching or protecting electrical circuits above 1000 V Motor starters for medium voltage starters
8536.10	Fuses
8536.20	Automatic circuit breakers
8536.30	Other apparatus for protecting electrical circuits Motor overload protectors
8536.41	Electrical relays and contactors for voltage not > 60 V
8536.42	Other relays and contactors 60 to 1000 V
8536.50	Switches, motor starters
8536.61	Lamp holders
8536.69	Electrical connectors
8536.90	Boxes, raceway, terminals, electrical splices and electrical couplings, and others
8537.10	Boards, panels, consoles, desks, cabinets and other bases, equipped with two or more apparatus...for electric control or the distribution of electricity...and numerical control apparatus: For a voltage not exceeding 1,000 volts

8537.10.60	Motor control centers and Programmable controls
8537.20	Switchgear and assemblies for a voltage > 1,000 V
8538.10	Boards, bases and panels for goods of 8537, without their apparatus Parts of programmable controls
8538.90	Molded and other parts for 8536 and 8537
8539.10	Sealed beam lamp units
8539.21	Other filament lamps, excluding ultraviolet or infrared lamps: Tungsten halogen
8539.22	Other filament lamps, excluding ultraviolet or infrared lamps: Other, of a power not exceeding 200 W and for a voltage exceeding 100 V
8539.29	Other filament lamps, excluding ultraviolet or infrared lamps: Other: Designed for a voltage not exceeding 100 V
8539.31	Discharge lamps, other than ultraviolet lamps: Fluorescent, hot cathode
8539.39	Discharge lamps, other than ultraviolet lamps: Other
8539.41	Ultraviolet or infrared lamps: arc lamps
8539.90	Electrical filament or discharge lamps: Parts
8541.40.20	Light-emitting diodes
8544.11	Winding wire of copper (magnet wire)
8544.19	Other (magnet wire)
8544.20	Coaxial cable and other coaxial electric conductors
8544.41	Electric conductors, fitted with connectors for voltage not > 80 V
8544.49	Electric conductors, fitted with connectors for voltage not > 80 V: Other, without connectors
8544.51	Electric conductors, fitted with connectors, voltage > 80 V but < 1,000 V
8544.59	Electric conductors, fitted with connectors, voltage > 80 V but < 1,000 V: Other, without connectors, of copper Other, not of copper

8544.60	Electric conductors, fitted with connectors, voltage > 1,000 V Not fitted with connectors and of copper Not fitted with connectors and not of copper
8544.70	Optical fiber cables
8545	Carbon electrodes, carbon brushes, lamp carbons, battery carbons, and other articles of graphite or other carbon, with or without metal, of a kind used for electrical purposes
8545.11	Carbon electrodes, of a kind used for furnaces
8545.19	Carbon electrodes: Other, of a kind used for electrolytic purposes Carbon electrodes: Other, not used for electrolytic purposes
8545.20	Carbon brushes
8545.90	Arc light carbons and other carbons used for electrical purposes
8546.10	Electrical insulators of glass
8546.20	Electrical insulators of ceramics
8546.90	Electrical insulators of other material
8547.90	Insulated metallic conduit
9018.12	Ultrasonic scanning apparatus
9018.13	Magnetic resonance imaging apparatus
9018.14	Scintigraphic apparatus
9022.14	Apparatus based on the use of X-rays, for medical, surgical, dental, or veterinary uses
9022.21	Apparatus based on the use of alpha, beta or gamma radiations: for medical, surgical, dental, or veterinary uses
9022.30	X-ray tubes
9022.90	Other apparatus, including parts and accessories
9028.30	Electricity meters
9028.90	Parts and accessories
9032.10	Thermostats: for air conditioning, refrigeration or heating systems
9032.89	Other instruments and apparatus: Other: Automatic voltage and voltage-current regulators (HVAC controls)

- 9032.89.60 Complete process control systems
 - Temperature control instruments
 - Pressure and draft control instruments
 - Flow and liquid level control instruments
- 9032.90 Other instruments and apparatus: Parts and accessories: Of automatic voltage and voltage-current regulators (Thermostat and HVAC parts)
- 9032.90.60 Parts of process control instruments and apparatus including programmable controllers
- 9405.10 Electric ceiling or wall fixtures, not of base metal
- 9405.40 Other electric lamps and lighting fittings, of brass
 - Of base metal (not brass)
 - Other lamps and lighting fittings, not of base metal
- 9405.99 Fixture parts of brass
 - Fixture parts, other than brass