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May 10, 2013

**To:** The Office of the United States Trade Representative (USTR)

**Subject:** Request for Comments Concerning Proposed Transatlantic Trade and Investment Agreement (78 FR 19566-19568, April 1, 2013)

The American Society of Mechanical Engineers (ASME) submits this response to the Office of the United States Trade Representative (USTR) request for information published in the Federal Register on April 1, 2013 (78FR 19566). The information is being sought to inform USTR on the proposed Transatlantic Trade and Investment Partnership (TTIP) agreement. In addition, Heidi Hijikata, ASME's Director of Global Development, requests to testify at the May 29 -30 using this submission as the basis of her testimony.

Founded in 1880, ASME is a not-for-profit scientific, educational, and technical organization for mechanical engineers, with over 130,000 individual members worldwide. It has no corporate members. ASME serves several important functions, one of which is the development and maintenance of over 500 voluntary consensus standards, used in over 100 countries around the world, associated with the art, science, and practice of mechanical engineering. These include standards for complex machinery such as boilers, pressure vessels, elevators, and escalators, and items as ubiquitous as nuts, bolts, and plumbing fixtures. These standards reduce the costs of goods and services; enhance safety, health, and quality of life; and facilitate innovation, trade, and competitiveness while substantially reducing the costs of government by providing a consistent and technically sound basis for regulation.

ASME also provides conformity assessment services to over 6,500 manufacturers in 75 countries in the areas of boilers, pressure vessels, and nuclear power components.

ASME's response below addresses three of the specific areas raised in the notice:

- General and product-specific negotiating objectives for the proposed agreement.

- Opportunities for greater transatlantic regulatory compatibility, including concrete ideas on how greater compatibility could be achieved in a particular economic sector, without diminishing the ability of the United States to continue to meet legitimate regulatory objectives, for example with respect to health, safety and the environment, and which sectors should be the focus of such efforts.

- Opportunities to reduce unnecessary costs and administrative delays stemming from regulatory differences, including how that could be achieved in a particular economic sector.

ASME has experience working with standards and conformity assessment issues involving Europe for 20 years. Among the sectoral standards and regulatory issues that have affected ASME and the companies that develop and use its codes and standards are boilers, pressure vessels, piping systems, nuclear power plant components, and elevators/lifts.

**PRESSURE EQUIPMENT (boilers, pressure vessels, and piping systems)**

Pressure Equipment (PE) is used extensively in the industrialized world. Everything from air receivers, to boilers used for generating electricity and heating buildings, to large petroleum refinery vessels contain fluids under pressure. Because this equipment is commonly found in industrial work sites and locations where large groups of people congregate, PE is a highly regulated sector due to the potential for damage to life and property in the case of a failure. Historically, each industrialized country developed its own system of design and construction standards combined with regulations and inspection requirements to arrive at an acceptable level of safety and reliability. As a result, the standards/regulation systems in the US and EU vary significantly, while both still comply with the principles for international standards defined in the World Trade Organization's (WTO) Technical Barriers to Trade (TBT) Agreement. In 1997 (mandatory in 2002), the European Commission's (EC's) introduction of the Pressure Equipment Directive (PED), including the European Committee for Standardization's (CEN's) development of new European (EN) standards to support it, impacted existing PE standards all over the world.

During the implementation of the new system, ASME's standards and the North American regulatory system were targeted by the EC in an attempt to create an environment preferential to new CEN standards.

PED IMPACT ON ASME AND ITS STANDARDS USERS

The immediate impact was on PE manufacturers/users of ASME standards. In the past, they had spent significant time and money to enable them to export equipment designed and built to ASME standards into each of the EU member states. This involved dealing with multiple regulations and inspection requirements and each country required a different solution. With the advent of the PED, everyone went back to square one in trying to figure out how to comply with the one single regulation for all of Europe. Developed under the New Approach, the PED sets down Essential Safety Requirements (ESR's), and then EN standards are developed under a mandate from the EC to comply with the ESR's.

EN standards developed under mandate are granted 'presumption of conformity' to the Directive – any other standard (like ASME's) can be used, but it is the responsibility of the manufacturer to demonstrate that all the ESR's have been met. To help users of its standards, ASME invested over $50,000 to publish guidance documents on how to use ASME standards under the new PED.

This effort identified three key areas where significant effort would be needed for manufacturers/users of ASME standards to comply with the new PED: materials of construction, qualification of personnel performing nondestructive examination (NDE), and qualification of welders.

Materials

European (EN) material specifications are afforded presumption of conformity to the PED. To use any other materials (such as ASME's), it is necessary to obtain European Approval of Materials (EAM), or

perform a Particular Material Appraisal (PMA). Early on, ASME invested over $10,000 to submit a series of its material specifications for approval under the EAM process.

The EC denied the request, citing that the materials were similar to existing EN specifications, so EAM's could not be issued. That meant that users of ASME's standards had to perform PMA's for every material used in construction. PMA's involve demonstration to the notified body (inspection organization) that all ESR's for materials have been met. This is a costly and time consuming process, as manufacturers must spend up to $10,000 for each grade of material appraised, and manufacturers utilize dozens of materials in construction.

One bright spot is that once an appraisal is performed, it can be reused for future construction under similar design conditions, but only by the manufacturer who conducted the original appraisal. ASME standards committees have been investing many hours of labor to adopt EN material specifications for use in ASME construction to help PE manufacturers and other ASME users avoid costly PMA's. The three most commonly used EN steel specifications have already been adopted and work continues on several more. There is no equivalent process for general acceptance of ASME materials either in the EN standards system or under the EC PED.

NDE and Welding Personnel Qualifications

The ASME and EU systems for qualifying technicians performing key functions (NDE and Welding) differ significantly. Under the ASME system, the manufacturers are responsible for qualifying such personnel in their employ. The EU system utilizes third party qualification organizations. To comply with the PED, PE manufacturers using ASME standards have to requalify their personnel to an EN standard using a European Recognized Third Party Organization (RTPO) for testing and approval – a costly and time consuming process.

In Europe, there are many RTPO's to choose from, but there are few operating in the United States. Again, it costs thousands of dollars to qualify one technician under the EU process, and each manufacturer employs many such technicians. However, once the qualifications have been performed, they can be used for future work – it is essentially a one-time expense. ASME standards committees again spent many hours developing revisions that allow a manufacturer to utilize a third party approval organization for NDE personnel. This acceptance of the European process eliminates duplication of effort for those ASME users who sell into the EU, while still allowing those doing only local business to continue with their traditional NDE qualification program.

PED IMPACT ON EUROPEAN PE STANDARDS

Long before the creation of CEN in 1975, major European countries like Germany, France and UK developed their own standards for PE. In Germany and France, they were developed by industry coalition organizations, while in the United Kingdom (UK), the British Standards Institute (BSI) held the secretariat. When the PED was introduced, the New Approach mandated that CEN develop harmonized European standards to provide presumption of conformity. Under European rules, once an EN standard has been developed, EU national standards bodies must withdraw their own national standards and adopt the EN standard. In France and Germany, the national standards body had no jurisdiction over pressure equipment standards, and both industry organizations chose to maintain their PE standards and work to make them comply with the ESR's of the PED. In the UK, BSI withdrew its national standard and redesignated it as a "public document," thereby enabling its continued use in the PE market, while

also working to make it comply with the ESR's. This demonstrates that in the PE sector, European industry (similar to the global industry) chooses to avail themselves of multiple standards solutions in a sector that utilizes complex engineered equipment.

Contrary to the rhetoric of the EU and the EC, there is no "one standard" solution to the needs of the global PE market.

ADDITIONAL DIFFERENCES IN REGULATORY APPROACH

It should also be noted that PE is regulated at the state/provincial level in the United States and Canada, whereas the European Commission has ultimate regulatory authority under the PED.

**COMMERCIAL NUCLEAR**

Commercial nuclear is regulated much differently than PE. As there is no European Directive in this area, there are no European Union (EU) standards. The Europeans will note that there are no mandatory standards anywhere in Europe, however a company shipping equipment to France would not be allowed to use any standard other than the French standard.

The Codes and Standards used depend on the supplier of the plant. For the Areva Evolutionary Power Reactor [EPR], French Codes and Standards are used [for the Westinghouse Advanced Passive [AP] 1000 and the General Electric Advanced Boiling Water Reactor (ABWR) ASME would be used].

When accepting a design for a plant to be installed, the regulator decides which codes and standards will be used, depending on the supplier of the plant. For example, for the Areva EPR under construction in Finland, the Finish regulator specified the French Codes and Standards [if the Westinghouse AP1000 had been selected, ASME would have been specified].

There are two Standards Developing Organizations (SDO's) in Europe that promulgate standards equivalent to ASME Nuclear Codes and Standards. In France, the French Association for the rules governing the Design, Construction and Operating Supervision of the Equipment Items for Electro Nuclear Boilers [AFCEN] promulgates the equivalent of the ASME Boiler and Pressure Code (BPV) Section III. In Germany the SDO is the Nuclear Safety Standards Commission (KTA).

Standards development in Europe is very different than standards development in the United States. ASME standards development is done using an open, transparent process and anyone can attend the meetings and participate. In Europe, participation is by invitation only. Recently, KTA agreed to form a German International Working Group under ASME BPV III.

Multinational Design Evaluation Programme (MDEP)

The Multinational Design Evaluation Programme (MDEP) was established in 2006 as a multinational initiative to develop innovative approaches to leverage the resources and knowledge of the national regulatory authorities who are currently or will be tasked with the review of new reactor power plant designs. Current MDEP members include national regulators from: Canada, People's Republic of China, Finland, France, India, Japan, Republic of Korea, Russian Federation, Republic of South Africa, United Kingdom, and the United States.

The MDEP Codes and Standards Working Group (WG) engaged the major SDO's from the USA, France, Japan, Korea, Canada and Russia (ASME, AFCEN, Japan Society of Mechanical Engineers (JSME), Korea Electric Association (KEA), Canadian Standards Association (CSA), and Research and Development Institute of Power Engineering (NIKIET) respectively) to participate in a code comparison project where the various codes were compared to the ASME Code (all of the other codes were originally based on the ASME Code but diverged over the years). The report has been published and is available free of charge.

Subsequent to the finalization of the code comparison report, the MDEP WG asked the SDO's to explore ways to converge the various codes and standards used around the world. This request led to the establishment of the Code Convergence Board that has been meeting regularly to discuss potential ways forward. Further, it must be recognized that changes made by SDO's must be evolutionary rather than revolutionary because even apparently minor changes can have a major cost impact in the nuclear power industry.

Codes and standards are intertwined with regulatory and accepted industrial practices. Therefore all revisions to codes and standards must be accepted by the regulators before being used by industry, before deciding to recognize the use of a code or standard, the regulator needs to review the document to determine if the new requirements will, if implemented, assure an adequate level of quality and safety. It needs to be understood that if the various regulatory bodies fail to act to recognize converging code rules, the SDO's will probably stop participating in the Code Convergence Board.

The MDEP effort demonstrates that technical convergence/cooperation does not necessarily lead to regulatory/administrative convergence.

**ELEVATORS/LIFTS**

An initial meeting between ASME and CEN on elevators/lifts was held in conjunction with the ANSI-European Standards Organizations (ESOs) Joint Presidents Group Meeting in Dublin, Ireland February 12, 2013. While ASME would be willing to discuss with CEN potential collaboration opportunities, ASME currently does not have any agreements of cooperation in place with CEN or CEN TC10. Should CEN wish to pursue specific recommendations and areas for potential cooperation, ASME is open to such dialogue but currently no agreements between the two organizations are in place.

**CONCLUSIONS**

ASME applauds the effort to increase transatlantic trade and investment through these negotiations. ASME's experience in these three sectors in Europe led to the development of the following three conclusions:

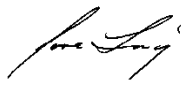
First, certain sectors (like PE) face multiple regulatory approaches around the world. Because different jurisdictions are addressing varying levels of risk, they decide on different regulatory approaches. While this creates more market segmentation for PE manufacturers, the WTO TBT Agreement and other guidance allow for such differences. PE manufacturers understand and appreciate this situation, but just need to know what regulations apply and how to meet them. While variations between the U.S. and European PE regulations did lead to increased costs and inefficiencies for both ASME and PE

manufacturers using ASME standards, those costs have mostly now been incurred and arbitrarily changing the system again would likely create unnecessary market disruption and even more costs.

Second, technical convergence/cooperation does not necessarily lead to regulatory/administrative convergence. It would be wrong to assume that increased alignment or harmonization of standards will necessarily lead to increased regulatory compatibility.

Third, there may be sectors, such as elevators/lifts, where increased cooperation between the relevant European Standards Organization and another SDO may lead to increased regulatory compatibility. Such discussions need to take place between technical, not political or administrative, entities and need to make business sense for the organizations involved.

Respectfully submitted,



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