IPC014-09

From: Theresa Zuraski [TZuraski@aami.org]

Sent: Friday, September 04, 2009 4:55 PM

To: Steve Cornish

Subject: RE: FOR REVIEW: proposed ANSI paper, "Liberalizing Regulation, Trade, and Development: Choosing Standards Based on Merit"

Attachments: AAMI comments on Merit paper.doc

Steve: Here are my comments. To be honest, I found it very difficult to wade through this a second time and I may have missed some new problems with the paper that were not there before. I tried to create a redline/strikeout version but that is not easy to do with all the fancy boxes and formatting.

One new point that I touched upon, and which I feel very strongly about, is the whole process of developing ANSI positions in broad groups and committees where most are not impacted by the thrust of whatever people are being asked to comment on or approve. I've observed over the years that most people will vote yes (no comments) rather than abstain, or absence of objection is deemed to mean acceptance rather than "don't care." This is not a phenomenon just within ANSI -- it's generally true for many associations -- and sometimes it may even be appropriate. However, when it comes to something that the affected interests feel as strongly about as how standards are used in regulation, I think it is worth reconsidering how and by whom these decisions are getting made.

Perhaps ANSI needs to consider adding some committees who could be consulted as appropriate for input on strategy based on the types of standards they are involved in/subject to (e.g., safety, IT, test methods, standards used in regulation, process control, etc). It may be that based on type of standard, there are good reasons to have different positions and strategy and that these can exist side-by-side within ANSI. However until we start thinking in those terms, we will continue to seek a single solution when there may not be one.

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4 September 2009

AAMI comments on *Liberalizing Regulation, Trade, and Development: Choosing Standards Based on Merit*

Background: The Association for the Advancement of Medical Instrumentation (AAMI) is a professional association of around 6,000 professionals from health care facilities, government agencies, medical device manufacturers, academia, and other associations. AAMI's main programs include standards development, education, certification of biomedical equipment technicians, and publications that address various healthcare technology management issues. AAMI is a leading developer of national and international standards for medical devices and other healthcare products, specializing in standards that have regulatory implications. The medical device industry is a major user of the voluntary standards system and one of the most highly regulated industries in the world. In the U.S., the industry is regulated primarily by the federal government although occasionally states enact or consider enacting legislation related to medical devices.

General Comments

The paper should focus either on use of standards by regulators for regulatory purposes, or on use of standards by government procurement agencies and others for "trade and development" purposes, rather than mingling the two. It is also confusing why there is so much focus on use of standards by government agencies for procurement as opposed to use of any other type of customer for that purpose.

With regard to use of standards in a regulatory context, it is highly questionable whether any paper is needed. However, if ANSI believes there is a need for this type of paper, it should draft a paper that puts forth a point of view that is based on a consensus of the directly and materially affected parties in the U.S. – i.e., representatives of regulated industries, regulators and users/consumers of regulated products – on what is in their best interests with regard to international standards used to support technical regulation. If those representatives do not agree a paper like this is needed, believe it could be more detrimental than helpful to their interests to issue such a paper, or if they are unable to agree on what the "compelling and interesting story" is, ANSI would be doing more harm than good to itself, particularly with respect to its reputation amongst regulated industries, and those of its members who would be affected by ANSI taking this position. Furthermore, the entire paper, with regard to use of standards in regulation, should be drafted by that group and completely replace the portions of this document dealing with regulation and standards.

We consider it extremely inappropriate for ANSI, as a membership association, to feature a handful of its SDO members in a "policy" paper to the exclusion and possible detriment of all other SDO members. Even if ANSI did not author the paper or pay the contractor who wrote it, we still were greatly surprised that ANSI would agree to circulate such a document for review by any of its committees or forums in this state. Either all SDOs should be equally featured, or none. This is not just a matter of asking other SDO's if they want to have their own examples included. Clearly various associations belonging to ANSI compete with one another for members, standards work and sales, and in other ways and ANSI should not put itself in the position of favoring, or appearing to favor, some members over other members. All of the references to what specific SDO's are doing should be replaced by what different sectors are doing in their approach to international standards.

Our preference is that ANSI drop this project entirely. Failing that, we think the best thing is, as noted previously, to split the paper in two and to form two task groups of members with an interest in pursuing these projects to re-write the papers so that they are more general, much shorter, relate to and support the strategic objectives of the directly and materially affected interests (industry, users/consumers, government) who are most impacted by international standards and ANSI's effectiveness in international organizations that it is a member of, on their behalf, such as ISO and IEC.

Specific comments

Any paper on use of voluntary standards by regulators needs to cover the following major points:

1. Voluntary standards should remain voluntary

   Throughout, the paper cites examples of regulators incorporating standards into regulation, talks about standards as the "basis for technical regulation," etc. If a standard, in whole or in part, is incorporated into regulation it ceases to be voluntary. This diminishes the value of being able to modify standards quickly (or at least more quickly than regulation can be changed) as technology changes, and allowing manufacturers the ability to argue that a specific device, for a specific reason, should not be required to meet a standard or a certain portion of a standard, but nevertheless meets the regulatory requirement and is safe. In medical devices, for example, neither the U.S. nor Europe (which together represent three-quarters of the world market) require that manufacturers meet standards. However, they do allow manufacturers to use voluntary standards as evidence that they meet regulatory requirements. In the case of Europe, meeting standards recognized by the EU as harmonized documents provides a presumption of conformance with the medical device directives. In the U.S., meeting voluntary standards that are recognized by the FDA can help expedite the review process though there is less of a direct relationship between standards and regulations as in Europe.

2. Who gets to choose (from the title and elsewhere in the document), and what are they choosing?

   If national governments are choosing what standards they are going to mandate industry to meet, and they choose different and conflicting "international" standards, this is hardly in keeping with the WTO TBT Agreement or with the interests of U.S. industry and consumers. Perhaps this is not the intent of the paper, but it appears to be encouraging that governments choose what standards to impose on industry (and therefore on consumers, since these standards affect what products are available to consumers, cost, etc). International standards, particularly when they have quasi-regulatory authority because of their use by regulators, are only effective in reducing or eliminating trade barriers if all governments choose the same international standard or group of standards to apply to the same product. Otherwise, we are back to 20 years ago when every country wrote its own national requirements and industry had to try to determine what was the same, what was different, and to meet the most stringent requirement or otherwise deal with conflicting requirements. Encouraging government to turn voluntary standards into mandated standards does not seem like a good way to convince industry (particularly at the CEO level) that it is worthwhile to participate in voluntary standards!

   Another type of choice would be to suggest that if there are several different standards for the same thing and government found all of them acceptable, then government could offer industry the choice of which standard it would use to show compliance with a regulation. Provided all of the national regulators had at least one standard on its "approved list" in common, it would deal with the problem of forcing industry to deal with different requirements for different markets noted above. However, we do not see that happening on a global basis and as one of my members put it, "We have a hard enough time just getting them to recognize a single standard and keeping up to date with it." Another major drawback to this concept is that most governments (at least in the U.S. and Europe) want to participate in standards activities that ultimately will be used by them, and industry certainly wants a voice in standards that will affect their products, so having duplicative international standards activities is very expensive for the participants.

   A third type of choice, which makes much more sense relative to the "multipath approach," is for the various interests (government, industry, users/consumers) to choose what organization they will use to develop international standards for a given type of product, test method, etc. This is easier to do with a confined and homogeneous industry like aerospace (one of the examples in the paper) than for industries such as medical devices, however, it is the only type of "choice" that makes sense in the context of promoting the value of international standards

to support international trade, harmonized regulations, etc.

3. Transition periods. No paper on the use by regulators of voluntary standards is complete without addressing transition periods. See ISO paper on standards and regulations for suitable text (suggested by U.S.) and/or *ISO/IEC Directives, Supplement – Procedures specific to IEC*, 2009 edition, clause 16.

4. National deviations. The example in Box 3 where the Chinese government wrote its own standard based on two other standards, while it may be true, is not in keeping with overall goals – e.g., having the government rely on voluntary standards rather than writing their own mandatory standards, keeping standards voluntary, etc. At the same time, there is a need to deviate from international standards ("global relevance") on occasion, but why not suggest methods that support U.S. interests and are more in keeping with the spirit of international adoption?

   AAMI, for example, has adopted numerous ISO and IEC standards and while most are verbatim adoptions, we also have adopted with deviations. The committee keeps the deviations to the least necessary to make the standard acceptable in the U.S.; only does technical deviations (i.e., the organization and text of the majority of the document are identical to the international standard, which reduces the possibility that technical equivalence has been lost), and indicates in the document each of the specific differences and why the U.S. decided to deviate. This makes it possible for manufacturers who sell in the U.S. as well as other markets to quickly and easily determine how the U.S. standard differs from the international standard. In addition, documenting the rationale for the change has led in some instances to the international community eventually modifying the international standard to be in alignment with the U.S. deviation, either through amendment or during the next revision. Last and perhaps most importantly, this method allows industry, government, and consumers/users to work together through the voluntary consensus process to decide on what national deviations are necessary and keeps the standard voluntary, rather than the government unilaterally deciding on deviations and making them mandatory.

5. International participation versus International acceptance – We disagree that having people from outside the U.S., by itself, make standards developed by US-based organizations "international." For example, foreign companies may participate on committees writing American National Standards because they sell in the U.S. and want a say on standards that impact products they export to the U.S. Particularly when discussing standards that are formally recognized by regulators, the only thing (from the perspective of our members) that makes a standard "international" is that the majority of regulators in countries where they sell their products are using the same standard.

   We also would note that participation by a government employee, even when they approve a document and are representing their agency on the committee, does not constitute by itself endorsement by that government agency. Recognition, adoption, etc. is a whole separate process.

   Last and perhaps most importantly, we are very concerned about the concept that any national standards-setting organization, provided they allow participants from outside of their country on their committees consistent with the WTO TBT, can claim their documents are "international" and promote them for incorporation into regulations around the world. Obviously that leaves the door open to other countries making such claims and the undesirable situation of different national regulators using different, and conflicting, national standards – claiming that they are actually "international" because the committee that wrote them had some people from other countries participating – which is completely contrary to the concept of using international standards to promote free trade.

Technical comments.

While it would be hard for me to agree that ANSI should support this paper as written since it is so contrary to the standards goals of my members, in the event ANSI decides to lend its name to this paper it should at least make the following technical corrections.

Box 2 – If you retain examples citing specific SDOs, the last two sentences of para 1 should be replaced by: "One such example is the three-part ISO 11137 series on *Sterilization of health care products – Radiation* The first edition of the ISO series was heavily based on two American National Standards (ANSI/AAMI ST31 and ANSI/AAMI ST32) and adopted back by AAMI as a revision of its documents. Through the ISO revision process, new AAMI guidance has been incorporated into later editions of the ISO standard and adopted back by AAMI. Current editions are recognized by FDA, approved by CEN, and recognized by industry and regulators around the world."

On page 19-20, the paper mixes IEC in with ISO giving the appearance that IEC is somehow subservient to or a part of ISO. Either just discuss ISO participation or have a separate topic for IEC (preferred option).

Box 7 – The final paragraph before the list at the end of the box, sentence 4, should read "Levels of electrical and mechanical safety parameters <u>for PET devices</u> are addressed….. Otherwise it implies the list at the end of the box is the exhaustive list of all standards recognized by FDA for all medical devices which is far from the case. Also, the last sentence of this paragraph should be on its own line as it is the beginning of the list of standards introduced by this paragraph

Regarding the list itself in Box 7:

- As noted in my comments on the May version of this document, I checked the FDA and CEN websites and EN 1441 is no longer recognized by the FDA and is no longer a European standard. ISO 14971:2007, *Medical devices - Application of risk management to medical devices,* is the document currently recognized by FDA, it is also an ANSI/AAMI/ISO standard (identical adoption) and a European Norm (EN/ISO 14971).
- UL 2601-1 – Again, I checked the FDA website in May and this does not appear on their list of recognized standards. They do recognize the 2nd edition of IEC 60601-1, and this summer they intend to recognize, at least in part, the 3rd edition.
- You might check with the NEMA imaging group (TAG administrator for IEC/SC 62B) about whether there are any IEC standards that address the safety aspects of PET scanners and that should be added to the list. It's not an area AAMI works in so my knowledge is limited to the horizontal standards that were listed.
- The note in bold at the end does not obviate the need to correct the list per my earlier comments. If you are going to give a snapshot of what FDA/CDRH has recognized, it should be accurate at the time you issue the paper. In addition, it is mixing up what standards are current (per the standards developer) and what standards are currently recognized by FDA, which is what this list purports to be by the introductory paragraph, "These standards are also recognized by CDRH:"

  FDA recognizes a number of superseded documents. At times this is because there is a delay in their approval process and the standard approval process, however at times it is because they do not agree with the newer edition. Sometimes they drop recognition entirely, with no apparent connection to the existence (or not) of a later edition. (This is also true, incidentally, of other regulators who recognize standards for medical devices.) It is therefore misleading to imply in the N.B. that there is any kind of connection between "current standards" and standards that are currently recognized by FDA. Therefore, either delete the N.B. (and correct the earlier list), or modify it to read "N.B. The standards listed above were recognized by FDA/CDRH at the time this paper was issued. FDA revises its list of recognized standards two to three times per year and readers should consult the CDRH website to determine what is currently recognized by the agency."

List of abbreviations, p.43 – all acronyms used in the paper should be listed. E.g., AAMI, ISO and IEC are used in the paper but do not appear on this list with their full names.

General Editorial Comment: The paper seems like a research piece rather than something that would persuade; perhaps some of the examples and, eg, the list of WTO members at annex could be removed to reduce the length. Also, there should be a clear statement of purpose at the beginning of the paper. I also found the paper difficult to understand in places (e.g, the last paragraph on p.7).

Thank you for the opportunity to comment.

Submitted by,

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From: Tim Fisher [tfisher@asse.org]

Sent: Tuesday, August 11, 2009 11:09 AM

To: Elizabeth Neiman; Steve Cornish

Subject: FW: FOR REVIEW: proposed ANSI paper, "Liberalizing Regulation, Trade, and Development: Choosing Standards Based on Merit"

Attachments: Choosing Standards on Merit.doc; Annex I WTOnotificationsreferencingUSdomiciledSDOs.xls

Steve: It is an interesting paper and has some good points in it. That being said – we (American Society of Safety Engineers) would not support it.

Some quick points:

1. I am not sure who the actual audience for this is? Based on the e-mail lanague I assume this is for parties outside the United States? Are we trying to make the case that ANSI Standards should trump other standards on an international level? Would this mean the Institute is pushing for American National Standards over ISO Standards? I have read the NSS before and admit to still not being clear as to what is being proposed. Perhaps I am not understanding this paper due to the audience it is meant for?

2. If this is meant to address ANSI Accredited SDOs overall - it really only comes across as an advertisement for the biggest SDOs within ANSI.

3. The paper seems to be going against the ANSI Essential Requirements Document itself. The Essential Requirements Document specifically notes one of our key missions is to avoid conflict and duplication. But, this paper seems to be encouraging conflict and duplication? I noted this: "Hopefully, it will also afford a greater awareness of the importance of freedom of choice and the ability, indeed, the *obligation* of manufacturers and governments to choose the best standards available, the standards that are most relevant to their needs, the standards that have earned their confidence." What does this mean? As an example – are we saying that the United States Government could ignore an approved American National Standard in favor of something from Germany because it might be more convenient?

4. ANSI may wish to move the conclusion up to the front – a summary at the front might be good?

5. This statement is on Page 6: "One of the most important features of the U.S.-based standardization system is that it is open to every nationality." I am not sure what this means – the paper seems to address both domestic standards and international activities. If we are talking about TAGs – there actually is very specific guidance addressing nationalities and opportunities to participate. I think the paper is more about domestic standards but we do mention international activities and TAGs.

6. Page 10: Why would ANSI state the following: "When one of these elements is out of balance, the resulting standard is more likely to be irrelevant, inappropriate, and/or ineffective, *i.e.*, it may be technically interesting or politically expedient, but it serves no real *need*. It may even act as a barrier to trade". Is this meant to be a slap at American National Standards? The initial thought I had when I read it was why would ANSI then administratively approve standards that are irrelevant, inappropriate, and ineffective.

7. I am not sure what this means: "In full consensus standards developing bodies and in non-traditional standards bodies, U.S. Government experts [1] and representatives of governments around the world are members of technical committees and serve in the same category as other technical experts." The term "technical expert" when we talk about domestic standards is generally a very specific interest category. The term "technical expert" had a specific connotation in the old model procedures. Government agencies in most standards initiatives I have seen are generally listed as governmental agencies and are not in the same category as technical experts.

8. "The National Technology Transfer and Advancement Act (NTTAA) became law in the United States in March, 1996". I think this is now referred to as Public Law 104-113. The title above was the name of the bill when approved even though it is still used. The public law should also be cited.

   http://standards.gov/standards_gov/nttaa.cfm

   I could be wrong also but OMB A119 is listed as a note on page 11 as being a predecessor to 104-113. OMB A-119 is still in effect and was revised to specifically address 104-113. Please see below:

   http://www.whitehouse.gov/omb/rewrite/circulars/a119/a119.html

9. From Page 19, Top of the Page: "It is estimated that in the U.S. today there are hundreds of "traditional" standards developing organizations - with the 20 largest SDOs producing 90% of the standards - and hundreds more "non-traditional" standards development bodies, such as consortia. This means that the level of U.S. participation is quite expansive as the groups themselves are comprised of individual committees made up of experts addressing the technical requirements of standards within their specific area of expertise. At year-end 2008, about 200 of these standards developers were accredited by ANSI; there were close to 10,000 American National Standards (ANS)." My thinking is that we should not be including developers if they are not ANSI accredited. I understand how this has been addressed before. But, we seem to be vouching for organizations who have not stepped up to the plate to have their activities vetted via the ANSI accreditation process.

10. Page six – this statement: "A standard's relevance is arguably related to the extent to which it is used." In my view, this is not accurate. For example, we at ASSE have a standard addressing the measurement of slip resistance. It is used on a limited extent since the interested audience is quite small. That being said – its relevance within this specific area is very significant. Bigger is not always better or indicates significance.

Thanks and Regards, Tim at ASSE

From: Bailey Squier [mailto:bsquier@dmis.org]
Sent: Monday, August 10, 2009 10:44 PM
To: Fran Schrotter
Subject: RE: FOR REVIEW: proposed ANSI paper, "Liberalizing Regulation, Trade, and Development: Choosing Standards Based on Merit"

Dear Fran:

You and I go way back, ***way, way*** back – so far you probably don't even remember me. But, even then we had the same dilemma, the same need for American National standards to be accepted by other nations. Even then, it was a quiet, desperate little war for some larger, richer nations to get ***their standards*** accepted, (or imposed upon) other countries, especially in the emerging 3rd world countries, because the economic repercussions could be very beneficial, or devastating. One country in particular, who shall not be named but referred to as France, wanted the entire world to embrace French standards (Normes) and all other world standards were insignificant by comparison. (They even insisted that all ISO standards organizations use French terms, and they still do – but it is not important, so nobody really cares.) They even created a French governmental department to fabricate French words to replace US invented computer terms. We were involved in an economic standards "war" where some governments used standards as an economic weapon, a block for imports from other nations, and all the ramifications thereof.

In my very long lifetime, I have observed that this situation has not changed significantly. Some nations will do ***anything*** to impose their standards on other nations. This 77 page document just sent out for review, seems to re-describe this situation in calm, reasonable, and intelligent terms. But the facts behind them remain the same, and I suppose always will as long as national pride and national economic stability are a concern. I have only scanned the document – who has time to study a 77 page document? – but the essence I see still screams the basic economic challenges. "Use OUR standards, or we will block your economic progress."

I would vote in favor of any position the US takes that does not hand over to any specific nation, nor to any international organization, any carte-blanche authority, or advantage over the US and our national standards. As far as I know, the US is the ONLY nation on this planet that does not have its national standards regulated by the government, nor are our standards developments associated with any government branch or agency. That is probably why the US, and only the US, offers the best choice for standards anywhere in the world. Free enterprise almost demands a free choice of standards. Government dictation of standards would cripple industry – and only industry is capable of creating meaningful standards. And, as always, in free enterprise system, only the best standards will survive. (Remember the video tape recording standards? One just fell by the wayside.) I DO get nervous over the word "liberalizing" because I am not sure what it means in this case, but I hope I have made

my concerns clear.

Best Regards,

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iiar®
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Date: 13 August 2009

To: Frances Schrotter
Senior Vice President and COO
American National Standards Institute
25 West 43rd Street, Fourth Floor
New York, NY 10036

Subject: ANSI Paper; "Liberalizing Regulation, Trade, and Development: Choosing Standards Based on Merit"

Dear Ms. Schrotter,

As an ANSI accredited Standards Development Organization, we support the procedures for standards development that include balance by the entities producing, reviewing and approving the standards. The concept of open, public review for all standards permits full examination by those having expertise in the field but also by those who are influenced by the requirements of the standard.

In our opinion, it is the transparency of the ANSI process that is reason for the adoption of so many ANSI standards into codes and regulations both inside and outside the United States. We also see the use of ANSI standards creating a level playing field for international trade.

We do, however, ask that you reconsider the elimination of Standards for Trial Use as a means of both public review and early dissemination of needed Standards information.

Because ammonia is the most efficient refrigerant available and has zero ozone depletion and zero global warming characteristics, the use of ammonia refrigeration systems is becoming more widespread. The IIAR will continue to create new standards to assist in the safe use of this environmentally benign refrigerant and we believe the ANSI procedures for the development of these standards is essential to insuring their acceptance worldwide.

Sincerely,

A. Bruce Badger

A. Bruce Badger, President

Cc. Executive Committee, SRC, file

From: Steve Oksala [mailto:soksala@scte.org]
Sent: Monday, August 17, 2009 4:10 PM
To: Fran Schrotter
Subject: RE: FOR REVIEW: proposed ANSI paper, "Liberalizing Regulation, Trade, and Development: Choosing Standards Based on Merit"

Fran -

Attached the paper, with my red line thoughts. Overall, I still don't think it is ready for prime time. The primary reason for this that I don't think it comes across as an integrated paper. Rather it is a series of discrete items tacked together. So it doesn't flow. There really isn't anything at the beginning that identifies what is going to be information is being conveyed, why, or to whom. So it isn't apparent what the author is up to, and there is no natural progression from topic to topic. Beyond that, I see three weaknesses.

1. There is a theme that competing standards are a good idea. The trouble is that this is a different message than the idea that we want one standard, but the source could be from a wider variety of places, including US organizations.

2. There is also a theme that standards should be judged by their acceptance. The trouble is that this may not be clear for a while - maybe a long while - and people need to make early decisions. One of the ways they can do that is by reputation, and accreditation is a valuable tool for this. But we don't give that any real credence - in fact we don't spend nearly enough time early to promote process. In the first half of the paper, one could easily infer that ANSI thinks that the only thing that matters is the output.

3. It's easy to see that the author is not familiar with the ICT industry. Not only through examples used, but through the whole chain of thought. There is even a discussion of governments, and ISO and IEC, but ITU isn't even mentioned.

Cheers,

Steve O.

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LIBERALIZING REGULATION, TRADE, AND DEVELOPMENT : CHOOSING STANDARDS BASED ON MERIT

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THE PURPOSE OF THIS PAPER

The purpose of this paper is to stimulate further interest in standards originating in the United States' system of standardization and to increase awareness of the role they already play in the global marketplace.

Hopefully, it will also afford a greater awareness of the importance of freedom of choice and the ability, indeed, the *obligation* of manufacturers and governments to choose the best standards available, the standards that are most relevant to their needs, the standards that have earned their confidence.

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THE U.S. BASED STANDARDS SYSTEM: COMMITTED TO A LIBERALIZED TRADING SYSTEM

International standards are the cornerstones of a liberalized trading system. When used as the basis for technical regulations and developed according to principles recommended by the WTO Committee on Technical Barriers to Trade [1], they are less likely to create unnecessary barriers to trade. International standards can also increase efficiency, enhance the quality of life, and transfer technology from developed to developing countries.

The TBT Agreement delegates certain responsibilities to international standards: (1) they must function effectively and appropriately; (2) they must fulfill legitimate objectives; and (3) they must be relevant. In this context, relevance is associated with regulatory and market needs, as well as scientific and technological developments. In the global market, relevance is associated with a standard's ability to solve real problems in real time.

As a summary, this presents an interesting "convergence" with the main points of Carl Cargill's recent paper (and much of his writing in past years). Because this says, in part by implication, that

1. The openness/fairness of the developing organization is not identified as a factor, so it is the end product that is relevant. How we got there is not. (This – at least in this introduction – does not even note the credibility of the developing organization as a factor in accepting future standards). This is perhaps an unforeseen consequence of trying to broaden the source beyond the big three.

2. Standards must be effective. The problem with this is that this can only be determined at some point in the future after products are being built or services provided that meet the standard. This may well not be determined with any certainty until it is far too late to go down a different path.

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The summary of this is that the world will see a bunch of various documents, some of them conflicting. It will only be after the fact that they will be recognized to be "standards". It also implies that the recognized standards could come from anywhere – even from a private company – so Microsoft Word, for example, fits the definition at this point.

A standard's relevance is arguably related to the extent to which it is used. Technology that originates in standards developing organizations domiciled in the United States is used in countless measure by WTO Members in the efficient production and testing of goods, in international trade, and in technical regulations. The widespread application of these standards is plainly evident from the most cursory examination of the technical regulations

[1] Decision: G/TBT/1Rev.8, 23 May 2002

of Member Countries; evidence that an ample supply of effective, relevant international standards has been produced by a network of standards developing organizations, i.e., *standards used in regulation, trade, and in building the capacity of developing countries around the world emanate from multiple sources.*

Multiple sources of international standards are especially useful to WTO Members. They provide regulators with choice and flexibility while reducing the need to base technical regulations on national standards.

Choice is a two edged sword, since it can be used to justify any number of standards that can be produced by players who want to get in the game. Do we really want to advocate a world of multiple standards? After all, one of the primary benefits of standards is that the prospective purchasers of conforming products don't have to try and determine which of the many standards (=products??) are best.

One of the most important features of the U.S.-based standardization system is that it is open to every nationality; its technical committees abound with experts from around the globe. No less important is its commitment to the TBT principles for the development of international standards [2] and the Code of Good Practice[3].

A good point, but it should have been raised earlier in the context of whether or not the nature of the SDO is relevant to the process. (See above). I expect that others, e.g. ETSI, could make a similar claim.

The U.S. based standardization system produces many international standards that do not exist elsewhere. It produces standards and test methods that are unique

Why is this good?

and standards that have given rise and safety to many of civilization's best endeavors, from the construction of basic infrastructures to the exploration of space.

There is something wrong with this sentence. The phrase "and safety" seems out of place.

These standards have become so deeply rooted in the texture of the world's economies that their absence or the lack of ongoing revisions to their technology would destabilize large areas of international trade and significantly reduce the quality of life on this planet.

This is a guide to a deeper understanding of this system, and the opportunities it offers regulators and exporters to use standards that are best suited to perform specified tasks, whether they are local or universal. A comprehensive map of the immense flow of technology from this system into the world at large is not practical; indeed it is not possible.

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[2] ibid.

[3] See Annex 3 of the TBT Agreement

This paper offers only a representational view of that flow, using examples taken from a large, diverse network of stakeholders.

The significance of the global usage of standards, whatever their origin,

See comments above; do we really want to say “whatever their origin”?

must be acknowledged, viewed, and weighed alongside the notion that the form taken by standardization models must take precedence over universal acceptance and relevance. The more pertinent question(s), in terms of a liberalized trading system, are (1) whether or not a standard facilitates or poses an obstacle to trade, and (2) whether or not a standard is effective and relevant to market needs and conditions.

WHAT IS MERIT?

Merit used as a noun is defined as "worth or excellence; high quality; defined as a verb, merit means "To earn as a reward or punishment; deserve."[4]

Assigning worth, or merit, to a standard is precarious at best, for what constitutes merit in the eyes of one may not constitute it in the eyes of another. In the case of merit, one size does not fit all.

That being said, there are general, or horizontal, positive attributes that can be assigned to a standard, whatever its technical objective. The assignment of merit can begin with the process that creates it. Here, there are accepted guidelines, such as the TBT Committee's *Decision On Principles For The Development Of International Standards.*[5]

Consistent with earlier comments. Here is a place where the openness of the ANSI system can be a significant point. But we do not make it. We don't even discuss the basics of the TBT criteria.

Other primary tests can be applied to a standard, also taken from accepted principles: The TBT Agreement, for example, requires that a standard be *effective* and *relevant*, and that it not act as a *barrier to trade*.

It can be argued that *use* is a benchmark of merit; that is, the standard has earned the confidence of a wide range of users. Users apply their own tests: Is the technology advanced? Does the standard produce highly reproducible results? Does it bring about the desired level of change or increase in quality? Is it current and updated regularly? Does it meet the user's expectations? Will it open markets? Is it doable? A regulator might require that a standard carry a reasonable expectation of compliance, or a credible rationale for its application. While some of these values may be anticipatory or subjective, a standard, in the most practical sense, is only as good as its user deems it to be. For the user, that can only be determined when the standard is *applied* and the results are calculated. Merit is an attribute, therefore, that is *earned after the standard is in play.*

While the concept of merit is important in the context of this paper, and while the direct or implied merits of standards are imbedded in the examples herein, the *freedom to choose* a

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[4] Standard Desk Dictionary, Funk & Wagnalls, Harper & Row, Publishers

[5] Decision Of The Committee On Principles For The Development Of International Standards, Guides And Recommendations With Relation To Articles 2, 5 And Annex 3 Of The Agreement G/TBT/1/Rev.8, 23 May 2002

standard based on performance, suitability, effects, i.e., its *merits*, is the key to liberalized regulation, trade, and development.

I addressed this earlier. I think it is a mistake for ANSI to say , in effect, that having competitive standards for the same thing is good – because that is what this paragraph says. That makes it difficult for the potential user; it is but one step removed from proprietary systems. It also makes it much easier for a country to develop its own standard and give preference, even indirectly, to it.

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WTO TECHNICAL BARRIERS TO TRADE AGREEMENT

The TBT Committee, in its *Decision On Principles For The Development OfInternational Standards* [6] notes that "Bodies operating with open, impartial and transparent procedures, that afforded an opportunity for consensus among all interested parties in the territories of at least all Members, were seen as more likely to develop standards which were effective and relevant on a global basis and would thereby contribute to the goal of the Agreement to prevent unnecessary obstacles to trade."

Finally!

The United States-based standardization system recognizes the principles outlined in the Decision of the TBT Committee as the ultimate authority

I find the use of the phrase "ultimate authority" a little frightening, since it implies something more legally than exists.

on the development of international standards. Furthermore, it recognizes that U.S. based standards developing organizations that apply these principles to their standards setting process are developing standards that are effective, relevant, and contribute to the goal of the Agreement. [7]

In addition, the American National Standards Institute (ANSI) has accepted the Code of Good Practice on behalf of more than 200 standards developing organizations in the United States.

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[6] Decision Of The Committee On Principles For The Development Of International Standards, Guides And Recommendations With Relation To Articles 2, 5 And Annex 3 Of The Agreement G/TBT/1/Rev.8, 23 May 2002

[7] See the U.S. Standards Strategy at www.ansi.org

RELEVANCE AND EFFECTIVENESS

The TBT Agreement requires Members to use relevant international standards, or the relevant parts of them, as a basis for technical regulations except when they would be ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued.

The TBT Committee's Decision on Principles for the Development of International Standards also states, "international standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries."

Ideally, industrial policy considerations, technical problem solving, and market needs converge in an international standard. When one of these elements is out of balance, the resulting standard is more likely to be irrelevant, inappropriate, and/or ineffective, *i.e.*, it may be technically interesting or politically expedient, but it serves no real *need*. It may even act as a barrier to trade.

A barrier to trade fulfills a need. Not what we want, but ....

When a standard satisfies only the objectives of a limited geographic or economic region, the *internationality* of the standard may also be called into question.

There are fields of technology and significant elements of trade where the international standardization organizations that are sometimes called *formal* or *traditional* supply only a fraction of relevant standards, and in some cases, none at all. For example, most Internet standards adopted by the Internet Engineering Task Force[8]

This is an interesting case. IETF's rules are such that I suspect it would be a stretch to consider that it meets the TBT criteria. This does not mean that IETF is not a good organization that produces good stuff. It does call into question whether the criteria needs to be revised to reflect today's world.

or the World Wide Web Consortium[9] would not "qualify" (according to Waymund Werle, 2001)[10] as international standards on which regulations or other standards should be

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[8] The Internet Engineering Task Force (IETF) is a large open international community of network designers, operators, vendors, and researchers concerned with the evolution of the Internet architecture and the smooth operation of the Internet. It is open to any interested individual.

[9] The World Wide Web Consortium (W3C) is an international consortium where Member organizations, a full-time staff, and the public work together to develop Web standards.

based. Few, however, would doubt their international application, universal acceptance, and use.

A large volume of standards and testing methods that emanate from the U.S. system are transposed into the national portfolios of WTO Members and/or are used as the basis for technical regulations; i.e., they play internationally significant roles in trade, they are imbued with the qualities of relevance, appropriateness, and effectiveness, they facilitate trade, and do not act as barriers to trade. (See Tables A and B).

N.B. The examples in Tables A & B exemplify standards developed in the U.S. system that are used in the technicalregulations of WTO Members. The magnitude of their numbers, however, and the extent of their reach are better understood when viewed from a perspective such as that of the WTO Notification process. Please refer to Annex I.

[10] Raymund Werle, Max Planck Institute for the Study of Societies, Cologne, Germany, *Standards and Standards Organizations in the International Free Trade Regime*, presented at the Workshop on Standardization Research, Universitat der Bundeswehr Hamburg, September, 2001.

U.S. POLICY: THE NATIONAL TECHNOLOGY TRANSFER AND ADVANCEMENT ACT (NTTAA)

The National Technology Transfer and Advancement Act (NTTAA) became law in the United States in March, 1996.[11]

The thrust and intent of the NTTAA is congruous with the Technical Barriers to Trade Agreement in that it directs the U.S. Federal Government to use standards developed by private sector standards organizations, to participate in the development of standards, and to notify an appropriate government office when it does not or cannot comply with the first provision.

THE ROLE OF U.S. AND OTHER GOVERNMENTS IN THE STANDARDS DEVELOPMENT PROCESS

In full consensus standards developing bodies and in non-traditional standards bodies, U.S. Government experts[12] and representatives of governments around the world are members of technical committees and serve in the same category as other technical experts; *i.e.*, they are stakeholders. Given their interest and investment, long before the enactment of the NTTAA[13] and to the present day, it is not surprising that government agencies are also the greatest users of these standards, citing them in regulations and in procurement contracts.

The relationship between U.S. SDOs and governments is often characterized as a partnership. The enactment of the NTTAA, the increase in government participation, and the use of voluntary standards has made government regulation and procurement more efficient and more globally relevant, especially when U.S. government representatives serve alongside their counterparts from other WTO Member countries.

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[11] http://ts.nist.gov/Standards/Conformity/nttaa.cfm

[12] Federal, State, and Local

[13] And its predecessor, OMB Circular A-119

The Tenth Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment [14] reports that 4,075 U.S. Government agency representatives were participating in 413 standards developing organizations in fiscal year 2006.

The report also cited measurable benefits from this collaboration, as evidenced by a reported $1.5 million in annual savings and 25,000 pages of regulations avoided by the Coast Guard through adoption of private-sector standards; a 90 percent reduction in baby walker injuries; and savings of hundreds of thousands of dollars in the inspection and testing of fire protection systems since the 1990s when the Department of Energy adopted private-sector standards addressing this area.

One outstanding example of public-private partnering concerns the Environmental Protection Agency (EPA) and the IEEE. EPA was actively involved in the development of the Electronic Products Environmental Assessment Tool (EPEAT), a tool that helps purchasers select and buy greener computers, laptops, and monitors. The criteria were developed with input from over 100 stakeholders and finalized through the consensus process run by IEEE into the IEEE 1680 *American National Standard for the Environmental Assessment of Personal Computer Products*. EPA projects that over the next five years, purchases of EPEAT rated products will result in reductions of more than 13 million pounds of hazardous materials, 3 million pounds of non-hazardous materials, and 600,000 megawatts of energy. The EPEAT program has gained solid interest in the EU, China, and India, and is expected to have a broad international impact.

There is no mention in this paper, as far as I can tell, of the ITU (or any other government run standards process that allows private sector participation). Given the importance of telecommunications, this seems like a big omission.

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[14] NISTIR 7413, April 2007 at www.standards.gov

ADOPTING, REFERENCING, AND USING

Governments use standards developed by voluntary SDOs in several ways. Some of the most common methods are listed below and illustrate the approach taken by the United States.

BOX 1. ADOPTION, REFERENCING AND USING STANDARDS IN THE U.S.

- **Adoption**: An agency may adopt a voluntary standard without change by incorporating the standard in an agency's regulation or by listing (or referencing) the standard by title. For example, the U.S. Occupational Safety and Health Administration (OSHA) adopted the National Electrical Code (NEC) by incorporating it into its regulations by reference.
- **Strong Deference**: An agency may grant strong deference to standards developed by a particular organization for a specific purpose. The agency will then use the standards in its regulatory program unless someone demonstrates to the agency why it should not.
- **Basis for Rulemaking**: This is the most common use of externally developed standards. The agency reviews a standard, makes appropriate changes, and then publishes the revision in the Federal Register as a proposed regulation. Comments received from the public during the rulemaking proceeding may result in changes to the proposed rule before it is instituted.
- **Regulatory Guides**: An agency may permit adherence to a specific standard as an acceptable, though not compulsory, way of complying with a regulation.
- **Guidelines**: An agency may use standards as guidelines for complying with general requirements. The guidelines are advisory only: even if a firm complies with the applicable standards, the agency may conceivably still find that the general regulation has been violated.
- **Deference in Lieu of Developing a Mandatory Standard**: An agency may decide that it does not need to issue a mandatory regulation because voluntary compliance with either an existing standard or one developed for the purpose will suffice for meeting the needs of the agency.

Source: www.standards.gov

TOY SAFETY: A FEDERALLY MANDATED SPECIFICATION

When drafting legislation to strengthen existing consumer product safety law,for example, the U.S. Congress recognized that there was already a national consensus standard for toys that was suitable for mandatory use across the industry. Under the terms of the U.S. Consumer Product Safety Improvement Act (CPSIA) of 2008, the A STM International Standard for toy safety, ASTM F963, became a federally mandated specification on February 10, 2009. Maintained by ASTM International Committee F15, Consumer Products, and its Subcommittee on Toy Safety, updates to the standard are submitted to the U.S. Consumer Product Safety Commission for consideration. Following review by the CPSC, the new edition of the standard may become effective under the law.[15]

EFFECTUAL REGULATION

Ideally, international standards function as the basis of the regulations of multiple markets, facilitating trade and creating regulatory harmonization as well. In reality, the needs and capabilities of the economies of the world vary; and regulators must often improvise technical solutions to match national or local customs or capabilities. They may use standards from various sources, the relevant parts of standards, combinations of standards, or modifications of standards. In other words, regulators routinely take pragmatic paths to regulatory destinations. (See Boxes 2 and 3).

The key to effectual regulation is *flexibility and freedom of choice*.

[15] U.S. toy safety standards and regulations are considered among the most stringent in the world and provide the model for many of the rules introduced in other countries. Input from the U.S. has also helped to shape the development of the International Or ganization for Standardization's family of toy safety standards, ISO 8124.

BOX 2. THE FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

One example of regulatory flexibility is employed by the United States Food and Drug Administration (FDA). The Food and Drug Administration Modernization Act of 1997 authorized the FDA to recognize voluntary consensus standards developed in an open and transparent process, such as those employed by U.S. domiciled Standards Developing Organizations and the International Organization for Standardization (ISO). These standards can also be developed in a U.S. standards-based organization and adopted as an ISO standard. One such example is ANSI/AAMI/ISO 11137, *Radiation.*

The FDA also lists (as of January, 2008) about 150 American National Standards.

BOX 3. TEST METHOD FOR EVALUATING COATINGS USED IN PRESSURIZED WATER REACTOR NUCLEAR POWER PLANTS AT SIMULATED DESIGN BASIS ACCIDENT (DBA) CONDITIONS

- Issued by the China National Nuclear Corporation and published in the Nuclear Industry Codes and Standards in the People's Republic of China

This standard, an example of freedom of choice, was written based on two standards, American ASTM D3911-95, *Standard Test Method for Evaluating Coatings Used in Light-Water Nuclear Power Plants at Simulated Design Basis Accident (DBA) Conditions* and French standard NF T30-900-1996 *Color Painting and Varnish: Test Method for Performance and Repairability of Coatings Used in Nuclear Industry at Design Basis Accident Conditions.* Due to the similarities in theory and methodology of both standards and differences in characteristic test curve of temperature-pressure, spray solution and specimens, this standard combined the similarities of both above standards and listed the differences as selective choices for users.

This standard is regulated by the Institute for Standardization of the Nuclear Industry and was prepared by CHI Zhaohua, CUI Lan, TANG Meiling, and LIU Wei. Date of Issue: 10/13/98 Date of Execution: 01-01-98

INTERNATIONAL PARTICIPATION

The standardization system based in the United States holds to the proposition that bodies which operate with open and transparent procedures which afford an opportunity for consensus among all interested parties will result in standards which are relevant on a global basis and prevent unnecessary barriers to trade.[16]

International experts can and do populate the technical committees of U.S.- based standards organizations. They represent companies, consumers, government agencies, and standards bodies. They may also represent countries that do not have a standards body. International members also participate in the governance of these SDOs and serve on policy-making committees and Boards of Directors, expanding technical and policy perspectives beyond those held by the United States. *See Table C.*

[16] G/TBT/W/40

THE SECTORAL MODEL

The organizational model that characterizes standardization in the United States can be referred to as the Sectoral Model. Standardization in the U.S. is decentralized and takes place in sector-specific bodies. While there are SDOs in the United States with unlimited scopes of interest[17], most standardization is organized into groups that share common industrial or disciplinary interests.

The hallmark of the Sectoral Model is efficiency. Each sector determines what aspects of standardization are most important to it: Speed, for example, is paramount in industries where technological innovations occur in rapid succession. Broader governmental representation may be required when the aim of standardization is in the public interest, i.e., the creation of health or safety regulations.

I think there is a general point to be made, at least by some, that there are many standards having nothing to do with health and safety that are in the public interest. Consider Internet standards! We need to take a broader view of this.

Wide international representation may be necessary to a standard intended for global use. The complexity of the product or its innovative features may require a high concentration of industry experts.

For producers, however, efficiency and time to market are the great advantages of this system, for wherever it occurs in the cycle of conception to shelf, standardization can alter production schedules and have profound effects on competition. The Sectoral Model matches standardization development with distinctive industrial, regulatory, and marketing requirements.

A HETEROGENEOUS COLLECTION

The United States standardization system is a heterogeneous collection of entities that combine regulatory and market considerations with technology, housing SDOs with international standards setting capabilities and those whose interests are primarily domestic. It is a system in every sense, a whole whose parts literally define *models of standardization*.

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[17] ASTM International is one such organization.

It should be noted, however, that there are standards emanating from various models of standardization in this system, including "non-traditional" bodies, whose global significance and usage is undeniable (See Box 4).

This is it? Just a note with no comments on whether this is good or bad?

One such "non-traditional" model is the consortium. A consortium is a group of companies formed to create a standard to address a single commercial need. In today's technology world, this generic term has taken on a secondary meaning, defining any collection of companies (and...sometimes, universities and government agencies as well) which for a finite time period work together to promote the commercial success of a new technology based product or service. Frequently, although not always, the central activity of the consortium is agreement upon, and promotion of, a technical standard (or standards) which is necessary to permit the products of multiple vendors to work together. (*Andrew Updegrove, Gesmer Updegrove, LLP, Copyright 2007*)[18]

BOX 4: ANSI ACCREDITED SDOS

Committee X9

Committee X9 developed the Personal Identification Standard nearly a quarter of a century ago. Known today as ISO 9564, the PIS is built into thousands of ATM machines around the globe and in software to backroom operating systems.

X9 is also the originating standards activity behind ISO 8583, a standard bit map messaging format that drives all global credit and debit card transactions which is now built into all software and banking systems and networks.

Telecommunications Industry Association (TIA)

TIA, with partners in China, Korea, and Japan, has developed one of the most successful standards to date for Third Generation ("3G") wireless communications, the cdma2000® standard. The CDMA Development Group ("CDG"), which tracks deployment of this standard (www.cdg.org), notes that as of May 2009, cdma2000 technology is being used in over 100 countries/territories, by 280 operators, and serving over 450 million subscribers.

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The former are full members and co-owners of any jointly developed technology. As such, they have sole control over any standards or specifications developed. The latter can receive license rights from any Promoter to the specifications developed by the Promoters in order to create products or provide services based on the specifications, but have no control over the specifications themselves. (See http://www.consortiuminfo.org/what/)

THE AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

The U.S. based system of voluntary standards bodies is coordinated by the American National Standards Institute (ANSI). ANSI accredits the procedures of many standards developing organizations in the U.S[19] and is the official U.S. representative to the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC).

It is estimated that in the U.S. today there are hundreds of "traditional" standards developing organizations - with the 20 largest SDOs producing 90% of the standards - and hundreds more "non-traditional" standards development bodies, such as consortia. This means that the level of U.S. participation is quite expansive

I don't think "expansive" is quite the right word; maybe "extensive"?

as the groups themselves are comprised of individual committees made up of experts addressing the technical requirements of standards within their specific area of expertise. At year-end 2008, about 200 of these standards developers were accredited by ANSI; there were close to 10,000 American National Standards (ANS). (See www.ansi.org)

THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

[19] Accreditation by ANSI signifies that the procedures used by the standards body in connection with the development of American National Standards meet the Institute's essential requirements for openness, balance, consensus and due process.

The United States participates actively in ISO standardization activities through the American National Standards Institute (ANSI)[20]. The ANSI Annual Report of 2006-2007 has tabulated these activities (and those of the IEC[21]) as follows:

[20] ANSI accredits U.S. TAGS

[21] International Electrotechnical Commission

BOX 5: ANSI PARTICIPATION IN ISO	
Participating "P" Memberships	563
Technical Advisory Groups	199
U.S. Administered T C Secretariats	30
U.S. Administered SC Secretariats	89
U.S. Held Chairmanships	96

BOX 6: ANSI PARTICIPATION IN IEC	
Participating "P" Memberships	154
U.S. Technical Advisory Groups	152
U.S. Administered TC Secretariats	12
U.S. Administered SC Secretariats	11
U.S. Held Chairmanships	22

Through these activities, technology developed in U.S. domiciled standards organizations provides the bases for many ISO standards. U.S. SDOs also provide technology and intellectual property that result in *mirror image* standards, i.e., standards whose contents have not been changed or affected by the ISO process. [22]

[22] Example: ASTM D7136, D7137 as ISO/DIS 18352

TOOLS OF TRADE

Global industries often describe standards as *tools*. The selection of a standard, as the selection of a tool, is based on whether or not the tool can be used to complete a task, or whether or not the standard can be used to solve a problem. A task-oriented approach to the selection of international standards is tantamount to the use of a toolbox, from which standards are chosen for their ability to solve specific problems. The standards' origins, or the process by which they are developed, may be less important to the manufacturer than the quality, technical merit, and the standard's applicability to the problem at hand.

Same argument that the source of the standard is less important. That may be true for the manufacturer, but what about the customer?

AEROSPACE: A GLOBAL INDUSTRY'S POSITION

The Strategic Standardization Forum for Aerospace (a broad stakeholder group which includes industry, government, regulatory agencies and standards developers[23]), has issued a Position Paper that urges governments, legislatures and contractors to avoid imposing laws or policies that mandate the use of certain standards based on which organization developed them and inhibiting the selection of the best standards based on technical merit:[24] Following is an excerpt:

"The aerospace industry is dedicated to producing safe, reliable, and technically excellent products. In order to do so, the industry will select and use standards based on their suitability to meet safety, regulatory, and other technical needs appropriate to their products. This principle is critical and essential to ensure safe and efficient design, build, operation and maintenance of the products of our industry. This requires selecting and using standards based on technical merit, which contain the data necessary to ensure quality aircraft. The aerospace industry urges governments, legislators, and cont ractors to avoid arbitrarily imposing laws or policies that mandate the use of certain standards based

[23] Example: The Boeing Company, a major stakeholder in the Strategic Standardization Forum for Aerospace, is the world's leading aerospace company and the largest manufacturer of commercial jetliners and military aircraft combined. It also operates the Space Shuttle and International Space Station for NASA.

[24] The full text of the SSFA Position Paper can be found at www.ssf-aerospace.org

on which organization developed them, and inhibiting the selection of the best standards based on technical merit. Actions taken or advocated to limit or influence selection based on any factor other than suitability for the purpose potentially incur grave risks to the safety and public confidence in the aerospace industry." (Publication date: March 2006)

The industry also states

"The Standards of choicefor the global aerospace industry must be recognized internationally without bias towards the process for development or for the label of the developing organization. Where applicable, those standards need to be made the basis for national, foreign, regional, and international regulation and law. Global standards should be open for input from all stakeholders in the industry in accordance with standards development principles set forth by the World Trade Organization." [25]

UNIQUE STANDARDS

From time to time, a standard is developed that virtually defines the product, i.e., only one standard or one set of standards exists that provides the characteristics of the product and/or its production or testing methods.

My reaction on reading this is that the author has never been exposed to the whole world of interoperability standards, or the telecom or computer industries where a standard (e.g. Ethernet) always defines the process.

Such a standard, by virtue of its matchless technology or universal applicability, may also act as the ideal international standard so often called for by global traders and governments alike: *the one standard that is accepted everywhere.*

Two such sets of standards that have emanated from the U.S. based system (plus one from the U.K.) are described below: the NEMA standards for PET Scanners and the ASTM and UK DEF standards for aviation fuel.

[25] *The Future of Aerospace Standardization,* A publication of The Future of Aerospace Standardization Working Group, Aerospace Industries Association of America, Inc., January, 2005)

BOX 7: NEMA NU-1, NU2 STANDARDS FOR PET SCANNERS

Positron emission tomography (PET) is a nuclear medicine medical imaging technique which produces a three-dimensional image or map of functional processes in the body.

The system detects pairs of gamma rays emitted indirectly by a positron-emitting radioisotope, which is introduced into the body on a metabolically active molecule. Images of metabolic activity in space are then reconstructed by computer analysis, often in modern scanners aided by results from a CT X-ray scan performed on the patient at the same time, in the same machine.

PET scanners are produced in the main by four global enterprises: Siemens, headquartered in Germany, Hitachi, Japan, Philips, the Netherlands, and GE in the United States. All four manufacture to the NEMA specifications.

NEMA Performance Standards: The NEMA standards NU 1and NU 2 are recognized by the U.S. FDA's CDRH and thus may be used in Abbreviated 510(k)s for emission tomographic diagnostic devices. They provide standardized methods for measuring performance parameters for and gamma cameras (SPECT) and positron cameras (PET). To the extent possible, these methods should be utilized in traditional as well as abbreviated 510(k)s. The NEMA standards are:

NU 1---- Performance Measurements of Scintillation Cameras (1994) and NU 2---- Performance Measurements of Positron Emission Tomographs (1994)

It is important to recognize that the NEMA standards only prescribe standard measurement methods. They do not specify acceptable levels of performance or safety. Acceptable levels of performance are assessed by a comparison to previously cleared devices, on a case-by-case basis, depending upon intended use, and the substantial equivalence criterion. Levels of electrical and mechanical safety parameters are addressed by other standards discussed below. These standards are also recognized by CDRH: IEC 60601-1, International Electrotechnical Commission, Medical Electrical Equipment, Part 1: General Requirements for Safety

IEC 60601-1-2, Requirements for safety; Electromagnetic Compatibility - Requirements and Tests

EN 1441 (1997), Medical Devices- Risk Analysis

UL 544, Standards for Medical, Dental Equipment, 3rd edition

UL 2601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety (This is the UL version of IEC 60601-1).

NEMA PS3, DICOM (Digital Imaging and Communications in Medicine) (set includes PS3-1 through PS3-13)-- This standard specifies formats for the exchange of radiology and other medical images.
N.B. The standards listed above were current at the writing of this paper. They are intended primarily for purposes of example and some will undoubtedly be updated or superseded at time of publication.

BOX 8: AVIATION FUELS

Aviation turbine fuels are used for powering jet and turbo-prop engined aircraft and helicopters. These jet fuels are made by refining crude petroleum and inspected to meet stringent standards and specifications. Two organizations have taken the lead role in setting and maintaining specifications for civilian and military aviation turbine fuel: the ASTM International (ASTM) and the United Kingdom Ministry of Defence (MOD). The Jet fuel standards that virtually define aviation turbine fuels are ASTM D1655 and the British Standard DEF STAN 91-91. There are minor differences between the two specifications.

Outside former USSR areas, there are currently two main grades of turbine fuel in use in commercial aviation: Jet A-1 and Jet A. The Jet A grade has a 7°C higher freezing point relative to Jet A-1 (maximum −47° C) and is used only in the United States. **The Jet A-1 grade is used in all other countries. *** Both are kerosine type fuels.

There is another grade of jet fuel, Jet B, which is a wide cut (a blend of gasoline and kerosine), rarely used except in very cold climates. Jet B fuel is made to ASTM D6615.

Military fuel, JP-8 or NATO F34, is manufactured according to military specification MIL-DTL-83133. The major difference between military fuels and commercial fuels is military fuels use additives. Otherwise, JP-8 and Jet A-1 are the same fuel.

Sources:

Chevron Aviation Report: *Aviation Fuels Technical Review*, 2006. http://www.chevronglobalaviation.com/docs/aviation_tech_review.pdf

Shell Aviation: *World-Wide Civil Jet Fuel Grades.* http://www.shell.com/home/content/aviation-en/productservice/aviationfuels/detail/worldwideciviljet_10081004.html

Mr. Stanford P. Seto, Belcan Corp., Mr. Fred E. Barnes, ASTM Technical Committee D2, Mr. David Bradley, ASTM International

TECHNICAL ASSISTANCE

In keeping with Article 11 of the TBT Agreement, *Technical Assistance to Other Members,* the United States Government, alone or in partnership with the voluntary standards community, provides numerous programs of technical assistance to developing countries. U.S. based voluntary standards organizations provide standards documents, educational programs and training as well to these WTO Members.

THE NIST STANDARDS IN TRADE PROGRAM

One example of government-private sector cooperation is the Standards in Trade Program offered by the National Institute for Standards and Technology (NIST). Since 1995, over 1000 attendees from over 35 countries have taken part in this program. The NIST program provides the opportunity to identify technical issues in standards and conformity assessment that might be considered technical barriers to trade, and sets the stage for future collaborative efforts. Expenses are paid by NIST with support from U.S. and visiting stakeholders for developing country participants. US Stakeholders include:

- Govt. agencies both within the US, and sometimes in-region
- Private sector
- Trade Associations
- Standards Developing Organizations
- Testing and Certification Laboratories
- Industry
- Professional Societies
- Academia

See Table D for examples of workshops held in 2006 and 2007.

These workshops have had major impacts on the economies of developing countries and have resulted in the additional application of standards developed i n U.S. domiciled organizations: For example:

- The India Oil Industry Safety Directorate (OISD) has announced that approximately 8000 km of new oil pipelines will be built to ASME's Pipeline standards and codes. The initial connection between ASME and OISD was made at the SIT workshop for the Oil and Gas Sector in India, 2005.[26]

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- Iraq's Ministry of Construction and Housing (MOCH) is establishing a technical team to study the international codes and standards developed by a US domiciled organization for adoption and use, with appropriate technical revisions, in an Iraqi National Building Code. The proposal came from the SIT workshop for Iraq on Standards and Codes for the Building and Construction Sector held in 2006.

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- ASTM Intl. is gaining considerable acceptance in the Latin American concrete market through its partnership with ASOCRETO, the Colombian trade association for concrete, which started at the SIT Workshop on Concrete and Cement for the Americas, December 9-13, 2002. Underwriters Laboratories is working with the National Fire Protection Association to provide the 2005 National Electrical Code to the Central America region in Spanish. The NEC 2005 will be used as the basis for national electrical codes in these countries. Collaboration started at the SIT workshop on Electrical Safety for Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua and Panama, March 27-31, 2006.

THE ASME MOU PROGRAM

ASME has MOUs in place with the following organizations for the purpose of cooperation and information exchange regarding standards:

IBNORCA, Bolivia

Shanghai Power Equipment Research Institute (SPERI)

China Special Equipment Inspection and Research Center (CSEI)

China Petroleum and Chemical Corporation (SINOPEC)

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[26] Various Indian government standards development and regulatory organizations including the Bureau of Indian Standards (BIS), the Oil Industry Safety Directorate (OISD) and the Petroleum and Natural Gas Regulatory Board (PNGRB) have recently referenced several ASME standards, including: ASME B31.4 Pipeline Transportation Systems for Liquid Hydrocarbons and Other Liquids, ASME B31.8 Gas Transmission and Distribution Piping Systems, ASME Boiler and Pressure Vessel Code Section VIII, Division 1; Pressure Vessels, ASME Boiler and Pressure Vessel Code Section IX; Welding Qualifications, ASME B16.5, B16.20, B16.34, B16.36, B16.40; Standards for Valves and Fittings, ASME B18.2.1 and B18.2.2, Standards for Screws, Bolts and Nuts

Quality Council of India (QCI)

Standards Organization of Nigeria (SON)

Palestinian Standards Authority, Palestinian Territories

SASO, Saudi Arabia

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THE FOLLOWING DETAILS WOULD BE BETTER OFF IN AN ANNEX.

THE ASTM INTERNATIONAL MOU PROGRAM

A unique program of technical assistance is offered by ASTM International. Initiated in 2001, ASTM International's MOU program promotes communication between ASTM International and national standards bodies worldwide, fostering awareness of the standardization systems of all parties involved. The program also facilitates the development of national standards that will aid each country's health, safety, environmental, and economic conditions. These agreements help avoid duplication of effort where possible and mutually promote the standards development activities of ASTM International and the national standards bodies participating in the program.

MOU's are designed to encourage, increase, and facilitate the participation of technical experts from around the world in the ASTM standards development process and broaden the global acceptance and use of ASTM International standards.

As a benefit of the MOU program, technical experts from any of the countries where MOUs have been signed can participate freely as full voting members in the ASTM standards development process.[27]. As of the writing of this paper, ASTM International had completed MOUs with 60 developing countries.

[27] Those wishing to know more should contact their national standards body for information on how to participate in ASTM International technical committees or visit *http://www.astm.org/cgi-in/SoftCart.exe/GLOBAL/mou.html?L+mystore+jzip2589+1195846365*

Underwriters Laboratories, Inc. has instituted a similar MOU program whose purpose is also to strengthen the relationship between UL and the accredited standards development organization of the country involved.

As part of the MOU, UL:

- Provides the national standards body with electronic access to UL's Standards Library for internal use;
- Considers negotiation of terms that would allow the other organization to adopt and distribute UL Standards in the country (if this is desired by the national standards body);

Encourages the national standards body designees to apply for membership on relevant UL standards technical panels ("STPs") so they may contribute to the development of UL Standards.

Since the institution of its program in 2006, UL has signed agreements with Israel, Saudi Arabia, Trinidad & Tobago, Costa Rica, and Bolivia, and is in negotiations for MOUs with Panama and Peru.

EDUCATION AND TRAINING PROGRAMS IN THE PRIVATE SECTOR

Standards Developing Organizations in the private sector also offer numerous educational and training programs to developing countries.

BOX 9: EDUCATION AND TRAINING PROGRAMS IN THE PRIVATE SECTOR

ASME	ASME brings Courses to Countries in their native languages. In-company training also available. There are also opportunities for professionals to become authorized instructors. View a complete list of ASME scholarships available to International students, GMET Global Training Program, a unique and globally collaborated training initiative of ASME on global management of engineering and technology and other programs at www.asme.org.
ASTM International	The ASTM Technical and Professional Training (TPT) program provides courses in the use of ASTM standards that impact a variety of technical areas. Not only are courses offered in a wide range of cities around the world, but they can also be brought on-site to business locations around the world. ASTM also provides full funding TPT Courses for MOU Partners. ASTM's Standards Expert Exchange Program hosts experts from at least 3 MOU Partners each year at ASTM Headquarters for one month of training.
IEEE	The IEEE is divided into ten geographic regions worldwide. Within those regions are 330 local Sections and 1,788 technical Chapters that unite local members with

	similar technical interests. A chapter is the technical subunit of one or more IEEE sections. Society chapters are the local link to the valuable resources available from the IEEE and its 39 technical societies. Chapter activities may include guest speakers, workshops, and seminars. Chapters provide society members with valuable opportunities to network at a local level - enabling both personal and professional growth.
SAE International	The new Automotive Supplier Excellence Program was launched in China in 2006. The program assists companies by enhancing product innovation and design capabilities, reducing costs, improving quality and facilitating product development by identifying specific organizational practices, processes and procedures that can be improved. This program is one of several that constitutes SAE's Corporate Technologies portfolio. Suppliers may engage in Standards Application Assistance, Targeted Technical Assistance and other programs, all of which call upon SAE International resources to help solve the problems of both U.S.-based companies with plants in China as well as Chinese companies. Throughout China and Korea, SAE continued to invest heavily in individual learning through professional development seminars and special learning events, such as customized symposia.

REMOTE PARTICIPATION

Developing countries, through the marvels of electronic achievement, are participating in the U.S. system of standardization at rates never before believed possible. Web Casts and seminars, online participation in technical committees, and electronic balloting are just some of the methods used by these SDOs to bring these members into the process of standardization and technology transfer.

PROGRESS AND DEVELOPMENT

The needs and capabilities of developing and emerging economies vary; and initiators of development projects must often improvise technical solutions to match national or local customs, resources, and capabilities. Using the same creativity employed by regulators, they may use standards from various sources, the relevant parts of standards, combinations of standards, or modifications of standards. As in regulation, the key to progress and development is *flexibility* and a *freedom of choice* (*See box 10 for an example*).

BOX 10: THE NATIONAL STANDARDS BODY OF ZIMBABWE

The National Standards Body of Zimbabwe, the Standards Association of Zimbabwe (SAZ), Technical Committee CH20 on Petroleum Products and Lubricants Extends Its Scope To Include Biodiesel and adopts ASTM D6751

In 2002, Zimbabwe began to promote research to extract biodiesel from seeds of a locally grown Jatropha *curcas* plant, a hearty succulent that can grow in the harshest of conditions. Jatropha has also been planted in Swaziland, Zambia, Madagascar, and Malawi for this purpose, creating thousands of jobs and improving rural employment in these countries. Zimbabwe's CH20 Committee adopted ASTM standard D6751, *Specification for Biodiesel Fuel Blend Stock B100 for Middle Distillate Fuels.* This biodiesel fuel blend stock uses soybean as feedstock. D6751 also references 22 ASTM test methods that have been tried successfully in Zimbabwean laboratories. A Zimbabwean research team has been established to characterize biodiesel blends made from Jatropha, using the ASTM specification and test methods as the technical base. Similar projects are underway for the production of ethanol from sugarcane. Again, ASTM standards will be used.

CONCLUSION

The ability to choose a standard based on its merits is inherent to progress, innovation, and trade.

The relative merit of a standard may be determined by the quality of its technical content and how it affects the flow of international trade.

Technical merit is the key to health, safety, workable infrastructures, effectual regulation, and the integrity of goods. In this regard, a standard may be judged by the quality of the technical reality it imparts to a product or process. The level of technical merit will be in direct proportion to the level of performance or reliability of the product or process in use.

But that can only be determined after the standard has been in place and used for a good while.

Fairness is also a mark of merit. Technical excellence notwithstanding, a standard cannot be applied without effect or consequence. Standards, most especially international standards, must also be judged in the light of their *intent*, i.e., they must not be developed with the aim of purposefully disadvantaging competitors or economies.

Perhaps the greatest test of a standard's merit, however, is the extent to which it is accepted and used. Despite the absence of a body of empirical knowledge, there is abundant evidence that the use of international standards from multiple sources is widespread and increasing.

As noted– interesting to a historian, but most folks have to pick a direction before they know the final result.

Many regulators in nations that are in stages of development or emergence are keenly aware that the ability to choose the standard that can best bring about needed change is crucial, whether or not that standard is applied in its original form or modified to suit local conditions and capabilities. Many are choosing standards from the U.S.-based system and applying them with great success and enormous rewards.

The United States-based standards system represents, above all else, opportunity. Its dedication to inclusiveness accounts for the wealth of international talent and the universality of ideas that make its standards so often the choice of regulators and manufacturers around the world.

The Standards Strategy of the United States acknowledges the value of other systems, and the value of any standard that has been produced in accordance with principles of international standardization as set forth by the World Trade Organization Technical Barriers to Trade Committee. In principle and in practice, it espouses flexibility, creativity,

and freedom of choice. The choice of standards based on merit is its watchword, as it has become for nations around the world.

TABLES

TABLE A: EXAMPLES OF U.S. SYSTEM STANDARDS REFERENCED IN REGULATIONS: CODES

American Society of Mechanical Engineers (ASME International)

A 2001 survey by the British Standards Institution on the acceptance of foreign design codes showed that the **ASME Boiler and Vessel Code** was accepted in the following countries:

Albania, Algeria, Argentina, Australia, Austria, Bahamas, Bangladesh, Bermuda, Bolivia, Burma, Canada, Chile, China, People's Republic of, Colombia, Costa Rica, Cuba, Cyprus, Denmark, Djibouti, Dominican Republic, Ecuador, Egypt, Ethiopia, Fiji, Gambia, Ghana, Republic of, Hong Kong, Hungary, Iceland, India, Indonesia, Iraq, Ireland, Israel, Ivory Coast, Jamaica, Jordan, Kenya, Kuwait, Lebanon, Libya, Malawi, Malaysia, Mauritius, Mexico, Morocco, New Zealand, Nigeria, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Puerto Rico, Qatar, Saint Lucia, Saudi Arabia, Singapore, Republic of, South Africa, Sri Lanka, Sudan, Swaziland, Taiwan (Republic of China), Tanzania, Thailand, Trinidad and Tobago, Tunisia, United Arab Emirates, Venezuela, Yemen, Republic of Zambia, and Zimbabwe.

National Fire Protection Association (NFPA)

NFPA publishes the National Electrical Code and the National Fire Codes. They are developed by NFPA technical committees and are adopted and enforced throughout the world.

International Code Council (ICC) The Uniform Building Code (UBC) developed by ICBO[28] is

[28]Beginning in 1915, code enforcement officials, or those municipal officials charged with the responsibility of enforcing building code laws, began regular regional and national meetings to discuss their common problems and concerns. From these meetings came the formation of three organizations of code enforcement officials: Building Officials Conference of America, later known as Building Officials and Code Administrators (BOCA) International, Inc; International Conference of Building Officials (ICBO); and Southern Building Code Congress International, Inc. (SBCCI). In 1994 these three organizations created the **International Code Council** (Code Council) with the intent of eventually providing one set of unified and correlated construction model codes. In 2000 the Code Council issued the first set of the **International Codes**, a complete family of codes covering both commercial as well as residential construction. Familiarly known as I-Codes, they are now used and implemented in all fifty states and by many Federal agencies including the Department of Defense, the State Department, the Architect of the US Capitol, National Park Service, the Veterans Administration and the U.S. Forest Service, as well as internationally

adopted in the Middle East, a region also prone to earthquakes; this includes Saudi Arabia in the Royal Commission of Jubail and Yanbu and at ARAMCO. In the last few years, the Kingdom of Saudi Arabia has worked with ICC to adapt the **2003 and 2006 editions of the ICC Codes** in their development of the Saudi Building Code (SBC) and will soon release and distribute the SBC in the Kingdom for building designs, first on a voluntary basis before making it mandatory. The Code Council has ongoing programs in Afghanistan, Pakistan and Egypt to improve these countries building regulatory systems. The United Arab Emirates (UAE) is studying the establishment of a building regulatory system. Europe and Central Asian countries have also expressed interest in the ICC's comprehensive building safety system.

All of U.S. Territories have previously adopted the UBC such as Guam, American Samoa, and Northern Mariana Islands. Other U.S. Territories in the Caribbean such as U.S. Virgin Islands have officially transitioned from the UBC and adopted the I-Codes in 2006 and Puerto Rico will soon transition from the UBC to the IBC. Non-U.S Territories such as the Bahamas have currently adopted the Florida Building Code which is directly based on ICC Codes. The Cayman Islands have adopted the Standard Building Codes by SBCCI years ago and are in the process of transitioning to the I-Codes.

The ICC staff has been working with Mexico on the development of Mexico's Residential Building Code which is based on the ICC's *International Residential Code* (IRC). The IRC will be customized broadly to meet the needs of Mexico's individual states.

Since the issuance of the first edition in 2000, several countries, including Jamaica, have obtained copies of the I-Codes and are reviewing and studying them for consideration to enhance their system, through a process of information exchange.

The International Association of Plumbing and Mechanical Officials (IAPMO) has gained significant recognition for its Uniform Codes. Published by IAPMO, the Uniform Plumbing Code, Uniform Mechanical Code, Uniform Solar Energy Code and Uniform Swimming Pool, Spa and Hot Tub Code are all developed under an ANSI consensus process.

Much of the Uniform Plumbing Code is utilized by the Philippines, Indonesia, Colombia, Venezuela, China, Vietnam and Taiwan, among others. Although these countries have not formally adopted IAPMO's Uniform Plumbing Code in its entirety, the essential aspects of the UPC were utilized and then tailored to fit the nations' particular needs rather than adopting the ANS verbatim.

Conversely, in India, the Kingdom of Jordan, Kuwait and Abu Dhabi of the United Arab Emirates, there was an enhanced interest in utilizing the UPC mostly as written, amending it only slightly to address geopolitical and religious issues. As a result of these adoptions and the ongoing application of the UPC worldwide, more than half of the world's population is protected by the health and safety provisions of IAPMO's Uniform Plumbing Code, an American National Standard.

TABLE B: EXAMPLES OF U.S. SYSTEM STANDARDS REFERENCED IN REGULATIONS

Country	National Mandatory Standard or Technical Regulation	Standards Developing Organization of Origin
Brazil		
	NBR 9378, Arc welding electric equipment– power sources of constant current and power sources of constant voltage – specification, 1986	ISO, NEMA,VDE,AFNOR
	NBR 10614 (Classification) NBR 10615 (Specification) NBR 10616 (Tests), Carbon-Steel covered electrodes for arc welding, 1989	AWS AWS/ASTM
	NBR 10617, Flux and Wire for Sub Arc Welding, 1989	AWS
	NBR 7565, Rotating Electrical Machines – Noise Limits, 1982 NBR 5597, Steel rigid conduit and electrical metallic tubing with protective coating thread, 2006	ANSI C93.1 ANSI/ASME B1.20.1
	NBR 5370 copper connectors, splices, terminals, separable connectors and ground rods for electrical conductors in power systems, 1990 NBR 13571 Ground Rods and Accessories, 1996	NEMA CC-1 NEMA CC-3 UL 467
	NBR 9513 Splices for insulated cables up to 750 volts, 1986	ANSI C119.1
	NBR 540 Distribution transformers for overhead lines, 1999	ASTM D1535
China		
	GB 13296-2007 Seamless stainless steel tubes for boiler and heat exchanger	ASME SA-213/213M; 2001

	GB 5310-1995 Seamless steel tubes and pipes for high pressure boiler GB 9052.1-1998 Liquefied petroleum gas of oil and gas field	ASTM A335:1990 ASTM D1835:1991
	GB 6245-2006 Fire Pumps	NFPA20-2003, UL448-1994, UL1247-1995
	GB 17840-1999	UL 752:1995
Jordan	JS 1060, Lighters – Safety specification for lighters, 1999	ASTM F400
	JS 118, Cement – Sulfate-resisting Portland cement, 2005	ASTM C150
	JS 1192, Insulating Materials – Bitumen saturated woven burlap fabrics used in roofing, 1998	ASTM D 1327
	JS 1193, Insulating material– emulsified asphalt used as a protective coating for roofing, 1998	ASTM D 1227
	JS 1710, Standard practice for evaluating the imaging performance of security X-Ray systems, 2005	ASTM F 792
	JS 1711, Standard practice for performance evaluation of In-Plant Walk-through metal detectors	ASTM 1309
Vietnam		
	TCVN 2693 : 2007Standard Test Method for Flash Point by Pensky-Martens Closed Cup Tester	ASTM D 93-06
	TCVN 4354 : 2007 Standard Test Method for Saybolt Color of Petroleum Products (Saybolt Chromometer Method)	ASTM D 156-02e1
	TCVN 6325 : 2007S Standard Test Method for Acid Number of Petroleum Products by Potentiometric Titration TCVN 6777 : 2007 Standard Practice for Manual Sampling of Petroleum and Petroleum Products	ASTM D 664-06a ASTM D 4057-06
	TCVN 7023 : 2007 Test Method for Vapor Pressure of Gasoline and Gasoline-	ASTM D 4953-06

	Oxygenate Blends (Dry Method).	
	TCVN 7330 : 2007 Standard Test Method for Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption.	ASTM D 1319-03e1
	TCVN 7757 : 2007 Standard Test Method for Water and Sediment in Middl e Distillate Fuels by Centrifuge.	ASTM D 2709-06
	TCVN 7758 : 2007 Standard Test Method for Evaluating lubricity of Diesel Fuels by the High-Frequency Reciprocating Rig (HFRR).	ASTM D 6079-04e1
	TCVN 2695 : 2007 Standard Test Method for Acid and Base Number by Color - Indicator Titration	ASTM D 974-06
	TCVN 2706 : 2007Standard Test Method for Particulate Contamination in Middle Distillate Fuels by Laboratory Filtration TCVN 3166 : 2007 Standard Test Method for Determination of Benzene, Toluene, Ethylbenzene, p/m-Xylene, o-Xylene, C_9 and Heavier Aromatics, and Total Aromatics in Finished Gasoline by Gas Chromatography	ASTM D 6217–03e1 ASTM D 5580 – 02
	TCVN 3172 : 2007 Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-Ray Fluorescence Spectrometry	ASTM D 4294 – 06
	TCVN 3182 : 2007 Standard Test Method for Determination of water in Petroleum Products, Lubricating Oils, and Additives by Coulometric Karl Fischer Titration	ASTM D 6304 – 04e1
	TCVN 6704 : 2007 Standard Test Method for Lead in Gasoline by X-Ray Spectroscopy	ASTM D 5059-03^{e1}
	TCVN 7759 : 2007 Standard Test Method for Free Water and Particulate Contamination in Distillate Fuels (Visual Inspection Procedure)	ASTM D 4176 – 04e1
	TCVN 7760 : 2007 Standard Test Method for Determination of Total Sulfur in Light Hydrocarbons, Spark Ignition Engine Fuel, Diesel Engine Fuel, Engine Oil by Ultraviolet Fluorescence TCVN 3180 : 2007 Standard Test Method for alculated Cetane Index by Four	ASTM D 5453-06 ASTM D 4737-04

	Variable Equation	
	TCVN 6702 : 2007Standard Practice for Utilization of Test Data to Determine Conformance with Specifications	ASTM D 3144-02
	TCVN 7248 : 2007 Standard practice for dosimetry in gamma irradiation facilities for food processing	ASTM 51204:2004
	TCVN 7249 : 2007 Standard practice for dosimetry in electron beam and Xray (bremsstralung) irradiation facilities for food processing	ASTM 51431:2005

TABLE C: EXAMPLES OF INTERNATIONAL PARTICIPATION AND PRESENCE

ASTM International	**125 countries** are represented in ASTM committees. Its Board of Directors is also internationally integrated, and at any time may include the heads of standards developing organizations from countries other than the United States.
ASME	More than **350** out of about 4000 technical expert volunteers serving on ASME standards committees are from outside the U.S.
IEEE	IEEE has more than 370,000 members, including more than 80,000 students, in **over 160 countries**; 319 sections in ten geographic regions worldwide; 1676 chapters that unite local members with similar technical interests; and more than 1,526 student branches at colleges and universities in **80 countries**.
NFPA	NFPA has more than 81,000 members representing nearly **100 nations** and 320 employees around the world.
SAE International	SAE International has more than 90,000 members - engineers, business executives, educators, and students from **more than 97 countries** - who share information and exchange ideas for advancing the engineering of mobility systems
UL	Underwriters Laboratories, Inc. works with more than 71,000 customers in **104 countries**, helping to enhance safety and quality on a global scale. Ul has 66 laboratories, testing and certification facilities worldwide.

TABLE D: SIT WORKSHOPS IN 2006 AND 2007

2006	
SIT Workshop on Electrical Safety for Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, and Panama	Objective: The workshop addressed the development and implementation of the safety of electrical systems in the United States and the participating countries; namely in the areas of the electrical installation code, electrical product standards, product testing and certification, and inspection and enforcement
SIT Workshop on Standards and Codes for the Iraqi Cons truction Sector	Objective: The workshop addressed the role of standards, codes and best practices that address fire protection, physical vulnerability and mitigation while contributing to enhanced trade of associated goods and services; and ways to identi fy current and future technical areas in which the United States and Iraq could cooperate.
SIT Workshop for the Middle East, North Africa, and Pakistan on Standards, Codes, and Conformity Assessment for Life Safety and Building	Objective: The workshop provided a forum for the discussion of standards and codes, their development, conformity assessment and regulation in the U.S. and the invited countries as they relate to life safety in the building constructor sector.
2007 SIT Workshop on Oil and Gas for South America	Objective: The workshop facilitated an information exchange on the regulatory framework pertaining to the oil and gas sector in the U.S. and invited countries and identified existing and emerging trends in oil and gas standards; oil and gas pipelines; petroleum and petroleum products for transportation.

U.S. – China Standards in Trade Workshop for Intelligent Transportation Systems – held in Beijing, China	First SIT Workshop held outside of the United States. Objective: Thi s workshop provided a forum for the discussion of standards and codes, their development, conformity assessment and regulation in the United States and China as they relate to intelligent transportation systems and their components.
SIT Workshop In Support of the Asia Pacific Partnership (APP) On Harmonization of Test Procedures	Objective: This workshop provided a forum for the discussion of standardization issues, in particular, as related to the harmonization of test procedures for electronics and Heating, Ventilation, Air Conditioning and Refrigeration (HVAC/R) systems, being addressed within the Asia Pacific Partnership (APP) on Clean Development and Climate

ACKNOWLEDGEMENTS

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A special debt of gratitude to Mr. William P. Delaney, who proofread and edited this paper in all of its iterations.

LIST OF ABBREVIATIONS

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASTM International	American Society for Testing and Materials (Formerly)
AWS	American Welding Society
CDRH	U.S. FDA Center for Devices and Radiological Health
EN	European Norm/European Standard
ICC	International Code Council
IEEE	Institute of Electrical and Electronics Engineers, Inc.
IP	Institute of Petroleum, UK, now called the Institute of Energy
NEMA	National Electrical Manufacturers Association
NF	Norme Française/French Standard
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NTTAA	National Technology Transfer Advancement Act
SAE International	Society of Automotive Engineers
SPS	Sanitary and Phytosanitary
SDO	Standards Developing Organization
SSFA	Strategic Standardization Forum for Aerospace
TBT	Technical Barriers to Trade
TAG	Technical Advisory Group
UL	Underwriters Laboratories, Inc.
WTO	World Trade Organization

From: cindy.fuller@x9.org [mailto:cindy.fuller@x9.org]
Sent: Tuesday, August 11, 2009 8:18 AM
To: Fran Schrotter
Cc: Elizabeth Neiman; Fran Schrotter
Subject: Re: FOR REVIEW: proposed ANSI paper, "Liberalizing Regulation, Trade, and Development: Choosing Standards Based on Merit"

Fran,

Very good paper. A paper like this on return on investment would be another great idea.
I will send Steve our minor edits.

Regards,

Cynthia L. Fuller
Executive Director

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Websites: www.x9.org,
www.iso.org/tc68,
www.iso20022.org

Secretariats: ISO TC68, ISO TC68 SC2, ISO TC68 20022 RMG

* Accredited by the American National Standards Institute

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"Fran Schrotter" <fschrott@ansi.org>

To "Fran Schrotter" <fschrott@ansi.org>

From: cindy.fuller@x9.org

Sent: Tuesday, August 11, 2009 8:23 AM

To: Steve Cornish

Subject: Fw: FOR REVIEW: proposed ANSI paper, "Liberalizing Regulation, Trade, and Development: Choosing Standards Based on Merit"

Attachments: Choosing Standards on Merit.doc; Annex I WTOnotificationsreferencingUSdomiciledSDOs.xls

Steve,

Edits to the Section mentioning X9 as follows:

Committee X9 - change to - ---- Accredited Standards Committee X9, Financial Industry Standards

In the financial services industry sector, a couple of examples demonstrate US technology moving into the global sector. ASC X9 developed the Personal Identification Numbering Standard more than a quarter of a century ago. Known today as ISO 9564, the PIN is built into thousands of ATM machines around the globe and in software to backroom operating systems.

X9, originated the formats in the US which became ISO 8583, a standard bit map messaging format that drives credit and debit card transactions gobally and is built into all software and banking systems and networks. The standard, more than three decades in use, continues to be a viable and appropriate option for the financial services industry due to its speed of use and reliability.

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Secretariats: ISO TC68, ISO TC68 SC2, ISO TC68 20022 RMG

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