Session III: International Standardization of Ophthalmic Goods and Services

The Impact of Globalization on International Standards for Health Care Products and Services

ABSTRACT: The role of the American National Standards Institute as the U.S. member of the International Organization for Standardization (ISO), U.S. National Committee of the International Electrotechnical Commission, and accreditor of American National Standards developers will be explained. The activities of standards committees relevant to the World Council of Optometry will be noted, including how the definition of requirements is being influenced by the evolution of globalization, deregulation and convergence of technology. Considerations of market pressures and potential impediments, such as technical barriers to trade and the "digital divide," will be identified. General consumer, conformity assessment and developing-country initiatives within the respective committees at ISO will be discussed. An overview of the new ISO 17024 standard for the accreditation of personnel certification bodies will be included.

INTRODUCTION:	Ms. Tone Garaas
KEYNOTE ADDRESS:	Hallenbeck: 45 minutes
OTHER SPEAKERS:	3 speakers at 20 minutes each
PANEL DISCUSSION:	30 minutes

Slide 1 – Title

Thank you, Ms. Garaas. Good afternoon everyone.

It is an honor to be here today representing the American National Standards Institute (ANSI) and the International Organization for Standardization (ISO). On behalf of these two organizations, I would like to congratulate the World Council of Optometry for hosting its first World Congress and take this opportunity to thank you for incorporating international standardization as one of your major conference themes.

Slide 2 – A Global Community

Modern circumstances require that all segments of our global society work together more closely for mutual benefit. By bringing together professional representatives of the healthcare industry, manufacturers, government regulators and legislators, consumer groups, academics and the others gathered here today, we can examine the issues facing the ophthalmology community in the broadest possible context.

My comments will focus on the ways in which globally relevant standards and related conformity assessment programs can assist in your endeavors. For those of you who may not be familiar with the terms:

Slide 3 – Definition of "Standard"

A standard is a document—usually established by consensus and approved by a recognized body – that provides rules, guidelines or characteristics for activities or their results. Typically, standards are considered to be guidelines that are used on a voluntary basis. They become mandatory when they are adopted or referenced into laws or technical regulations.

But standards are just good ideas unless products conform to them. Conformity assessment is the complementary element to standardization.

Slide 4 – Definition of "Conformity Assessment"

The evaluation of a system, process, product or person to a specified standard often results in a "certification" statement. Product certification, for example, is especially common in areas that relate to quality or safety and health issues.

The total "standardization package" comprising standards and conformity assessment programs:

- facilitates market acceptance of products, processes, systems and personnel;
- clarifies how to improve the safety of products for the protection of the consumer;
- promotes worldwide trade; and
- reduces costs.

Slide 5 – ANSI's Role . . . .

Within the United States, ANSI is the organization that administers and coordinates the voluntary consensus standards and conformity assessment systems. I will describe in a moment ANSI's role in the approval of American National Standards and our representation of U.S. interests in various regional and international forums.

ANSI also promotes consumer confidence by accrediting organizations that are involved with the assessment of quality and environmental management systems. We accredit product certification bodies in more than 30 different program areas, and more recently, have begun to accredit organizations that certify personnel.

Like the World Council of Optometry, the Institute is a private, non-profit membership organization. We are not a government agency or a regulatory body. Nor are we a standards developer. Rather, ANSI provides a forum where subject matter experts from U.S. industry, government, academia and other sectors

can work cooperatively toward the development of voluntary standards that ultimately benefit the nation and the world.

Slide 6 – World Standards Cooperation

As the country's official member body, ANSI ensures that U.S. interested parties have immediate access to the standards development processes of the International Organization for Standardization (ISO) and its sister organization, the International Electrotechnical Commission (IEC).

ISO and IEC are non-governmental organizations.

A third organization, the International Telecommunication Union, was established as an impartial, international organization within which governments and the private sector could work together to coordinate the operation of telecommunication networks and services and advance the development of communications technology.

The members of ISO and IEC are not delegations of national governments, as they are in the case of ITU. Nevertheless, ISO and IEC occupy a special position between the public and private sectors. This is because, on the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations. This latter example best describes ANSI.

ISO, IEC and ITU often collaborate with organizations such as the United Nation's Economic Commission for Europe (UN/ECE) where governments can harmonize their regulatory practice.

International standards contribute to making the development, manufacturing and supply of products and services more efficient, safer and cleaner. They make trade between countries easier and fairer. They provide governments with a technical base for health, safety and environmental legislation. They aid in transferring technology to developing countries. In general, international standards serve to safeguard consumers and the users of products and services.

To a certain extent, there is an alignment here with the work of the WCO. Your organization's mission is to facilitate the enhancement and development of eye and vision care worldwide and to promote advancement of the science of optometry for the benefit of mankind.

You do this by working with a global network of optometrists and by promoting high standards of education and practice. You perform a critical coordination function for your industry and devote a considerable portion of your resources to generally support aid programs directed at societies in need.

On behalf of the entire standards and conformity assessment community, I am pleased that you have expressed your interest in cooperating with organizations such as ANSI, ISO and others to advance your goals.

By working in partnership with the more than 150 nations that participate in ISO and IEC activities – including more than 110 developing countries or economies in transition – collectively we can help to advance the globalization of trade and critically important issues relating to optical health and safety.

Before we continue, let me share with you a bit of background information about ANSI, ISO and our organizational approaches to global standardization.

First, a few words about the American National Standards Institute . . .

Slide 7 – ANSI Federation

ANSI itself is 86 years old. It was founded in 1918 by five engineering societies and three government agencies that recognized the need for a focal point for standards coordination, harmonization and information.

The Institute's membership includes a diverse representation of more than 800 companies, academic institutions, professional societies, trade associations, consumer representatives and government agencies that come together for mutual benefit.

Among our members are several organizations that also belong to the WCO, including the American Optometric Association (represented by my colleague on the panel, Mr. Weaver), the Vision Council of America, and Alcon Laboratories. The Center for Quality Assurance in International Education is also involved in ANSI's conformity assessment activities.

Slide 8 – ANSI-Accredited Standards Developers

ANSI does not itself develop standards, but many of our members do. As of January 1, 2004, there are some 200 ANSI-accredited standards developers across the spectrum of industry. Many of you may already be familiar with two of our nation's oldest standards setting organizations: ASTM International and Underwriters Laboratories.

As of January 2004, there are more than 10,000 American National Standards (ANS), including 15 that have been developed by the Optical Laboratories Association – an organization that was founded in 1894 to serve the needs of the optical laboratory industry.

The OLA sponsors and administers the ANSI Z80 Committee and serves as the ANSI Z80 Secretariat. The ANSI Z80 Committee is an ANSI accredited standards development committee that addresses equipment used by eye care professionals, as well as prescription and non-prescription ophthalmic products.

Numerous other standards on optical-related topics have been developed by the American Society of Safety Engineers and the Industrial Safety Equipment Association, including American National Standard Z87.1 - *Practice for Occupational and Educational Eye and Face Protection.*

Another standards developer in the ophthalmic arena is the Optics and Electro-Optics Standards Council, or "OEOSC" which developed an American National Standard for optical glass and has two additional projects currently under development.

These statistics address only domestic projects that may lead to the approval of an American National Standard. Given the trend toward globalization, the U.S. standards community is even more actively engaged in ensuring that American interests are well represented in the development of globally relevant standards.

Slide 9 – Collaborative Efforts

ANSI will often work in partnership with other national bodies or with regional standards and conformity assessment organizations in the Americas, Europe, the Middle East, Africa, and the Pacific Rim. Through this collaboration, standardizers can adjust to the market economy and develop consensus positions on issues that will be applicable in the international environment.

Through our memberships in both ISO and IEC, and our relationships with other national standards bodies, we have been quite successful in advancing the concept of "global relevance." This concept emphasizes the value of a single international standard that can be used and implemented as broadly as possible by affected industries in countries around the world. I will speak more about this point in a few moments.

Slide 10 – ISO Standards Development

As I noted in my opening remarks, ISO is a federation of some 148 country members engaged in the development and dissemination of documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics to ensure that

materials, products, processes and services are fit for their purpose. It is the largest voluntary standardization body in the world.

ISO has been developing voluntary technical standards over almost all sectors of business, industry and technology since 1947. The organization has generated a portfolio of about 14,000 standards developed by some 3000 technical committees, subcommittees and working groups.

ISO addresses standardization needs in fields including nuclear energy, information technology, material handling and electronics. Alongside these traditional engineering committees and design-based standards are projects ranging from quality and environmental management, to new and innovative standards for the service industry and most recently, for personnel certification programs.

Its common business model is a solid one based on developing standards to meet market requirements, consulting and involving all stakeholders through a network of national committees, developing international consensus and seeking effective relationships with other international organizations.

Slide 11 – Cardinal Principles of Standardization

It is important to underline that the value of globally relevant standards lies primarily in the role that they play as a means of opening markets and facilitating trade.

International standards are the result of best practices that are shared and adopted on a global scale. They greatly help to enhance safety and security and will help to develop consumer confidence and protection while respecting the legitimate interests of all stakeholders.

Standards also help to simplify the utilization of existing and new technologies – focusing on interfaces and interoperability, reducing costs and complexity, opening markets and fostering broader access to products and services.

The World Trade Organization considers international standards an instrument to fight the so-called "technical barriers to trade." The use of incompatible national technical standards – especially when the differences are not based on a specific need – forces foreign suppliers to sustain additional costs and burdens to adapt their products to meet unique local standards and requirements.

Slide 12 – Key Factors Impacting Standards-setting

Technical barriers to trade are actually considered one of the most severe protectionist measures, just after tariffs and imposed quotas.

The deregulation of many sectors – including the health care industry – is leading to competition which, in turn, calls for voluntary international standards to support a level playing field, as well as progress and sustainable development.

Technological convergence is creating new products, new services, new markets, and new stakeholder expectations with requirements that need collaborative responses.

Globalization calls for increasing confidence in conformity assessment and the mutual acceptance of test results and certificates.

Slide 13 – The Concept of "Global Relevancy"

ISO's standards – and those developed by other international standards organizations with a view of global relevancy – make an effective contribution not only to the opening of markets and to the equitable development of world trade, but also to the protection of safety and health for the world's citizens. They enable the development of a harmonized, stable and globally recognized framework of technologies, best practices and agreements.

Within your industry, collaborative standards development has been the norm for many years. In ISO, this includes the activities of Technical Committee, or "TC" 172, *Optics and photonics*. In a few moments, my colleague on today's panel, Mr. Koeppen, will speak to you about the work of this technical committee and its standards development activities.

U.S. perspectives on work underway with ISO TC 172 are coordinated by groups that we refer to as TAGs – this stands for U.S. Technical Advisory Groups. In addition to its role as an ANSI-accredited standards developer, the Optics and Electro-Optics Standards Council serves as the U.S. TAG for ISO TC 172.

OEOSC's role as a U.S. TAG is to review drafts of proposed international optical standards so that it can formulate the U.S. position regarding the suitability of those drafts to become international standards, and to transmit that input, through ANSI, to the ISO technical committee. The committee is also responsible for reviewing U.S. national optical standards to determine which of them should be offered as drafts for new international optical standards.

ANSI believes that it is the responsibility of the standards community to always remain responsive to the evolving needs of its constituents. Programs must constantly monitor and adapt to meet the changing needs of industry, government, the healthcare sector, and others.

Historically, we have seen that companies that assume a leadership role in standardization may realize a strategic advantage in the marketplace. A company that successfully introduces its technology to a standards-setting committee may gain a lead-time advantage that allows them to positively impact the market for its products while their competitors are playing "catch-up." This company may re-allocate resources to the development of "next generation" technologies, rather than to the re-tooling of an existing product line to encompass a standard that was more heavily influenced by a competitor.

Slide 14 – Fundamentals of Globally Relevant Standards Development

While this concept remains true, today ANSI is a leading advocate for a flexible, sector-based structure and management within the ISO and IEC. The U.S. recognized long ago that the diverse needs of the global standards community cannot be addressed by a single, rigid, top-down system of standardization. This is why ANSI is fully committed to a system in which the market dictates the timing, content requirements, and number of standards that are to be developed under a voluntary, consensus-based, standards process.

In IEC, there now exists a new set of procedures that will help make a single standard applicable in every region of the world – even though there may be certain *essential differences* in *the mandatory requirements* of the standard.

To some of you, that probably sounded like true "*Standards Speak*."

Let me explain what this means with an example: The conditions for testing and rating a particular piece of ophthalmic equipment in North America might be different from the test methods and rating systems in Asia. With the new IEC policy, both sets of conditions can now be identified in the same IEC standard. Both sets of conditions can also be identified as "equivalent." Now, the same standard can be referenced anywhere in the world, even though some requirements for implementation can differ depending upon location.

ISO approved its global relevance policy in 2003. Its policy recognizes both differing *technical* requirements as well differing *market* requirements.

One example of the way ISO's policy might be implemented is through "normative referencing." This procedure allows the technical experts sitting on an ISO committee to include in a standard a normative or "mandatory" reference to one or more existing standards that *already* meets the needs of global users.

Effectively, this means that an ISO standard could refer to an existing OLA, OEOSC, or other standard. When this happens, industry saves both time and money by not having to transpose a standard that is

already globally relevant into an ISO standard. There is no added value in transposing the documents, plus it enables the technical experts to decide which are the best standards to reference.

The goal of the ISO policy is to achieve the objective of "*one standard, one test, accepted worldwide*."

Slide 15 – One Standard – One Test – Accepted Worldwide

I've addressed "global relevance" as the mechanisms in achieving the "One Standard" dimension of this policy. Now I will address the goal of "one test, accepted worldwide . . ."

Continuing pressures in the global marketplace to preclude redundant and costly barriers to trade drive the need for acknowledgement of equivalency across boundaries. Accordingly, ANSI is involved in several international and regional activities to achieve consistency in conformity assessment and widespread acceptance of its results.

As I noted in my opening remarks, conformity Assessment is defined as "any activity concerned with determining directly or indirectly that relevant requirements are fulfilled." Conformity assessment activities applied in today's marketplace include accreditation, certification, inspection, registration, supplier's declaration, and testing.

As an example, let's focus on product certification. Most users of consumer eyewear or eye care would be unable to assess whether a product meets a standard simply by looking at the product.

The use of a well-written standard in a conformity assessment process adds credibility and validity to the process. The standard should specify all essential characteristics of a product. Test methods should be capable of evaluating the conformity of a product to the specified requirements in a manner that produces test results that are within an acceptable accuracy range. Results should be consistent from test to test; results should also be reproducible.

In the global arena, diverse user requirements often make it difficult to develop "equivalent" tests and test results. The key factors for success are coordination and cooperation in the development of "similar" requirements that can be recognized globally.

Slide 16 – Developing Nations and Consumer Involvement

To this end, ISO's Conformity Assessment Committee, known as ISO/CASCO, has been working in conjunction with the ISO Committee for Developing Country Matters (ISO/DEVCO), to leverage conformity assessment services in support of developing countries. Global organizations such as the International Accreditation Forum (IAF) and regional bodies such as the Inter-American Accreditation

Cooperation (IAAC) and the Pacific Accreditation Cooperation (PAC) are all working to advance these goals.

Bi-lateral agreements – rather, agreements between two or more nations for the mutual recognition of accreditation and or certification marks – are especially helpful in the advancement of global recognition and the concept of a single test and single mark.

Often, the ISO Consumer Policy Committee (ISO/COPOLCO) works with CASCO and DEVCO to provide the linkage between consumers and the standards world. Consumers are the ultimate beneficiaries of standards since they purchase the products and services that are built to these guidelines. Consumer involvement is vitally important.

Slide 17 – Techno-Globalization and the "Digital Divide"

This Congress is testimony to the march of technological evolution in the Optometric community. And the business plan of ISO/TC 172 underscores this expectation. To quote,

> "within a generation, optics has gone from being one of the rather traditional aspects of the physics curriculum at school and university to one of the dynamos of the revolution in communication and information technology that will profoundly influence the new millennium",
>
> (and)
>
> "it is expected that the photon will be the basis for a technical revolution in the next century like the electron was the one for the 20th century".

The theme of World Standards Day 2003 was "Global Standards for the Global Information Society". This is indicative of the international standards community's commitment to promoting an action plan to define a roadmap for governments, businesses and other forces of society to bridge the digital divide.

This means, to paraphrase the Universal Declaration of Human Rights, a vision of standards essential role in the achievement of an inclusive society where all citizens share information and ideas regardless of borders, gender and social distinctions.

Slide 18 – Convergence/Connectivity of Standards and Conformity Assessment

As the entire world becomes more familiar with not only the existence of standards but the process of standards development, the market will better understand how to judge the adequacy of various marketplace components beyond the obvious aspects of product quality.

The linkages with the systems within which these products are created, delivered and serviced, as well as the competence of the professionals involved in the workforce will be increasingly vital.

Slide 19 – People, the Premier Resource

The common element throughout the customer-supplier chain is people, as all of us are involved in defining our requirements as customers, and meeting these expectations as suppliers. And this thread, this linkage, is apparent by reference in standards across the full spectrum of sectors and applications.

Here is the increasingly familiar process model from the latest revision of ISO 9001 for Quality Management Systems. Certainly the qualifications of the personnel resources in any enterprise are key to its customer satisfaction and continued viability and success.

Slide 20 – Conformity Assessment Framework

The ponderous term, "Conformity Assessment", often confuses the consumer – yet it couldn't be more self-explanatory.

What may complicate understanding is the hierarchy, or framework, of formal mechanisms for enhancing consumer confidence through independent attestation that requirements are met.

Although there are a variety of ways to assess conformity, from self-declaration to accredited "3rd Party" (independent) certification, the object is to assure customer acceptance via enabling confidence that the standard is fulfilled.

Slide 21 – Requirements for Conformity Assessment Bodies

Where accredited third party certification is the method of choice in the marketplace, there exist international standards prescribing the requirements for both certification bodies, and the accreditors who assess their competence.

Accreditors must comply with ISO/IEC Guide 61 (soon to be succeeded by ISO/IEC Standard 17011), and certification bodies are assessed for conformity to ISO/IEC Guides 62 or 66 (soon to be replaced with ISO/IEC Standard 17021), Guide 65, or ISO/IEC Standard 17024 depending on whether the object of certification is (respectively) a system, product or person.

Slide 22 - ISO/IEC 17024 General Requirements

ANSI's newest accreditation program was developed with the publication of the ISO/IEC 17024 Standard in 2003 to meet the demand by personnel certification bodies for international recognition.

In short, the 17024 standard defines the requirements for certification body structure, including requisite management system documentation, control, and review.

Equally important elements are prescribed for the people employed by the certification body, especially examiners.

And the third major section lays out the requirements for the certification process, from application through recurring recertification.

Slide 23 – ANSI Accreditation to ISO/IEC 17024
Demand is further driven by employers who increasingly yearn for assurance of their workforce competence, and employees who want certifications that increase their employability.

Although many different concepts and uses for the term "accreditation" exist in the U.S. for oversight of professional certificate and/or certification programs, none have heretofore been based on a consensus International Standard.

In the vanguard of demand for this recognition are professionals in health care (especially technicians of all disciplines), food services and information technology.

Slide 24 – Convergence/connectivity of Standards and Conformity Assessment (Reprise)
ANSI's mission is, "To enhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems, and safeguarding their integrity".

A primary metric of our success in fulfilling this mission is the confidence instilled in the marketplace by standards developed under the aforementioned cardinal principles and conformity assessment based on internationally recognized norms.

When these linkages are successful, the resulting confidence in all dimensions of the marketplace (be it a system, product or person) is multiplied, rather than a just a sum of the parts.

Slide 25 - Conclusion
The roles of ISO and ANSI . . . the roles of the World Council of Optometry . . . and the roles of other members of the global standards and conformity assessment communities are intimately linked – certainly for economic reasons if not also for many others.

Collectively, we support global industry and the worldwide sale of their products. From a purely economic perspective, about 80 percent of global merchandise trade is affected by standards and by regulations that embody standards. In terms of the U.S.-European economic relationship, this means that standards influence an estimated $200 billion in transatlantic trade. These numbers are already high and evidence shows that they continue to rise.

What are the other forces affecting the ophthalmic industry internationally?

What is the future of your standards work domestically and globally?

You may already know the answers to these questions. And some of these questions may answered by my colleagues on this afternoon's panel.

Either way, by engaging in the processes and policy initiatives these questions address, each of you certainly has the ability to affect the outcomes.

The standardization process itself is a long-term pursuit. Those of us in the standards policy business know that patience, more than any other attribute, is essential. Open, ongoing communications between stakeholders and global trading partners while sitting at the standardization table are fundamental to successful trade.

But patience and persistence are worth the investment.

We must continue fostering these positive relationships with our global partners if we are to be successful in our cooperative efforts to establish globally relevant international standards. Equally important to buyer confidence are considerations of how conformity to the standards requirements is assessed. Our ultimate goal is to achieve a level playing field in the international standards arena, and an assurance that the needs of all nations are taken into account in IEC and ISO standards development.

The success of all our efforts is tied directly to the willingness of U.S. interests to commit the resources required to ensure a strong presence in the international standards process.

There has never been a more important time for the ophthalmic industry to assume a leadership role in domestic, regional and global standards and conformity assessment activities.

ANSI and ISO are ready to be your partners. We look forward to working with you.

Thank you for your time and attention.

<< END >>

<<NOTE TO LANE: Q/A to follow all the speakers on this panel>>