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## WHY THE U.S. MUST REMAIN INVOLVED IN THE ISO STANDARDS DEVELOPMENT PROCESS

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The U.S. must remain involved in the International Organization for Standards (ISO) standards development process if it hopes to remain competitive in the international marketplace. Unfortunately, individual companies often have difficulty in maintaining participation due to the cost and time commitment required. The AIAG effectively represents members' interest through the collaboration efforts of its members. This article outlines several of the reasons why active participation is necessary and highlights some recent successes where participation has been effective.

### ISO Standards Development

ISO standards are written by Working Groups (WG) of Subcommittees (SC) to Technical Committees (TC). There are many of each. Representation to a TC is by country. Each country has a Technical Advisory Group (TAG) to facilitate its membership in a TC. The TAG appoints subject matter technical experts to the SCs and WGs to write the standards for the various subjects.

For example, ISO TC 159 is tasked with standardization in the field of ergonomics, including terminology, methodology and human factors data as its overall scope. Subcommittee (SC) 3 addresses the fields of anthropometry and biomechanics. The U.S. TAG to ISO TC 159/SC3 is tasked by the American National Standards Institute (ANSI) through the Human Factors and Ergonomics Society (HFES) to supply technical experts to the various work groups created by SC3 to address standards proposals and projects. Another example is ISO TC 199 which addresses the safety of machinery of which TC 199/WG5 focuses on risk assessment.

Confused yet by the jargon? This is a significant challenge to working effectively in the ISO arena which is part of the reason long term participation is necessary. Attending one or two meetings just is not very effective.

Standards are usually written at the WG level. Experts develop proposals that generally reflect a market requirement or a technical need. The proposals are requested by various national technical or standards-making bodies. The standards are based upon consensus among the interested parties. The standards that result are voluntary but may be adopted by national standards making bodies or regulatory authorities and may become part of international agreements.

### Fast Tracking

As with any committee effort, developing international standards is not an easy activity. Efficiencies are often gained by adopting existing country level standards that have been proven effective. The European Committee for Standardization (CEN) and ISO formalized this process through the Vienna Agreement of 1999. The Vienna Agreement allows "technical cooperation"

and sharing between ISO and CEN with the result that CEN standards projects may be “fast tracked” into ISO. This means that existing European standards can be relatively quickly promoted to become ISO standards by fast tracking. Part of the intent of fast tracking is to minimize additional discussions and modifications to standards that have already achieved consensus.

A significant concern with fast tracking CEN standards is that they represent European viewpoints, sensibilities and methods. While our European colleagues continue to bring excellent work into the standards arena, it is still true that European standards fast-tracked into ISO may require modification to better apply to the larger audience of potential users that ISO represents. Not surprisingly, the European community plays a major role in the direction of international standards. The fast track approach works very well for all parties concerned, as long as all parties’ concerns are addressed in the base CEN standard.

The more traditional approach is to write the standard essentially from scratch. This effort often starts with an existing literature, guidelines, etc. if available, which is scoped out and developed into a draft standard. Although this process may be slower, it results in standards that may better reflect international efforts and consensus throughout.

### **U.S. Involvement in ISO Standards Development is Important**

“If you don’t want someone else making the rules for you, you’d better do your homework and come to the table with ISO.” This statement was made by an experienced standards participant at an ANSI committee meeting on industrial equipment. Given the continued growing role of the ISO in standards development, this statement rings true for nearly all standards fields.

A significant issue concerning U.S. involvement is the fact that ISO standards can become government regulations carrying the weight of law. In the EU, violation of standards can result in criminal penalties in some instances. Thus not knowing what the standards require and failing to meet the requirements can result in someone in your company spending time in a European jail.

Participating in the WG or SC that is responsible for writing the standards is therefore critically important to ensure that the language in the document works for U.S. manufacturers. However, not all participation is equal. Early involvement with the standards writing effort is key to influencing the document. For example, Bob Fox joined ISO TC 159/SC3 WG 4 (Human Physical Strength) when several major standards projects were already well underway. At that point in time major changes to the standard scope and content were not possible. Too many discussions had been held and too many consensus decisions had already been made. Conversely, joining a WG early in the standards development or revision activity affords significantly better opportunities to impact the document. The only way to keep abreast of new work items and WG formations is to maintain involvement in the ISO standards development community. In many cases this is part of the services that AIAG provides to its members; keeping abreast of the activities and supporting participation on the WGs, SCs and TCs.

### **Politics and Technical issues**

One question that often arises is the impact of politics on standards. Through the consensus process it can be said that the best technical solution(s) tend to rise to the top in nearly all instances. Although there has been the rare “pet project” which has presented problems, the consensus process works remarkable well to provide technically sound solutions. This is true

despite that fact that sometimes different technical approaches derive from different histories or politics.

For non-technical issues, politics does occur. And unfortunately, there are many substantive non-technical issues. For example, in ISO TC 199/WG5 (risk assessment) the existing ISO 14121 standard included the statement that “all hazards, hazardous situations, and hazardous events with the machinery shall be identified.” The U.S. delegation worked very hard on several occasions to get and keep this phrase modified to:

the essential step in any risk assessment of the machinery is the systematic identification of reasonably foreseeable hazards, hazardous situations and/or hazardous events during all phases of the machine life cycle.

The key point is the use of the terms “reasonably foreseeable.” In the context of the U.S. legal system and the responsibilities of U.S. manufacturers, this phrasing is extremely important. Without the U.S. involvement on WG5, this phrase would not have changed to reflect U.S. concerns. This is an example of how U.S. involvement in the ISO process is both important and can have significant impacts to AIAG members.

### Successes

Within TC 159/SC3, the two most active ISO SC3 working groups are WG 1 (Anthropometry) and WG 4 (Human Physical Strength). Significantly, the U.S. convenes (chairs) WG 1 which means it has greater influence on some of the decisions affecting the document development. WG 1 continues to work on a number of projects involving standardized anthropometric data collection and the eventual compilation of a global anthropometric database.

WG 1 is currently working towards the goal of a standardized global anthropometric database. The projects making up this effort are:

- ISO NP 7250-1 (Body measurement definitions and landmarks),
- 7250-2 (Statistical summaries of body measurements from individual ISO populations) and;
- 7250-3 (Worldwide and regional design values).

The ISO 7250-1 was originally a CEN lead and was voted for renewal. Work is proceeding on NP 7250-2 and the countries represented on WG 1 are reviewing data for submission with data delivery later this year. A draft data compilation may be available in about a year. These efforts will culminate in a database that will be very useful to anyone designing products and workplaces for global populations.

Bob Fox and Wayne Maynard serve on WG4. In January of this year the US TAG voted unanimously to approve the ISO 11228-2, “Ergonomics – Manual Handling, Part 2: Pushing and Pulling” and ISO 11228-3, “Ergonomics – Manual Handling, Part 3: Handling of light loads at high frequency.” Both of these standards projects have been under development in WG 4 for the past six years and paralleled CEN projects in the CEN TC 122 WG4. This CEN WG meets concurrently with the ISO TC 159/SC3 WG4 and its projects are introduced into ISO per the 1991 Vienna Agreement.

Bob encouraged and participated in major rewrites of the ISO 11228-2 and 3 projects to give them a broader base of application and appeal. The FDIS 11228-3 “Handling of light loads at high frequency,” in spite of its somewhat misleading title, addressed the assessment of upper

extremity repetitive motion activity. The “Occupational Repetitive Action” or OCRA technique developed by Enrico Occipinti and Daniela Colombini of the University of Milan was the assessment method incorporated in the CEN standard. As part of the ISO rewrite, the standard was rewritten to address more what an assessment method should include and to allow for the incorporation of other assessment methods contingent upon the needs, training and resources of the ultimate user.

With the conclusion of the ISO 11228 series of standards, WG 4 is now proceeding on the development of an applications manual for potential users of those standards.

The US TAG to ISO TC159/SC3 will hold its annual meeting in July chaired by Bob Fox. Along with its review of the progress and technical aspects of the various standards projects, the US TAG is also involved in efforts through the HFES to get more human factors/ergonomics professionals and companies interested and involved in standards work.

#### Safety of Machinery - WG5

Currently the safety of machinery is addressed in three separate international standards: ISO 12100-1 (hazard identification), ISO 12100-2 (risk reduction) and ISO 14121 (risk assessment). To the casual observer these three standards might appear to address pieces of a single process. They do. However, in the early development of the safety of machinery standards (circa 1990), these pieces were separated for non-technical reasons and have remained so for the past 15 years. During the discussions of risk assessment, WG5 kept bumping into the limitation that risk reduction absolutely could not be addressed in 14121 because risk reduction was addressed in 12100-2. This obstacle occurred even though all the technical experts agreed that there was no point in doing risk assessment unless one intended to do risk reduction. Midway through the four year revision effort for ISO 14121, members of the U.S. delegation began working in parallel on a revision of the U.S. packaging machinery standard ANSI/PMMI B155.1. This standard was revised to integrate the entire risk assessment process into one document, applicable to both suppliers and users of packaging machinery. This revision was completed in 2006 and accomplished what the WG5 members claimed could not be done. Subsequently the U.S. machine tool industry has followed this approach also. The feasibility of combining the three ISO standards was also introduced at the TC 199 level and then referred back to the WG5. At the most recent meeting of WG5 in March 2007, a most remarkable event occurred. European members of the WG5 engaged and led the discussion on combining these three standards. The conversation had changed dramatically due to the U.S. participation in the standards development process. Bruce Main observed:

It seems that many times we attend meetings and there is no overt outcome for which we can show value. This is an exception. Through the ongoing efforts of the U.S. delegation to WG5, we have managed to move many of the Europeans from “it cannot be done” to advocating that it should be done.

#### Conclusion

The U.S. and EU have different social controls for reducing risk. This stems from the differing histories of business-labor-government relations, differing legal and liability systems, different collective bargaining systems, differing prior regulations, and differing cultures. Understandably, EU standards writers tend to focus on EU concerns, just as U.S. writers tend to focus on U.S. concerns. Yet through active participation in the ISO consensus process, international standards can be developed rendering effective useful solutions for both markets.

The U.S. needs to remain actively involved early in the ISO standards development process, and AIAG helps member companies by doing so. Otherwise we will face playing by rules we may not like nor can we change.

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