WORKSHOP ON INTERNATIONAL STANDARDS FOR MEDICAL TECHNOLOGIES (26-27 February 2004)

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Subjects

- AAMI and its role in medical device standards.
- Successes and challenges of AAMI, the US system and national and international standards bodies.
- Frame of reference: Strong US legislative and regulatory framework for government standards was replaced by reliance on voluntary standards. Foundation for this presentation and AAMI program.

AAMI

- AAMI is a US-based standards developing organization with strong involvement in international standards.
- AAMI also provides education, information, certification and communications programs for the manufacturing industry, governments, hospitals and other health care institutions and health care professionals. AAMI's members come from all these organizations and disciplines.

Standards Activities: Major Areas

- **Electromedical**
- **Sterilization** technology
- **Quality systems** and risk management
- **Cardiovascular implants, active implantable medical devices, and biological evaluation of medical devices**.
- Technical information reports, technology conference reports, and position statements on a wide range of issues of concern to the health care community
- AAMI experts are also available to members and nonmembers for technical advice.

Scope

- Over 100 national and international technical committees and advisory groups under AAMI administration.
- AAMI members play a significant and highly supportive role in the development of medical device standards with worldwide application.

Challenge

- AAMI and its members made a purposeful decision to share intellectual property and income with ANSI, ISO and IEC, in the interest of internationalizing standards.
- We are still sorting out the implications of this since this income is used to develop and defray the cost of adopting international standards.
- To a great and increasing extent, this “sharing” has really meant an increasing loss of these property rights and income.
- US funding issue that affects international participation and adoption of international standards.

New Approach

- The AAMI international standards program was refocused and expanded with the emergence of the European Union's "New Approach" to the use of standards.
- AAMI believes that the concept of the European approach has contributed to the use of standards as an important resource for regulation and commerce. We commend European policy makers for their leadership and foresight.

AAMI and International Standards

- AAMI has worked very closely with leaders all over the world to provide secretariat support in important areas of international standards. The US industry strongly supports globally harmonized standards.
- International standards and an effective international system make good business sense to a global and highly regulated industry.

AAMI and International Standards

- Another form of support is AAMI's policy of adopting ISO and IEC standards as new or revised American National Standards.
- New ANSI funding polices will require AAMI to reevaluate this policy. Hopefully, this issue can be resolved. An example of how a national issue can have international implications.
- Industry support mitigates impact. Sales secondary to standards development.

Success

- In a relatively short period of time, the world community, working through ISO and IEC, has developed a comprehensive body of medical device standards that serves the world public and economy. All involved should be commended for this tremendous undertaking and result. A successful process and result.

Principles of AAMI Program

- The value of the standards system and standards comes from the industry and professions, who have the most knowledge about technology.
- Government, ISO, IEC and national bodies have an important role in oversight and aspects of development.
- They are, however, primarily customers or users of standards and experience dictates that they must not drive the creative process unless there are compelling reasons of public interest**.**

Industry and Professions

- Standards are resources for commerce and improved health care, not just projects or commodities. Industry and the professions must generally determine if and when standards will be written. They have the knowledge.

Use of Limited Resources

- AAMI has strived to create only the level of infrastructure necessary to enable industry to develop standards.
- Industries support the ISO and IEC system since they provide the infrastructure and process needed to produce the standards industry and the pubic need.
- Consortia are, however, a rational response to unnecessary process and expense for some industries. Shifts a funding burden to those who support the system. A challenge.

Other Principles

- One universally adopted standard and one test method is important for markets and government regulation.
- Reduces duplication of effort and standards. Duplication of effort and standards should be avoided at both the national and international level.
- AAMI works through ISO and IEC wherever possible to achieve one standard.

Other Principles

- “Choices” of standards is a particularly burdensome concept in a regulatory context. Lack of consensus?
- Regulators and industry should be able to rely on one consensus standard and not have to choose among different standards.

Other Principles

- Standards should be developed only where there are clear patient safety needs validated by risk assessment. Avoid standards of convenience; restrict technology?
- Should address only essential requirements and permit technology innovation.

Context for Standards

- Standards only provide a frame of reference or context for safety and performance.
- A resource or context to be used by professionals experienced and sophisticated in the development, management and utilization of medical technology.
- ***Standards are not panaceas.***
- ***They have limitations.***

Conclusion and Summary

- This workshop provides public acknowledgment of a successful system and the tremendous productivity and success in the development of critically needed international standards in the medical device field.
- To date, ISO, IEC, ITU-T appear to have created the infrastructure and system necessary for the development of needed standards and have achieved important goals, e.g., patient safety and harmonization.

Conclusion

- As noted, we should view with pride and a strong sense of accomplishment all that has been accomplished, with great leadership, teamwork and collaboration among many countries in the medical device standards field.
- We will aspire to do even better in the future.