



Standards for Medical Applications and Documentation

In the column this time I will cover some domain specific standards: user interface standards which pertain to specific industries, markets, or particular aspects of user interface design. Two rapidly progressing domain specific UI standards efforts have come to my attention lately: standards for medical industry devices and standards for manuals and documentation.

Medical User Interface Standards

In the United States, there has been a burgeoning interest in designing the user interface for devices and computer systems used by medical professionals and patients. The Association for the Advancement of Medical Instrumentation (AAMI) is a major developer of standards for the safety and performance of medical devices. AAMI is a professional organization composed of engineers, physicians, researchers, technicians, and others with an interest in the medical equipment industry. Its stated mission is to bring together the developers, users, and government regulators of the medical industry. AAMI is an accredited standards development organization for the American National Standards Institute, the major independent standards agency for industry in the United States.

An existing human factors standard exists for medical devices, developed by AAMI: ANSI/AAMI HE 48-1993 *Human factors engineering guidelines and preferred practices for the design of medical devices*. This is a revision of an earlier standard, ANSI/AAMI HE 48-1988. This standard is oriented to principles for hardware design. Coverage of human computer interaction is inadequate. Indeed, HF 48 is heavily based upon MIL-STD-1472D, a standard for the U.S. Department of Defense for the human factors of weapons and military control systems (and one which has been the source material for numerous human factors standards and guidelines

in hardware design). However, this is out of step now with the medical device industry, which are increasing incorporating computers and other software user interfaces to control medical equipment. Human computer interaction is becoming increasingly important in this domain.

Fortunately, ANSI/AAMI HE 48 is now undergoing its five-year revision, completion is expected in 1998. Gardner-Bonneau (1997) notes that greater attention to HCI is one goal of the revision committee. (Other areas of development include attention to design process, standards specific to individual medical domains, and attention to users with less professional expertise, e.g. family members working with patients at home). The HE 48 revision committee met for the first time at the AAMI conference in Washington, DC last June. At that meeting, the committee decided to make the revised HE 48 a two part document. The first part would be a design process document. The second part would be much like the current document, but revised with new material and will include examples from specific medical domains. (For more information, see Gardner-Bonneau, 1997).

For those interested in joining the AAMI Human Engineering Committee, you may contact the coordinator Margie Breida by Internet email at Margie_Breida@aami.com or by phone at +1 703 525 4890 (ext. 213).

Documentation Standards

Manuals and documentation is an often overlooked part of the user experience in computer systems. Yet there is a body of knowledge about how to design usable end-user documentation. "Users don't read manuals" we are told, an oft-cited aphorism (but poorly supported). So often, in the design process, manuals are done quickly and with little attention – even by user interface designers themselves. I've observed that this is exactly the kind of situation where interests in

standardizing a domain – in order to improve it – occurs. And, indeed, there are some interesting standards activities developing in this domains.

According to Phoha (1997), the American Nuclear Society (ANS) developed an ANSI standard in 1995 for documentation of engineering and scientific software. The approved and released standard is ANSI/ANS 10.3-1995. The standard is not a rigid standard on the form of documentation but more along the lines of guidelines on the content of documentation. According to Phoha, ANSI/ANS 10.3 specifies four content blocks for a software document: the abstraction, application information, problem or function definition, and programming information. The standard describes what is expected of the contents in each of these four sections. The standard also recommends what to include in the "shrink wrap" package and how to label them (e.g. floppy disks, manuals). This standard is directed at scientific and engineering software, and does not address the needs of general consumer and business software.

In England, the British Standards Institute (BSI) also has an approved and released standard for computer documentation, BS 7830:1996, *Guide to the design and preparation of on-screen documentation for users of application software*. (For those in the U.S., this BSI standard can also be obtained from ANSI.) More on this standard in future columns.

Another standard is in the process of development by the Human Factors and

Ergonomics Society (HFES). This is also being developed under the management of the U.S. agency ANSI, and will be numbered ANSI/HFES 400 when it becomes an approved standard. This is a guidelines document which is directed generally at all devices which need manuals, it is not specifically a computer documentation standard. The activities of this committee are progressing rapidly, with one working draft already completed.

There are more places to find standards and guidelines on computer documentation, for example, the US Department of Defense also has contributions in this area. In future issues of this column, I will track the progress of these and other

documentation standards as they develop.

References

Gardner-Bonneau, D. (1997, Summer). AAMI human engineering committee meeting report. *MSRTG News*, 9(3), 2, 11.

Phoha, V. (1997, October). A standard for software documentation. *IEEE Computer*, 30(10), 97-98.

Notes

AAMI standards can be searched or browsed at <http://www.cssinfo.com/info/aami.html>

ANSI standards can be ordered from them at +1-212-642-4900 or, now, on a trial basis, by the Internet, see <http://www.ansi.org/shop.html>

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