Letters to the Editor

validation and verification

I just read my copy of the first 2009 issue of *IEEE Engineering in Medicine and Biology Magazine* and was disappointed to see confusing information being disseminated in the "Senior Design" column on "Design Verification in Capstone Design Courses." The fundamental systems engineering concepts of 1) customer needs, wants, and desires; 2) product performance requirements; 3) design verification; and 4) validation were either misrepresented or incorrectly defined. These engineering concepts are critical elements in the development of safe and effective medical devices.

Product requirements are a subset of the discovered customer needs, wants, and desires that the designing organization believes are technologically and economically feasible; they are not identical, i.e., one is a subset of the other. Validation is the experimental process of demonstrating that the design implementation (e.g., the actual product, process, or service) meets the requirements; it is the process of ensuring that *you did right thing* and is fundamental to medical device safety and effectiveness. Design verification is one of the three engineering activities ensuring that *you did things right*:

- verifying that the product requirements (inputs to the design activities) correctly correspond to the selected customer needs
- verifying that the design specifications (outputs of the design activities) correctly correspond to the agreed-upon product requirements
- verifying that the design implementation (the physical realization of the design) correctly corresponds to the design specifications.

These are nontrivial concepts defined by over 50 years of publications in the open literature, incorporation in international consensus standards [e.g., International Standards Organization (ISO) 13485:2003, which is harmonized with ISO 9001:2000], and U.S. Food and Drug Administration (USFDA) design control regulations (21 CFR 820.30) promulgated in 1996. I recently traced part of the evolution of these concepts in a 2005 *Journal of Biomedical Informatics* article. These are central concepts in my engineering practice with the FDA-regulated firms and, in my colleagues' and my personal experience, a source of continued confusion in the device industry. The incorrect information in this first 2009 issue only furthers that situation. In fact, it is because the uninformed improperly interchange the English words *requirement* and *specification* with the historical systems engineering terms of art *requirements* and *specifications* that the modern terminology is now (respectively) *design inputs* and *design outputs*.

The article states (p. 87) "the best way to *verify* a design is to use it in its intended service environment for its intended service life." The article's illustrative example of testing the catheter (p. 88) summarizes a set of four requirements stating the testing of these in a simulated use environment is "design verification." This is not correct! The study of the design implementation (the actual product) by "expected users in an expected use environment" (or a correct simulation thereof; 21 CFR 820.30(g) and ISO 13485:2003 §7.3.6) is validation and not design verification; the purpose is to demonstrate that we did *the right thing*, not that we *did things right*. Design verification, for this particular example, would ensure that the specifications were properly translated into the physical prototype; this might entail a study to verify that the proper bore size was produced, proper balloon materials were utilized, and proper chemical welding process was employed in attaching the catheter to the balloon if they are constructed in separate pieces. Prior to that activity, it is necessary to verify that the formulated requirements faithfully represent the selected customer needs and that the designed specifications properly fulfill the agreed-upon requirements (21 CFR 820.30(f) and ISO 13485:2003 §7.3.5).

Verification demonstrates that you built what you designed; validation demonstrates that you built what you agreed the stakeholders want. It is the execution of these systems engineering activities, in the proper manner and sequence, which provides assurance of increased safety and effectiveness for medical devices. Having the IEEE disseminate incorrect information directly counteracts all the ongoing efforts to assist manufacturers to produce safe medical devices. These fundamental systems engineering concepts are critical to the development of safe medical devices and the foundation of international regulations and consensus standards. Letting this misinformation stand unchallenged and uncorrected is a serious disservice to the medical device community, the practitioners, and the patients they serve.

G.M. Samaras
Senior Member, IEEE

Response from Dr. Goldberg:

Dr. Samaras is correct in his statement that the terms *validation* and *verification* were used incorrectly in my column. He is also correct that the literature contains many confusing references to the two terms, which was the source of my error. According to ISO 9000:2005, verification (Section 3.8.4) is defined as "confirmation, through the provision of objective evidence, that specified requirements have been fulfilled" and validation (Section 3.8.5) is defined as "confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled" [1]. Validation has more to do with meeting customer needs (making the right product), and verification has more to do with the processes used to produce the product (making the product right).

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In comparing the two definitions, the differences between "specified requirements" and "requirements for a specific intended use or application" are ambiguous. This may be contributing to the confusion present in the literature, to which Dr. Samaras refers, regarding the interpretation of use of these definitions. In most situations, verification occurs upstream of the final product, where validation involves the final product design. There are situations where verification and validation occur simultaneously on the final product. ISO 9000 family of standards is flexible enough to allow this approach. What is most important is that an organization completes both phases.

I do not agree with Dr. Samaras' assertions that 1) the terms *customer needs* and *performance requirements* were misrepresented or incorrectly defined and 2) the uninformed improperly interchange the English words *requirement* and *specification*. In my column, I did not state that product requirements and customer needs are the same. Based on my 14 years of medical device design experience and according to several current design textbooks, target product specifications are generated from customer needs. These specifications are then translated into design concepts. Product specifications are "the precise description of what the product has to do" [2]. This includes information on how the product must perform (performance requirements). Product specifications are measurable and provide a means for determining whether the customer needs have been met. If product testing indicates that performance requirements have been met, then one can conclude that customer needs will be met. According to ISO 9000:2005, a specification (Section 3.7.3) is "a document stating requirement" and a requirement (Section 3.1.2) is a "need or expectation that is stated, generally implied or obligatory" [1]. Thus, I see no misuse or confusion of these two terms as claimed in his letter.

I strongly disagree with Dr. Samaras' assessment of the impact of confusing the terms *validation* and *verification* in an *IEEE Engineering in Medicine and Biology Magazine* column. He states "having the IEEE disseminate incorrect information directly counteracts all the ongoing efforts to encourage manufacturers to produce safe medical devices." He also states "letting this misinformation stand unchallenged and uncorrected is a serious disservice to the medical device community, the practitioners, and patients they serve." While I agree that it is important to correct errors that appear in publications, I absolutely disagree that confusing the terms *validation* and *verification* in a magazine column would have any effect on the compliance of medical device manufacturers with design controls or their desire to produce safe medical devices. As long as both the validation and verification phases are completed [as required by the FDA Quality System Regulation (QSR) and the ISO 9000 family of standards], then all of the activities needed to produce safe medical devices will have been completed, and confusing the name of the two phases would have no impact on the medical device quality. Dr. Samaras' statements greatly exaggerate the potential impact of the error that appeared in my column.

Finally, the focus of my column is on teaching of the senior biomedical engineering capstone design course. Each column deals with different aspects of the course, including course administration, grading, course deliverables, projects, developing skills (teamwork, communication, and project management), and lecture topics. The title of my column appearing in the January/February 2009 issue of *IEEE Engineering in Medicine and Biology Magazine* was "Design Verification in Capstone Design Courses." It should have read "Design Validation in Capstone Design Courses." The goal of the column was not to provide readers with an overview of design controls but to show fellow educators how to incorporate design controls into their capstone design courses. Many capstone design course instructors fail to recognize the value of design controls and thus do not include them in their courses. The purpose of my column was to share with them how other capstone design course instructors and I (with limited resources) incorporate design validation activities into our courses, enabling us to teach our students something about design controls. My ultimate goal was to convince fellow educators of 1) the importance of design controls in producing safe medical devices and 2) the need for their students to understand design control requirements to better prepare them for their careers.

I agree with Dr. Samaras on the importance of design controls to the development of safe medical devices, and I appreciate his feedback regarding design validation and verification terminology.

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References

[1] *Quality Management Systems–Fundamentals and Vocabulary*, ISO 9000:2005.
[2] K. Ulrich and S. Eppinger, *Product Design and Development*, 4th ed. New York: McGraw-Hill/Irwin, 2004.

Strategies for Plasmid DNA Delivery

Our review article "Strategies for Delivery of Nonviral Plasmid DNA-Based Gene Therapy" was published in the Drug Delivery issue of the *IEEE Engineering in Medicine and Biology Magazine* (E. R. Arulmuthu, D. J. Williams, and H. K. Versteeg, "The arrival of genetic engineering," *IEEE Engineering in Medicine and Biology Magazine*, vol. 28, Jan./Feb. 2009, pp. 40–54). Unfortunately, this heading does not accurately reflect the contents of the article. Although a correction to the title cannot be published at this stage because of publication and citation constraints, we would appreciate the publication of this letter with its short title "Strategies for Plasmid DNA Delivery" in the *IEEE Engineering in Medicine and Biology Magazine*, so that readers requiring to know more on this topic can be directed to our publication in the Jan./Feb. 2009 issue.

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and Hendrik K. Versteeg