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Validation Engineering in Ergonomics: Theoretical Perspectives

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A number of ergonomists have described or developed methodological models for the design, development, and evaluation of ergonomic products and processes. These models can be shown to be subsets of a classical methodological approach – well known in the hardware and systems professions, recently "discovered" by the software profession, and now beginning to be applied to ergonomics. This classical method – here called validation engineering (VE) – is a structured, systematic approach to business and technical risk reduction and user hazard mitigation. The VE lifecycle consists of a series of feedback and feedforward loops. The feedback loops consist of validation testing (implementation vs. requirements), verification testing (of requirements, specifications, and implementation), incremental hazard analyses, and post-deployment corrective and preventative actions. The feedforward loop consists of needs assessment, translation of needs to quantifiable requirements, translation of requirements to quantifiable engineering specifications, translation of specifications to implementation, and deployment of the product/process. Ergonomists can benefit both from using the VE approach and participating in efforts that use this approach

The application of ergonomics does not operate independently of product or process development and should not be viewed as standing alone. It is best considered within a validation engineering framework.

WHAT IS VALIDATION ENGINEERING?

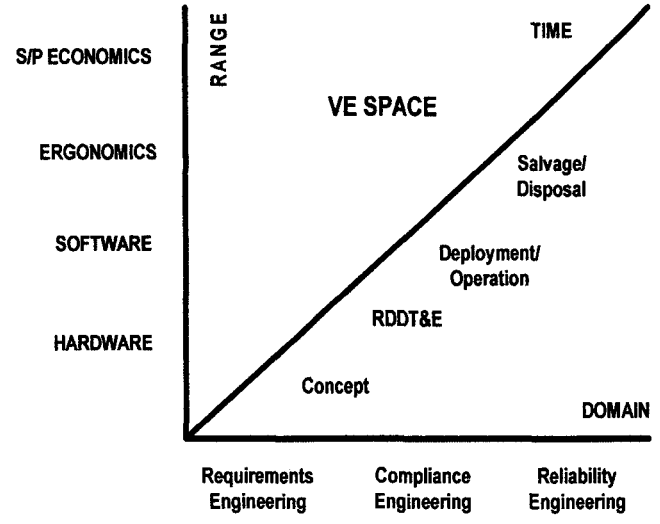
Validation engineering (VE) is a structured, systematic approach to system risk reduction over the full lifetime of the system (from cradle to grave). It is of particular importance in new product development of complex systems. Your ability to predict system behavior reliably increases with increasing levels of validation. Un-validated systems have a high degree of uncertainty (complexity) in their behavior; ***validation engineering decreases the complexity of system behavior***.

VE is a proactive hazard mitigation process maximizing the likelihood of reducing errors and time to market. It is a structured, ***risk***-based, iterative approach to the research, design, development, test & evaluation (RDDT&E), deployment, and salvage/disposal of products and processes. It is a formal process that emphasizes transparency and clarity of known objectives and constraints.

The associated workload ranges from minimal (using a box of 3"x5" cards) to significant (maintaining a complex relational database); the workload level is proportionate to (a) project criticality (impact on human life, property or the environment) and (b) product or process complexity (e.g., project size, time constraints, and team geographical distribution). From an organizational maturity perspective, organizations may be ranked in VE as (I) inactive, (II) reactive, (III) interactive, or (IV) proactive. Certain regulated industries (e.g., FDA-regulated firms) are required by law to be proactive (Level IV) in their validation engineering efforts.

The VE Space

The **domain** of validation engineering is the triumvirate of requirements engineering, compliance engineering, and reliability engineering; the **range** of validation engineering activities is the system hardware, software, ergonomics, and seller/ purchaser economics. The three dimensional representation is shown below.



As a **lifecycle** process, it begins with the initial conceptualization of the system, it is continually applied throughout the research, design, development, testing and evaluation (RDDT&E) phase, in the operational phase (with periodic revalidations), and finally, when the system is obsolete, in the salvage and disposal phase. The **feedback** loops of this lifecycle model (see next figure) consist of validation testing (implementation vs. requirements), verification testing (of requirements, specifications, and implementation), incremental hazard analyses (HA), and post-deployment corrective and preventative actions (CAPA). The **feedforward** loop consists of needs assessment, translation of needs to

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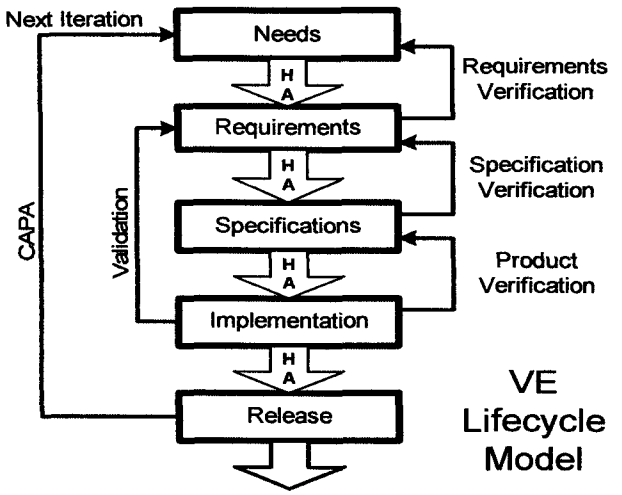
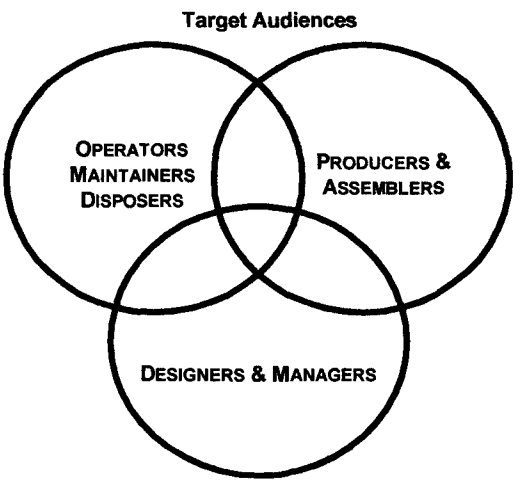
quantifiable requirements, translation of requirements to quantifiable engineering specifications, translation of specifications to a product/process implementation, and the deployment of the product or process.



Ergonomic considerations participate in a manner similar to hardware, software, and economic considerations in the development of requirements, in compliance with appropriate regulations and standards, and in the engineering of system reliability.

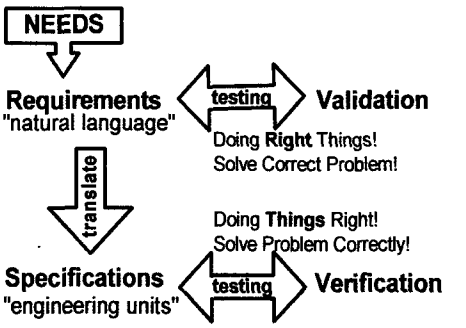
Requirements Engineering

From a product development process perspective, one can obtain a more detailed view of requirements engineering. The first step in the iterative process is identification of the needs of the system users - which presupposes that you have correctly identified the real user populations (manufacturers, assemblers, operators, clinicians, consumers, maintainers, disposers, etc.).



User needs assessment is a complex activity that often has been implemented by marketing personnel with ad hoc engineering support; in fact, it is a central area of expertise and practice in ergonomics. Some examples of need assessment techniques include interviews, questionnaires, and ethnomethodological studies, brain storming, problem-domain storyboarding, prototyping, literature reviews and ergonomics laboratory research, as well as evolutionary (rapid & iterative) development techniques. Both from a good business practices perspective and from a FDA regulatory perspective, they must be implemented in a statistically valid manner, so that the results truly represent the populations under study.

Once the user needs have been determined, the next task is to translate the needs that will be met into requirements. This activity also requires the knowledge and skills of ergonomics.



Requirements are the foundation of the validation process and a crucial source of the engineering design specifications. Defective requirements are the principal cause of incorrect or inadequate system designs and failed validations. Common flaws include not selecting the proper target audiences and assuming you already know the user needs. Properly formulated requirements are natural language statements (e.g., English) that are understandable by the user populations, by the design team, and by seller and purchaser management. Properly formulated requirements must be traceable to specific user needs, must be clear, complete, and internally consistent, and must be verifiable and testable (quantifiable).

Proper requirement formulation is an interdisciplinary engineering activity that necessarily includes ergonomics expertise to represent properly the discovered needs of the various user populations. A central activity of ergonomics is translating user needs into requirements (and then requirements into engineering specifications). If this is reminiscent of "concurrent engineering" discussions, it is because it is the same discussion (see Eisner, 1997). Just as electronics engineers must make sure the mechanical engineers leave enough room for their printed circuit boards, and the software engineers make sure the electronics engineers put enough memory in the circuitry for their code, and the manufacturing engineers make sure standard parts are not replaced (without good justification) with custom parts, so ergonomists make sure the design team actually meet the users' real needs. And, when difficult engineering trade-offs are encountered, the ergonomist on the design team must ensure that the user's needs are properly considered - because if they are not met,

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either the product will not be a success or it will encourage new competition in the market!

Once the requirements are properly established and verified against the user needs, the next task is to translate these natural language statements into engineering design specifications. Engineering design specifications are the true basis for the product design and are quantitative product attributes with associated units and tolerances. Once again, the ergonomist can play a crucial role on the design team, directly impacting the work of the rest of the team and the final design of the product:

1. From a **hardware ergonomics** perspective, the ergonomist not only has access to tabulated anthropomorphometric data and human perceptual data, but is trained to properly use these data in the realization of engineering designs.
2. From a **software ergonomics** perspective, the ergonomist is trained to participate in the design of user interfaces, to conduct task analyses on the proposed logical operation of the product, and to participate in the design of training, operation, and maintenance materials.
3. From an **environmental ergonomics** perspective, the ergonomist can assist the design team in assessing how known workspace environmental modalities can impact the use and reliability of the proposed design (e.g., interference with ability to perceive various types of warning indicators, level of tolerable complexity of device operation, etc.).
4. From a **macro-ergonomics** perspective, some ergonomists can assist the organization in harmonizing the design of the product with the way the purchaser organization does business; from inside their own product development organization, these same ergonomists can be called upon to help harmonize their own organization with the product development process, with the manufacturing process, with the product distribution process, and/or with the product field support process.

The next step in the VE lifecycle process is product implementation; this includes iterative pre-production development of the product (in increasingly more refined form) and mass production of the product. The ergonomist can add significant value to both of these processes. In the pre-production stage, the ergonomist can provide a number of analytic evaluations of the product including heuristic analyses, managing expert reviews, and conducting laboratory-based usability analyses. As required by the FDA Quality System Regulation, test procedures that are appropriate for their intended use (validated test procedures that possess the appropriate sensitivity, specificity, and reliability), properly calibrated equipment, and tests that are statistically valid must be employed for usability studies. In the production phase, the ergonomist can assist in job redesign, the development of job aids, as well as recommendations on environmental and organizational issues that would enhance the productivity and job satisfaction of production personnel.

Compliance Engineering

There exist a "hidden" set of changing laws, regulations, and standards (both national and international). They impose design, testing, implementation, and disposal constraints on the organization. Furthermore, they vary across industrial sectors and political boundaries, thus confounding the successful product development process. Compliance engineering involves the identification, applicability assessment, design impact, test design, and operation/disposal considerations required to conform to these constraints. Compliance engineering is an important source of requirements - constraints being the inverse of requirements.

There exist a large number of ergonomics standards; they address various aspects of the profession's activities and they are not generally well known outside the profession. The ergonomist on the product development team plays a critical role in identifying, interpreting, and designing the product to conform to these constraints.

Reliability Engineering

One normally thinks of reliability engineering in terms of parts wearing out or undiagnosed software faults or failures. However, there is another dimension to the reliability equation - the user reliability and use errors. Typically, non-ergonomist designers consider only the most obvious failure modes or well-know use errors. Ergonomists, by contrast, are trained to use analytical and laboratory techniques to discover the more subtle - but potentially more hazardous - use errors. With these same techniques, putative mitigations can be evaluated and the residual risks can be properly assessed.

Risk reduction is managed through risk identification, risk assessment, risk mitigation, and then re-assessment of residual risks. All members of the design team, including the ergonomist, utilize standard risk analytic techniques (e.g., fault tree analysis, failure mode effects and criticality analysis, or hazard and operability studies). However, the ergonomist begins not from an analysis of the mechanical or electronic parts or from an analysis of the program structure, but rather from a task and function analysis; the focus is ***the interface between the device and the user***. Unlike the other members of the design team, the focus is on:

1. ***hardware issues*** (e.g., size, feel, color, and arrangement of physical controls and displays and the impact on their use with and without surgical gloves),

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2. ***software issues*** (e.g., mental workload issues, logic of operations issues, training materials, etc.),
3. ***environmental issues*** (e.g., the crisis of a patient in cardiac arrest, the boredom and reduced vigilance at the end of a shift, light levels during day and night operations), and
4. ***organizational issues*** (e.g., purchaser organization administrative procedures for handling/using product and for scheduling work time, including multiple shifts, etc.).

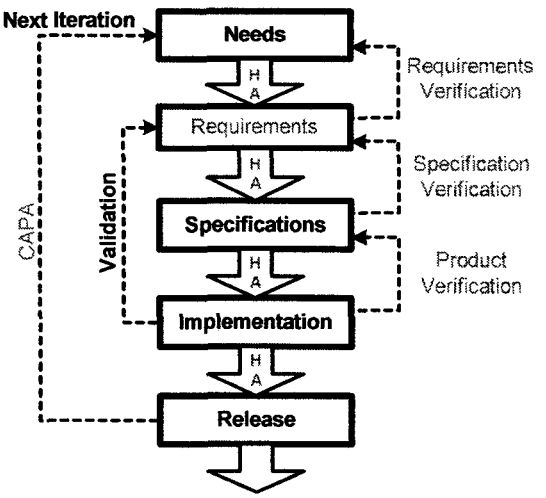
At the end of each step in the VE lifecycle, it is essential to update the hazard analysis! The hazard analysis essentially has a "gating function", permitting transition to the next step or looping back to the previous step. From an ergonomics perspective, hazards associated with the transition from "needs" to "requirements" include such items as whether all the requisite user populations have been properly identified and whether needs elicitation is statistically valid, so that it can be relied upon to properly represent the user populations. Ergonomically-oriented hazards associated with the transition from "requirements" to "specifications" include such items as whether physical size constraints (based upon gender, nationality, etc.) are being adequately translated into mechanical engineering specifications. The proper formulation of use risk items, just as the proper formulation of requirements and engineering specifications, is a context dependent process that is the domain of trained ergonomists. The proper formulation of use risks involves continual and intimate involvement of the ergonomist with the rest of the product design team.

COMPARISON WITH EXISTING LIFECYCLE MODELS

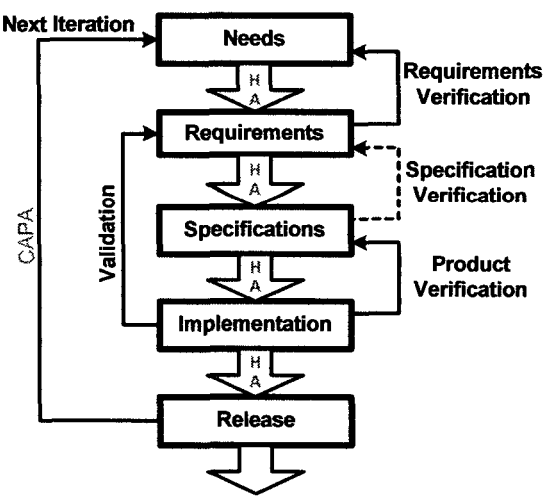
A number of ergonomics lifecycle models have been published over the past two decades. These include the excellent works of Gould & Lewis (1985), Mantei & Teorey (1988), Nielsen (1992), Kreitzberg (1996), Mayhew (1999) and Endsley (2002). They do not comprise a comprehensive list of models and anything not **explicitly** stated in the published model was assumed to be absent for this analysis. A graphical analysis (see below) of these six models indicates that each of these models constitutes a subset of the classical VE model and that, in the aggregate, they contain essentially all the elements of the VE lifecycle model.

Gould & Lewis (1985) emphasize iterative design with careful study of users and empirical measurements. Mantei & Teorey closely follow the classical model, but omit the incremental hazard analyses, do not identify the testing process involved in verification of the design specifications and the CAPA process. Nielsen (1992) also emphasizes iterative design and empirical testing cycles, careful study of the user and establishment of usability goals (requirements). Kreitzberg (1996), Mayhew (1999), and Endsley (2002) all emphasize iterative designs, emphasis on the user, and product verification.

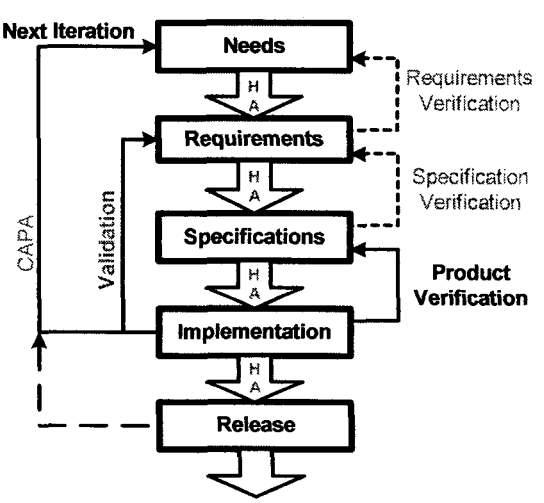
Gould & Lewis (1985)



Mantei & Teorey (1988)



Nielsen (1992)



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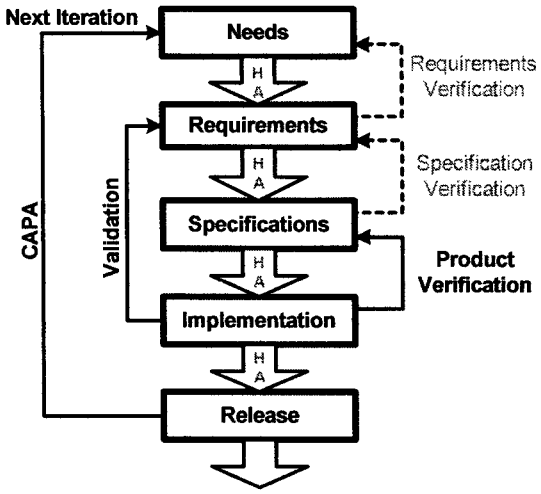
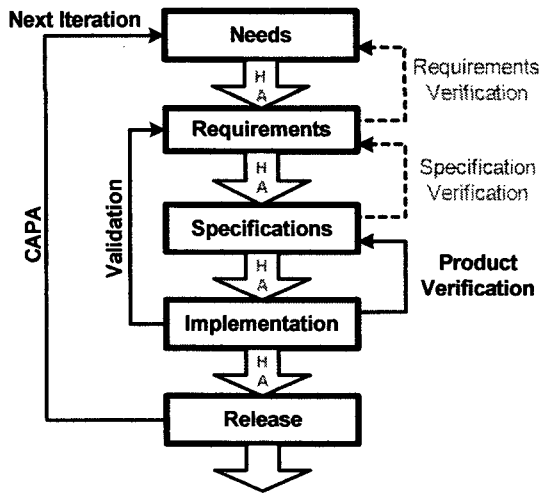
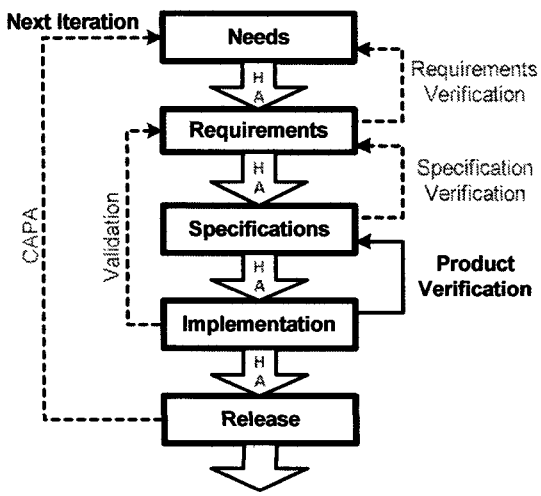
Kreitzberg (1996)



Mayhew (1999)



Endsley (2002)



CONCLUSIONS

Validation engineering is a "cradle-to-grave" structured, systematic approach to system risk reduction in product or process development. It is based upon the triumvirate of requirements engineering, compliance engineering, and reliability engineering; it applies to hardware engineering, software engineering, human factors engineering, and seller/purchaser economics.

Validation engineering clearly elucidates the important role that ergonomists should play in product or process development. It clarifies for project managers the complementary roles of hardware, software and human factors engineers. Finally, it justifies the continual involvement of ergonomists throughout the project lifecycle – rather than just at the beginning or the end!

Based upon the preceding graphical analysis, we see that each published ergonomics lifecycle model may be viewed as a subset of the classical VE lifecycle model. Furthermore, in the aggregate, these models contain essentially all the elements of the classical model (except for explicit inclusion of the iterative incremental hazard analyses).

The ergonomics profession can benefit from the application of the classical VE approach as well as contributing to their organization's product/process development efforts utilizing the VE model.

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