Use Error Analysis in a Product Development Cycle

Proactive assessment to drive design

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Product development organizations have well-established processes in assessing potential hazards for both process and design. However, these processes either do not apply to use error or they treat the human component of systems in a superficial, non-formal way. While some user-centered effort is directed at analyzing and reducing error, with a reliance on traditional user-centered activities, formal human factors methods that specifically address use error and regulatory needs are scarce and only now are gathering steam. A formal Use Error Analysis (UEA) process was developed by HE Consulting Staff to identify potential use error during initial product design. This process generates an exhaustive, predictive list of use errors. Then potential users familiar with the product environment determine the frequency by which the error would occur and the severity of the effects. Once it is determined which errors should be mitigated, the process allows product risk assessment teams to determine the probable causes of the use error. These causes are directly addressed through system design or other mitigations as appropriate.

The process defines use error and failure modes based on well-established error taxonomies that have been used to assess critical events after the fact. Placing these taxonomies into an FMEA process brings out the predictive power they possess. This UEA process has been successfully incorporated into formal hazard analysis processes in an FDA regulated environment[1] and used to influence numerous projects. Examples of where this process has been used is in satisfying regulatory pressures to demonstrate safety and positively influencing product design with minimal effort added to the project while adhering to traditional quality and regulatory principles.

This formal method of assessing use error has merged established use error taxonomies, psychological context and agreed-upon task analyses with traditional risk management procedures. In this manner all participants of the hazard analysis team are working from the same set of guidelines and understanding of the work environment while integrating with well learned, traditional product development activities. This method facilitates the understanding by the hazard analysis team of use error at a level sufficient for valid and useful analysis and mitigation formation consistent with current models of hazard assessment (e.g., it defines use error and resultant failure modes in the same manner as traditional methods assess failure

[1] Indeed, this process directly addresses aspects of the FDA guidelines that call for the evaluation of error before market release and during product design.

modes and their causal hazard conditions). Ultimately, the process moves traditional risk management beyond treating the user as a causal agent of system failure and places the focus on the system or process being analyzed. That is, it defines the user and use error in the same manner as traditional risk management activities assess system components and in the same shared language.

This formal definition of use error and its subsequent failure modes and causes has led to breaking down other barriers in a less formal sense. The present author has experienced developers assess potential designs in terms of a common understanding of use error and its ramifications; the front lines of risk mitigation, so to speak. That is, sharing a common understanding of use error and its causes across development team members allows for early (and ongoing) discussion and assessment of design options and provides for exploratory usability testing opportunities.

In many product development environments, Human Factors (HF) activities have been conducted outside of traditional product development and life cycles. In such a state, HF work may or may not be incorporated into product design. Inclusion of user centered testing results is typically at the whim of product management and dependent on their respective perceived effort to do so. Likewise, a common obstacle for folding sound HF results into a more traditional quality and risk management program is the need to modify, at best, and redo, at worst, the program so as to accommodate human factors research. Until recently, the effort may not have been worth the outcome because HF research was viewed as a "luxury" or optional activity. Given regulatory events over the last decade or so, HF work must be incorporated into product development and risk management activities to satisfy regulatory guidance and directives; yet the disconnect between user-centered activities and traditional methods and deliverables remains an obstacle. The predictive Use Error Analysis method presented here was designed to blend effortlessly into hazard management thus product development and, indeed, become central to analytically assessing risk associated with product design. The method has allowed human factors to overcome many of the natural obstacles that have prevented inclusion of user centered results in established design control processes.

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