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## "Design Control" and Scientific Investigations - Is There Any Linkage?

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Introduction: The quality assurance requirements that apply to the effort to achieve safe transportation, storage, and disposal of high-level nuclear waste specify that "design control" be applied to design activities. That effort also involves extensive scientific investigation activities to, among other things, develop information that may be used in engineering design activities. Individuals who are charged with the implementation of such quality assurance requirements have come to a variety of conclusions about whether there is any firm linkage between design control and the conduct of scientific investigations. This paper contends that there is a reasonable and necessary linkage between "design control" and scientific activities, though not a connection that has traditionally been made and not one addressed in the QA standards for radioactive waste management programs.

Discussion: In each of the various quality assurance standards that are utilized to govern projects in both the government and civil sectors, some portion is devoted to the topic of assuring that the design of the "systems, structures, or components" that are the focus of the project is carried out in a sound, thorough, technically competent manner. Utilizing the approach of assuring quality by attention to the "front-end" activities, the concept is that engineered items are only likely to perform correctly if they are designed correctly. Examples of these standards, and their corresponding "design control" sections, include:

- 10CFR50, Appendix B - Section III, Design Control
- ANSI/ASME NQA-1 - Section II, Basic Requirement 3, Design Control, and Supplement 3S-1, Supplementary Requirements for Design Control
- DOE/RW-0333P, "Quality Assurance Requirements and Description" - Section 3.0, Design Control
- ANSI/ASQC E-4 - Section 3.2, Design of Data Collection Operations, and Section 4.2, Design of Systems

Clearly, the issue of controlling the design of the product or project output was heavy upon the minds of those wise individuals who developed these standards. But these documents, at least the early ones, upon which the later ones are heavily based, dealt with

engineered facilities. How do these requirements apply to scientific investigation activities, which any scientist will tell you are considerably different than engineering efforts?

One clear-cut relationship between design and science has to do with design inputs. The engineers who design repository systems need information from geotechnical investigators to develop and refine their designs. Similarly, the engineers who design the storage and transportation systems need data about the spent fuel or other radioactive materials that are to be shipped or stored, in order to develop their designs. Scientific data may become design input; does that mean that design controls need be applied to the scientific activities that generate the data? Well, no. Information is not design input (and therefore not subject to "design controls") until that information is specifically selected as design input by the designer. That need to definitively select data as design input distinctly separates scientific activities that generate data from design activities that use it.

The Waste Isolation Pilot Plant (WIPP) project, for disposal of defense-related transuranic wastes, has made a linkage between design control and scientific investigations, however. WIPP project scientists apply design controls to the physical experimental set-ups used for acquisition of site characterization data at the WIPP site. The WIPP project QA Program has been based on NQA-1, which is primarily oriented on engineered facilities. In an effort to apply that standard comprehensively and conservatively, WIPP investigators have chosen to apply design controls to that portion of their investigations to which those controls seem to most readily fit - the hardware. That approach, however, is a misinterpretation of the intent of the design control sections of NQA-1. The intent, where design controls are applicable at all, is to apply those controls to the main focus of the work, not to apply design controls to the tools and devices used to perform the work.

For scientific investigation activities, the concept of "design control" implies a structured approach to devising the conduct of the investigation activities themselves. It does not mean controlling only the design of the peripherals, such as the equipment arrangement or instrumentation; it means designing the research activities, themselves. This is where there is a sound and meaningful linkage between the ideas behind the "design control" sections of the cited standards and the performance of scientific activities. And, ironically, that linkage is ignored in all but one of those QA standards. The only cited QA standard that addresses the function of thoughtfully designing scientific investigations, ANSI/ASQC E-4, is not applicable to federal radioactive waste management efforts. Therefore, the benefits of applying design control concepts to data collection and analysis activities are absent from radioactive waste disposal projects.

In order to make scientific activities more robust, and the results of those activities more worthwhile, those QA standards should include requirements, concerning the planning and execution of scientific activities, for a structured methodology for determining the sequence and number of data points to be taken. Such a structured approach to developing an experiment should ensure that a desired confidence level in the representativeness of the data is achieved, as well as that the various factors (including

random variation) affecting the data are separated. One such methodology is statistical design-of-experiments. While statistical design-of-experiments is not appropriate for every data collection activity, this methodology provides the same type of structure and rigor in determining how an experimental effort will be performed as design controls provide for how a physical system will be fabricated or constructed.

Conclusion: In addressing the question of whether "design control", as specified in current QA standards, applies to scientific investigations, the conclusions have been that it only applies to the experimental equipment set-ups or that it does not apply at all. However, in applying the concept behind the design control requirements to the process of scientific investigation, a stronger linkage becomes apparent, although one that is not addressed in those QA standards. Design controls apply structure to the engineering of physical systems; a parallel approach would apply structure to the process of devising an experimentation activity. One rigorous, consensus-accepted methodology for doing so is the use of statistical design-of-experiments to determine what data will be obtained, in what quantity, and at what locations, in order to achieve the objectives of the experimentation activity.

#### References:

1. ANSI/ASME NQA-1, 1994, "Quality Assurance Requirements for Nuclear Facility Applications", American Society of Mechanical Engineers, New York
2. ANSI/ASQC E-4, 1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs", American society for Quality Control, Milwaukee, WI
3. DOE/RW-0333P, 1995, "Quality Assurance Requirements and Description", Rev. 5, U.S. Department of Energy Office of Civilian Radioactive Waste Management, Washington, DC
4. 10CFR50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants", Code of Federal Regulations, Title 10, U.S. Government Printing Office, Superintendent of Documents, Washington, DC

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