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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
San Antonio Office

TRIP REPORT
September 26, 1994

SUBJECT: American Society for Quality Control Energy and Environmental Quality Division Annual Conference

DATE AND PLACE: September 18-21, 1994
Tucson, Arizona

AUTHOR: Robert D. Brient

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TRIP REPORT
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SUBJECT: American Society for Quality Control Energy and Environmental Quality Division Annual Conference

DATE AND PLACE: September 18-21, 1994
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PERSONS PRESENT: The conference had over 300 attendees, a list is available from the author of this report upon request. Tom Trbovich of Southwest Research Institute Quality Assurance and Dick Trigilio of Division 17 were among the participants. None from the Nuclear Regulatory Commission Division of Waste Management staff attended.

BACKGROUND AND PURPOSE:

This trip was the author's annual professional development opportunity. This conference, the seventh attended by the author, brings together Quality Assurance (QA) professionals from all aspects of the energy and environmental fields, including utilities, regulators, Department of Energy (DOE) and its subcontractors, and many consultants to these groups.

SUMMARY OF PERTINENT POINTS AND ACTIVITIES:

Continuing a trend in this American Society for Quality Control (ASQC) division, this conference has increasingly become an environmentally oriented forum. Of the 21 technical program sessions, 8 covered general topics, 9 were oriented toward environmental QA, 2 with research and development, and only 2 directly associated with energy QA issues. High-level waste, low-level waste, and mixed waste QA regulations and the methods to implement them were the most frequent topics. A group of Yucca Mountain DOE and participant QA personnel discussed the transition to a single QA Requirements and Description applicable to all, from the previous individual QA Program Descriptions for each participant. Total Quality Management (TQM) was also addressed frequently. The theme of the conference "Breaking Tradition for Improvement," was carried through in the each of the technical sessions.

The author of this report attended sessions involving changes in the DOE arena, quality management issues in the Research and Development (R&D) community, TQM with DOE, the Civilian Radioactive Waste Management QA Program, hazardous waste storage management, and problems in application of quality standards to R&D programs.

The sessions on R&D were particularly applicable to the Center for Nuclear Waste Regulatory Analyses (CNWRA). The presentations considered QA applications ranging from very basic, fundamental research to applied research. Several of the presentations dealt with trying to apply NQA-1 (e.g., compliance oriented QA standards) to R&D activities. To address this, DOE issued order 5700.6C, which is broadly organized into the categories of management, performance, and assessments (a variation on Deming's

Plan-Do-Check-Act cycle) that provided an opportunity to return to QA fundamentals, and to break away from orthodox QA practices. The CNWRA has always biased the interpretation of QA criteria toward our specific scope of work and the use of our products. Apparently DOE NQA-1 programs, and the assessments of those programs, failed to provide for proper consideration of the specific work scope and use of the research work. Frank Hood of Battelle Memorial Institute, in his presentation entitled "Difficulties Encountered When Applying NQA Standards to R&D Activities" indicated that a graded approach based on risk is the key to successful application of these standards. The CNWRA has recently proposed (to NRC) a similar approach, but using importance to licensing as the basis for grading. Hood's presentation is attached.

The proceedings of the conference are available from the author of this report if requested.

IMPRESSIONS/CONCLUSIONS:

This conference remains the primary gathering of waste management quality assurance people and discussions involve the most current approaches to implementing effective QA programs. The presentations attended and personal contacts made were satisfying from a professional development perspective.

PROBLEMS ENCOUNTERED:

None.

RECOMMENDATIONS:

None.

AUTHOR:

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Senior Research Scientist — Quality Assurance

Date: 9-27-94

CONCURRENCE:

Bruce Mabrito
Director of Quality Assurance

Date: 9/27/94

TWENTY FIRST ANNUAL NATIONAL ENERGY
AND ENVIRONMENTAL QUALITY
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PROBLEMS IN THE APPLICATION OF QUALITY STANDARDS TO R&D PROGRAMS

DIFFICULTIES ENCOUNTERED WHEN APPLYING NQA STANDARDS TO R&D ACTIVITIES

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Quality Director

Battelle Memorial Institute
Environmental Systems & Technology Division
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ABSTRACT

The NQA standards were originally intended to ensure that the design and construction of facilities and hardware for nuclear power plants were done to accomplish its intended purpose and to protect public safety. The basic products of research and development (R&D) contractors are knowledge and technology, supported by data which, in general, can be validated and replicated. The R&D contractors found that the NQA standards cannot be easily and directly applied to R&D processes which primarily produce data, not hardware. Graded approach based on risk is key to the successful application of the NQA standards to R&D activities.

Background

The application of NQA standards to research and development activities extends the scope of these standards from nuclear design, production, construction, and operational activities to include basic research, applied research, and development work.

The NQA standards were written to serve the needs of a specific, regulated industry: the commercial nuclear power industry. More specifically, they were written for application to the "siting, design, construction, operation, and decommissioning of nuclear facilities."[1]

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(1) ANSI/ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities.

The NQA standards are consensus standards; their application to the R&D community affects a group of people who were not represented as such in the consensus process until 1990. Also, R&D people tend to work in an organizational context that is less formal and hierarchical than the context assumed in the NQA standards.

The standards exhibit a logic and language, and have an internal structure appropriate to large construction projects, rather than the collegial setting often associated with R&D.

Hypothesis

The NQA standards can be applied to R&D, recognizing that ambiguity and uncertainty can be managed to some extent, based on the nature of the activities.

Research & Development

To tailor the NQA standards to R&D activities, one must understand their nature and characteristics. In 1990, the ASME NQA Committee chartered an R&D Quality Working Group to represent the R&D community in consensus standard activities. This paper draws on a White Paper[2] developed by that Working Group to describe difficulties encountered in applying NQA standards to R&D activities. Members of that Working Group are listed in Appendix 1.

The term "research and development activities" applies to two types of activities: the first type results in science (i.e., work that results in the advancement of knowledge), and the second includes activities that support R&D (e.g., procurement, maintenance, and operation of facilities). Research and development is frequently done in a collegial and collaborative setting, without the degree of formal structure associated with design and construction activities in a regulated environment.

Support activities to R&D accommodate application of the NQA standards, much like those for which the standards were intended. However, the NQA standards' logic and structure do not match the logic and workings of R&D science activities. Also, there are significant language differences between that used in the NQA standards and R&D work.

Practices followed by the R&D community are intended to assure quality of the work, e.g., peer review, publication of experimental results in refereed journals, and the use of laboratory notebooks for documentation.

Technology Life Cycle

The technology life cycle is depicted in Figure 1. It shows the progression of technology development, commercialization, and retirement in process phases of basic and applied research and development, engineering, and production until process completion.

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(2) ASME NQA Committee Working Group White Paper, A Description of Difficulties Encountered When Applying NQA Standards to Research and Development Activities, October 1993.

Application of NQA standards to the R&D side of the technology cycle requires more creativity than conventional NQA applications; however, it is a reasonable approach to ensure that a consistent level of quality is achieved throughout all phases of the cycle. The process interface nodes between basic and applied research and development phases afford an opportunity for "life-cycle" quality problems, analogous to the design interface challenges of a manufacturing operation. By assuring a consistent application of quality performance expectations to R&D activities, the interface between development and engineering can be accomplished smoothly, and design quality problems can be minimized. Traditionally, R&D is accomplished as discrete tasks rather than integrated efforts. For basic research, where uncertainty is a significant operational factor, the lack of a "life cycle" approach is understandable. However, the rest of the technology cycle can be treated from a process perspective, anticipating the needs of the next phase of the cycle.

Basic research does not lend itself well to a priori establishment of milestones. The timetable for completion of basic research tasks in preparation for the ultimate measurements generally cannot be predicted because of unanticipated events. By its very nature, basic research is that phase of R&D which is subject to the highest level of uncertainty, clouding the issue of milestones. The results of testing a basic research hypothesis will always be "good" because they could not be predicted with certainty.

Applied research is a process initiated with the intent of solving a specific problem or meeting a practical need. Successful results will be applied to a future development activity. Proof of principle usually occurs in the applied research stage, and, with its more explicit objectives, warrants a set of milestones. This leads, naturally, to the need for a records system that can protect patent rights by ensuring an orderly procedure for maintaining the necessary documentation. Good documentation is also needed to ensure reproducability of results—an essential element of good science.

Development activity entails the application of proven theory and its extension to a practical situation. Because the developmental objective is to accomplish goals which have not been achieved previously, a degree of uncertainty exists as to the ultimate success of the effort. The plan that governs a developmental activity leads to a more structured management of the process. Tests, with or without acceptance criteria, are prescribed with requirements that are commensurate with the complexity and scale of the effort, with the associated risk to the public and workers, the environment, and future success of the project.

Graded Approach

Graded approach is the process by which the extent (level of rigor) of application of control is determined. It is a process by which the level of analysis, extent of documentation, and rigor of control associated with specific work is controlled commensurate with the importance to safety, the magnitude of risk involved, life cycle state of a facility, or work or programmatic mission.

To best meet the R&D application needs of the technology life cycle, the NQA standards must be interpreted in terms of uncertainty and risk management. The "graded approach" needs to be predicated on the criteria of relative importance (or significance), relative mission priority, consequences of event occurrence (or non-occurrence), and probability of occurrence associated with the activities being managed (as well as the operating conditions).

The first two considerations (i.e., significance and priority) allow categorization of R&D activity conditions and nature. This categorization defines the level of importance of the project and allows determination of the set of risk evaluation criteria that needs to be applied to the R&D activity. They will, in turn, define the set of management controls needed to ensure success within the assumed range of risk.

Risk is the fundamental consideration in grading the application of control systems. It is not just associated with ES&H concerns. Risk addresses the relative importance to any business success factor, including safety, the environment, public health, programmatic mission, profitability, etc. It deals with the level of ambiguity to be dealt with in the project; it provides the quantitative and qualitative expression of possible loss, which considers both the probability of an event occurrence causing harm or loss, and the consequences of the event, both of which express elements of uncertainty.

The R&D Project

For R&D, a critical phase for success is in the project "design", i.e., discovering the needs and expectations of the customer/sponsor (stakeholders and the general scientific community expectations may also need to be considered) and planning an ethical research project to meet those needs. Translating the project design into action should be organized around NQA requirements, as depicted in Figure 2.

Risk determinations are made before and during the project design phase, and are re-validated during the life of the project when design changes occur or research results indicate the need to do so. To ensure effective risk management takes place, a set of risk evaluation criteria should be established during project design, and carried forward and updated as needed during the life of the project. The elements of risk management associated with the research project cycle are shown in Figure 3, including those associated with the core and supporting work processes needed to accomplish and measure project performance. Risk is a general concern that extends beyond ES&H factors; it must be considered as a condition for success in all aspects of work, including business objectives.

Elements of Risk Management

Broken into a basic format for application, the following risk management queries are made for each contemplated activity:

- Relative importance of accomplishing the proposed R&D work to the prospective customer, the proposing organization, and stakeholders,
- Relative priority for accomplishing the work to the prospective customer, the organization, and the stakeholders,
- Potential consequences resulting from doing (or not doing) the work to customers, the organization, and stakeholders, and
- Probability of occurrence of postulated consequences.

The aggregated results of the above inquiries indicate the relative need to assume the risk of business activities, phrased in NQA terms.

The method and criteria used for risk evaluation and to aggregate the results depend on the nature of the activities being contemplated. For example, a standard industry practice may involve an unacceptable level of risk for a particular application unless additional safety controls are used. A standard practice of using a fixed-wing airplane to survey wildlife activities may involve an unacceptable level of risk during low-level, slow flight in hilly terrain unless performance boundaries are specified (e.g., no surveillance when gusting conditions above 20 knots exist) to ensure flight safety conditions are maintained, although there is no intent to exceed safety limits.

Risk Evaluation Criteria

Risk evaluation criteria can be formulated from the success factors for a contemplated activity. Success factors allow the performance boundaries for activities to be defined, and support the risk evaluation.

If, using the previous example, the normal practice for surveying elk was to count the number of elk (with an accuracy of plus or minus five percent) while they were grazing in a meadow, and the new mission objective was to fly low and slow enough to count the number of points on elk antlers, in mountainous terrain, possibly during thunderstorms, one would expect to examine the risk potential due to "unusual" operating conditions. Quantifying success factors, to the extent possible, aids in identifying hazards and risks to achieve performance objectives.

Success factors for the example could include:

- Airplane must operate safely within mission performance boundary conditions.

Importance: Flight safety depends on operating within the defined performance envelope for the airplane. Mission data-taking conditions must be within the defined operating limits of the airplane, or undesirable flight characteristics might result (e.g., stall).

Priority: Ability to perform the desired flight conditions must be verified before proceeding further in conduct of the project.

Consequences: Severe adverse consequences might result (e.g., airplane crash) if the airplane were operated outside its performance envelope. Positive consequences are that mission objectives can be accomplished if the airplane is operated within its performance envelope.

Probability: If the mission conditions are verified to be within the performance envelope of the airplane, the probability of departing from controlled flight, from other than natural phenomena, is low; and the probability of accomplishing mission objectives is high.

Result: Matching performance capabilities of an airplane with mission performance boundary conditions will help ensure safe operation during data acquisition activities. (Natural conditions that influence flight capabilities must always be coped with by pilots.)

Likewise, other success factors can be assessed and risk management conclusions drawn based on establishing relevancy of the elements of importance, priority, consequences, and probability.

- Flight must be conducted in accordance with applicable regulations, and the approved test plan.

  Result: Risks due to airplane condition (as maintained) and pilot currency rating are minimized for the specified flight conditions; also, mission flight objectives will be met safely.

- Specified data must be obtained during flight.

  Result: Mission objectives are planned to be achievable, mission conducted as planned, and desired data gathered.

- No unforeseen conditions encountered during flight.

  Result: Mission planning done effectively, with the cooperation of Mother Nature.

Conclusions

The NQA requirements can be tailored to R&D activities by accommodating communication challenges and by considering the operational characteristics of the work process as well as examining all of the success factors for a high-quality end product — in terms of risk management.

APPENDIX 1

ASME NQA COMMITTEE WORKING GROUP ON QA REQUIREMENTS FOR R&D

Membership in the Working Group has changed during its existence. The following list is composed of the current membership (as of March 1994).

Member	Affiliation
D. Rex Beach	Lawrence Livermore National Laboratory
David Burrows	University of Georgia, Savannah River Ecology Laboratory
Spence Bush	Pacific National Laboratory
Peter Bussolini	Los Alamos National Laboratory
John Dronkers	Lawrence Livermore National Laboratory
Allen Goland	Brookhaven National Laboratory
Joe Gutierrez	Los Alamos National Laboratory
Frank Hawkins	U.S. DOE-NE
Glen Hayes	EG&G Idaho, Inc.
Robert Heddrick	EG&G
Frank Hood	Battelle Memorial Institute
Nelson Jarmie	Los Alamos National Laboratory
George Kidd	Martin Marietta Energy Systems
Ford Knight	Westinghouse Hanford Company
James Koonce	Lawrence Livermore National Laboratory
David Lee	Sandia National Laboratory
Paul Melroy	Martin Marietta Energy Systems
Ronald Michels	Lawrence Livermore National Laboratory
George Roberts	Babcock & Wilcox
Edward Robitz	Babcock & Wilcox
Marvin Shear	Brookhaven National Laboratory
John Stanley	Lawrence Berkeley Laboratory
J. Robert Wayland	Sandia National Laboratory

FIGURE 1. TECHNOLOGY LIFE CYCLE

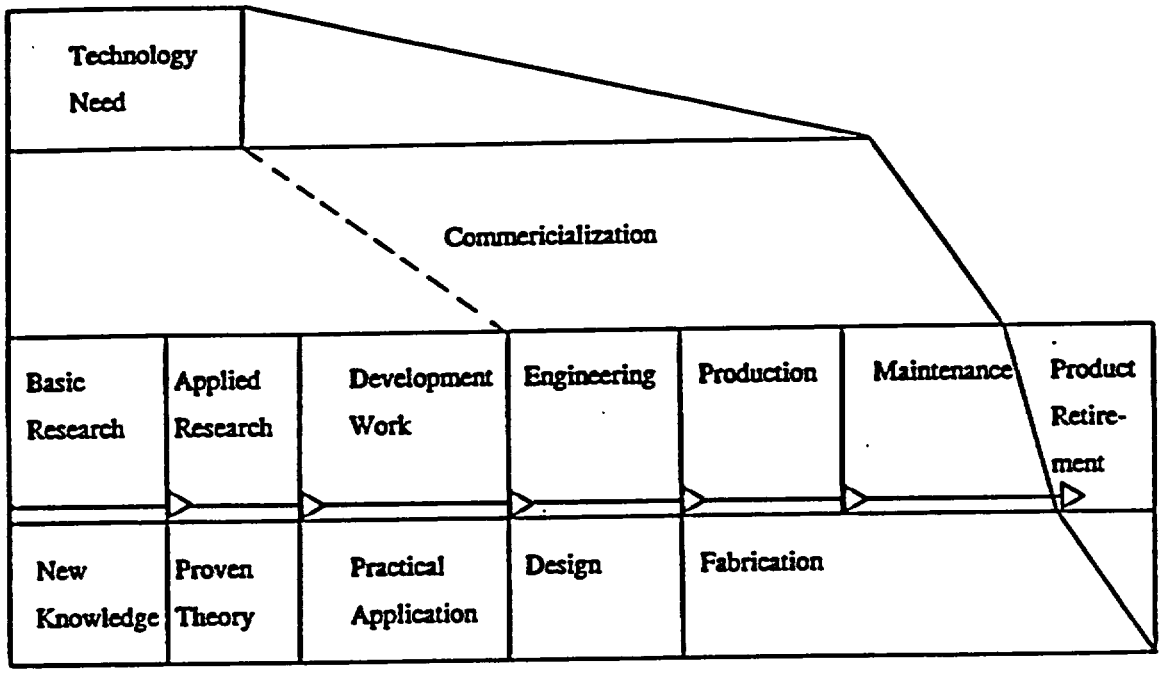
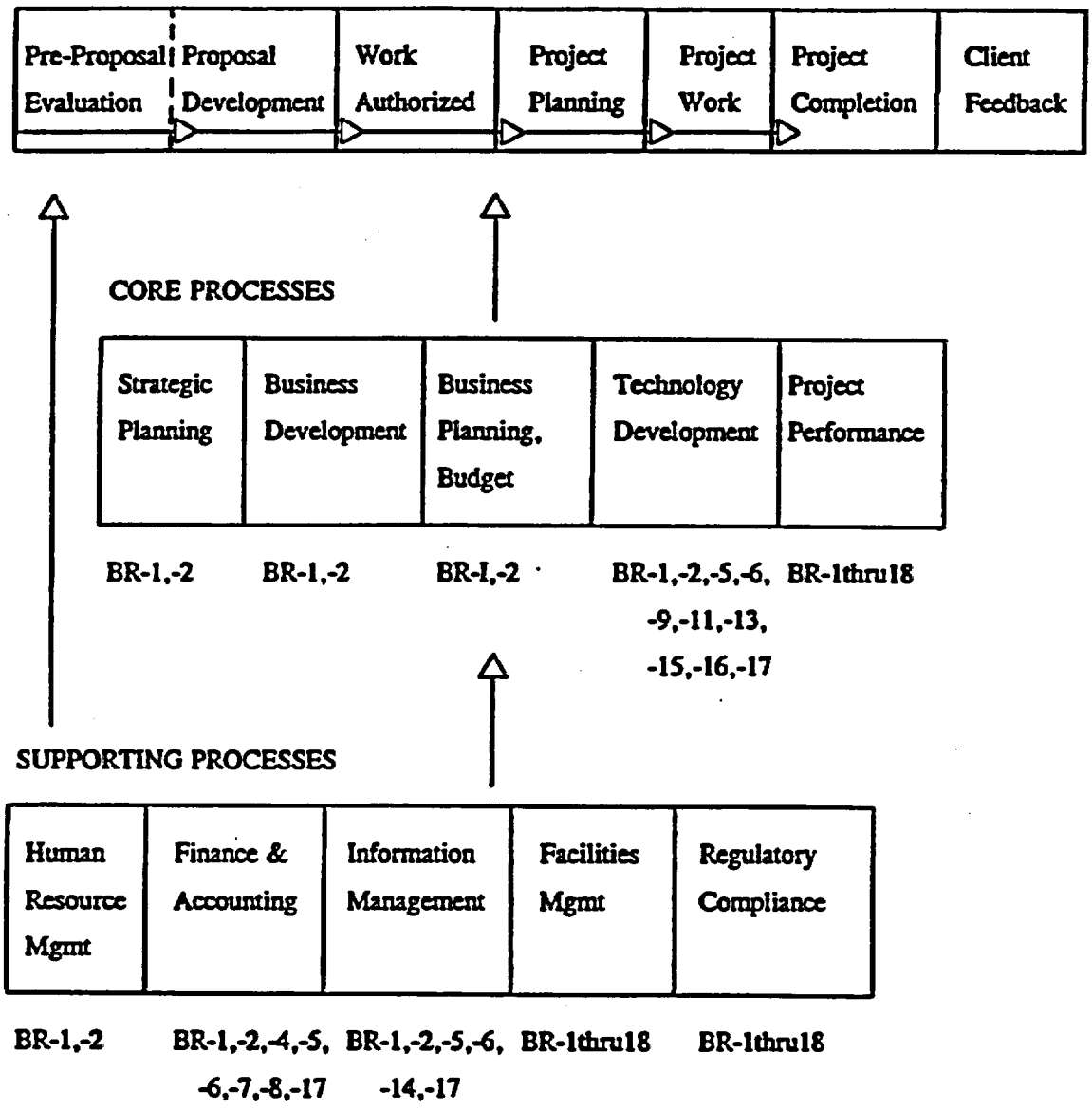


FIGURE 2. THE RESEARCH PROJECT AND NQA APPLICABILITY



Note: (BR) indicates NQA-1 Basic Requirement number.

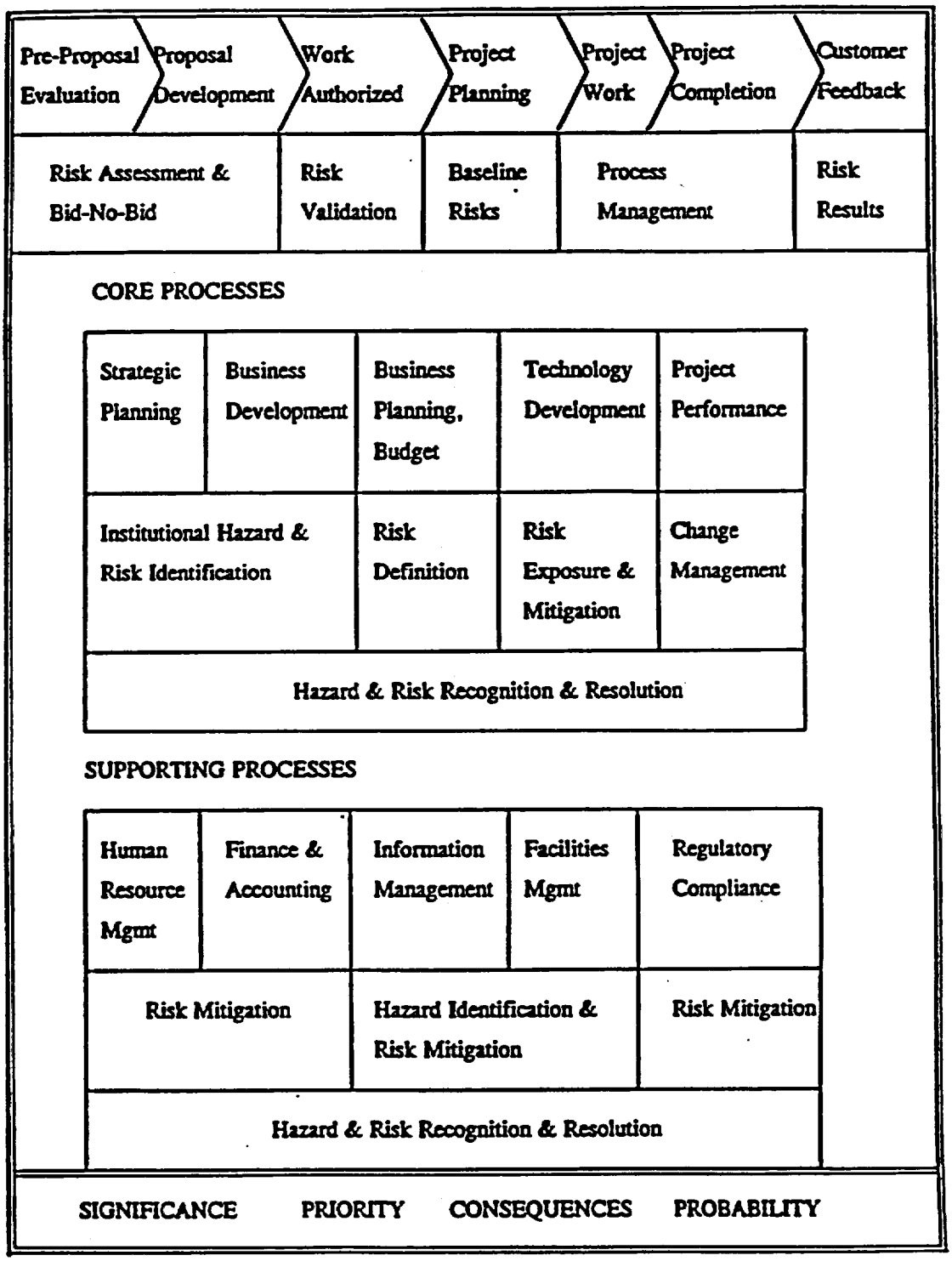



FIGURE 3. RESEARCH PROJECT RISK MANAGEMENT ELEMENTS