Graded Approach

A Working Paper

QM

Quality Management

September 1993

TRAINING RESOURCES AND DATA EXCHANGE TRADE

QUALITY MANAGEMENT
GRADED APPROACH WORKING PAPER

Compiled by the

Training Resources and Data Exchange (TRADE)
Quality Management
Special Interest Group

for the

Office of Nuclear Safety Policy and Standards
Assistant Secretary for Nuclear Energy
U.S. Department of Energy

September 1993

This report was prepared under contract number DE-AC05-76OR00033 between the U.S. Department of Energy and Oak Ridge Associated Universities.

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TABLE OF CONTENTS

INTRODUCTION

The primary objective of a quality management program is to provide controls over work performance so that desired results are achieved. The philosophy or underlying basis behind the graded approach is to increase the number and levels of controls over work that presents increased risk (i.e., more risk = greater controls, less risk = less controls). This concept is supported in U.S. Department of Energy (DOE) Order 5700.6C, "Quality Assurance," by requiring that quality assurance programs (QAPs) be based on performance objectives and that quality assurance controls be established based on analysis of risk associated with accomplishment of the objectives.

The Training Resources and Data Exchange (TRADE) Quality Management Special Interest Group (QM SIG) collected information on the trends and responsibilities throughout the DOE system to grade the application of quality management programs as one of their projects for FY93. A survey questionnaire to gather this data was developed and reviewed by the QM SIG Steering Committee. A copy of the questionnaire is located in Appendix A.

SUMMARY OF RESPONSES

A total of 48 responses were received to the survey questionnaire. Responses were received from a broad range of DOE-sponsored programs. Not surprisingly, three categories of programs dominated the responses: Research and Development (R&D), environmental restoration and research, and weapons programs. The distribution of the programs represented is as follows:

R&D	70
Environmental	53
Weapons	19
Others	6

This working paper summarizes the responses received on the questionnaires by type of program and provides a generalized summary of all the comments. The information and

lessons learned in this working paper will be useful to those individuals developing and employing a graded approach to their quality assurance programs.

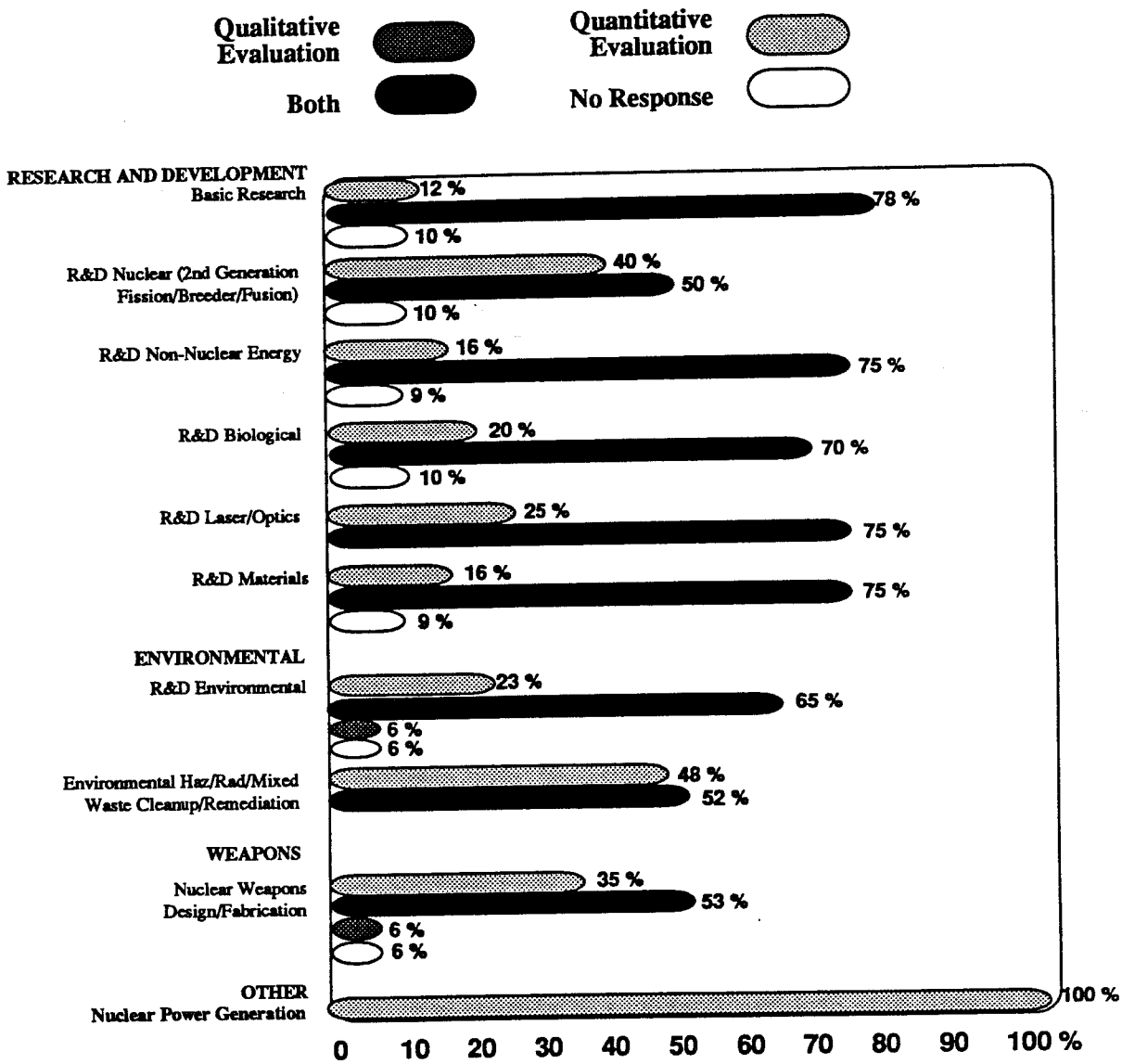
Programs are trying to grade the application of QM programs but with no formal guidance published by DOE or professional organizations [i.e., American Society for Quality Control (ASQC)]. Programs are having considerable trouble and limited success with this potentially very useful and economical concept. Reference documents that define graded approach include: DOE Order 4330.4A (October 17, 1990); Safety Guide 830.310 (June 6, 1991); DOE-ER-STD-6001-92; DOE Notice-Graded Approach (November 4, 1992). Formal processes such as those being developed by the Environmental Protection Agency and DOE for collection of environmental data (e.g., data quality objective process, observational and safer methods) are needed for other work processes such as R&D, design, procurement, construction, and operations.

Overall, the respondents are using most of the same methods and processes for applying their grading programs. Many facilities are in the early stages of developing a graded approach program, or they have not started the process. The respondents show many of the same trends in developing and implementing graded approach programs.

The Nuclear Quality Assurance (NQA) 1, 2, and 3 standards are the primary standards used by the responding facilities. Most facilities using NQA 1, 2, or 3 also use it in combination with other standards (e.g., EPA QAMS-005/80; DOE Order 5700.6C; QC 1, 2; ANSI N45.2 and its daughter standards; ISO 9000 or ANSI/ASQC Q90 series; or MIL-Q9858A). The guideline used most often for applying quality assurance controls to work is that all requirements apply unless exempted. More facilities use both formal and informal mechanisms to determine the degree of quality assurance programmatic controls over work. A combination of qualitative and quantitative methods is used by the majority of the facilities to grade their quality assurance programs. (See chart on page 3). The criteria that are used to develop the methods of grading quality assurance programs are based on environmental impact, risk, regulations, nuclear safety, mission-based (project or facility mission success-dependent), health physics, complex or unique design, administrative, public relations impact, and data quality objectives (respectively). The majority of the responding facilities grade their applications based upon

risk, using both the assessment of the probability of failure and the assessment of the consequence of failure.

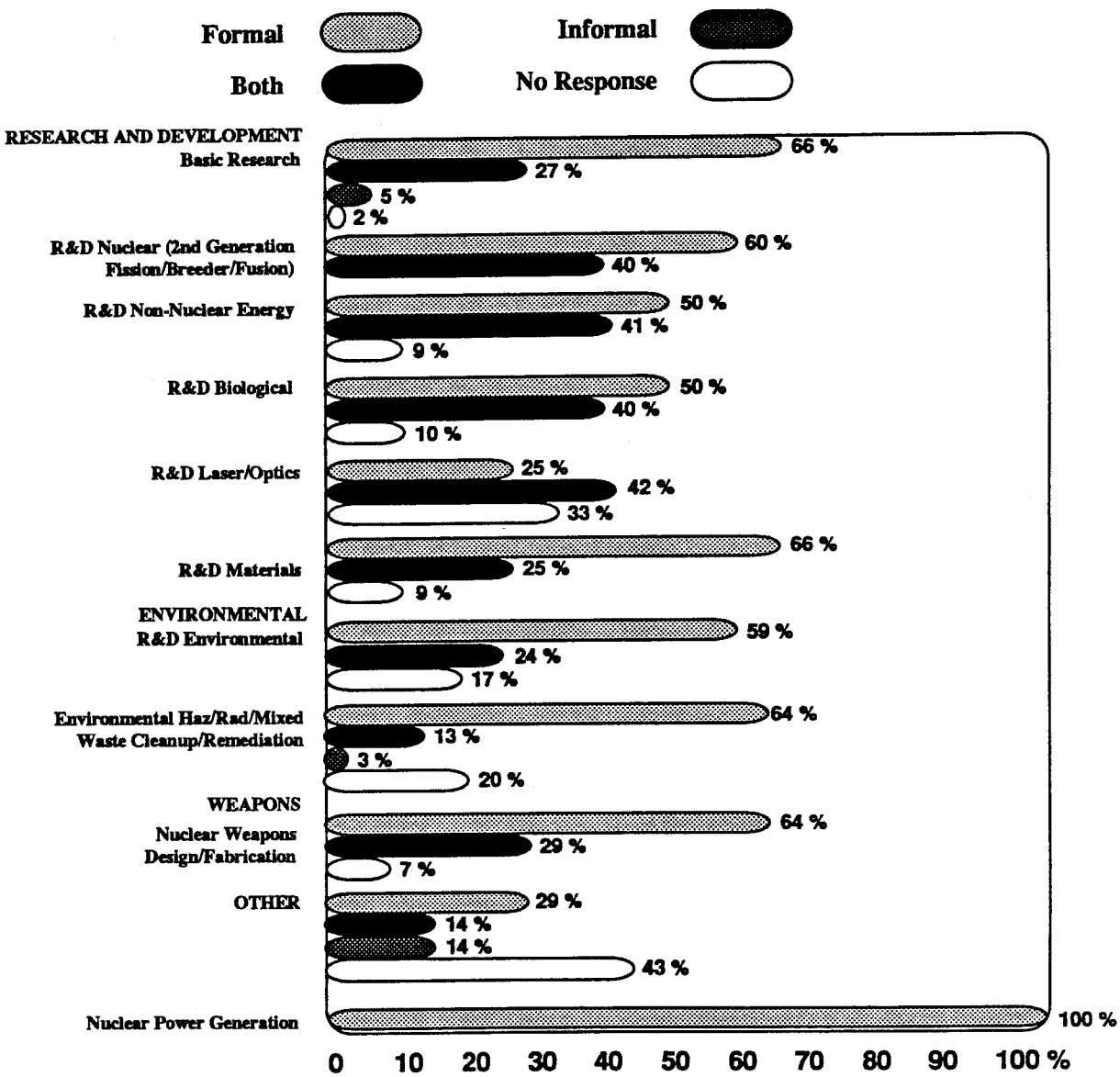
METHODS USED FOR GRADING A QUALITY ASSURANCE PROGRAM



The line organization/management is responsible for performing risk assessments for the purpose of quality assurance programs in all the organizations. The line organization/management is also responsible for determining the degree of quality assurance programmatic controls, with assistance from the quality assurance organization or environment, safety, and health (ES&H) organization. When two organizations are responsible for performing risk assessments, the organizations work as a team to reach a consensus. Most of the facilities are just starting a formal graded approach program and were unable to judge their success at the time of the survey. The responding facilities reported that it is important to focus on critical areas, be uniform across the organization, and use the judgment of your best staff to develop a successful graded approach program. Additional lessons learned in developing a graded approach program include: provide additional training, trust your best people, and learn to work as a team to make decisions.

All the responding facilities with established graded approach programs use readiness reviews for activities with higher risk, and those just starting their graded approach programs reported that they would use readiness reviews. The criteria used for determining the need for readiness reviews for the majority of the facilities include: safety, risk, past performance and baseline checklist, or external requirements. The majority of the respondents use a formal readiness review to determine the need for a graded approach program.

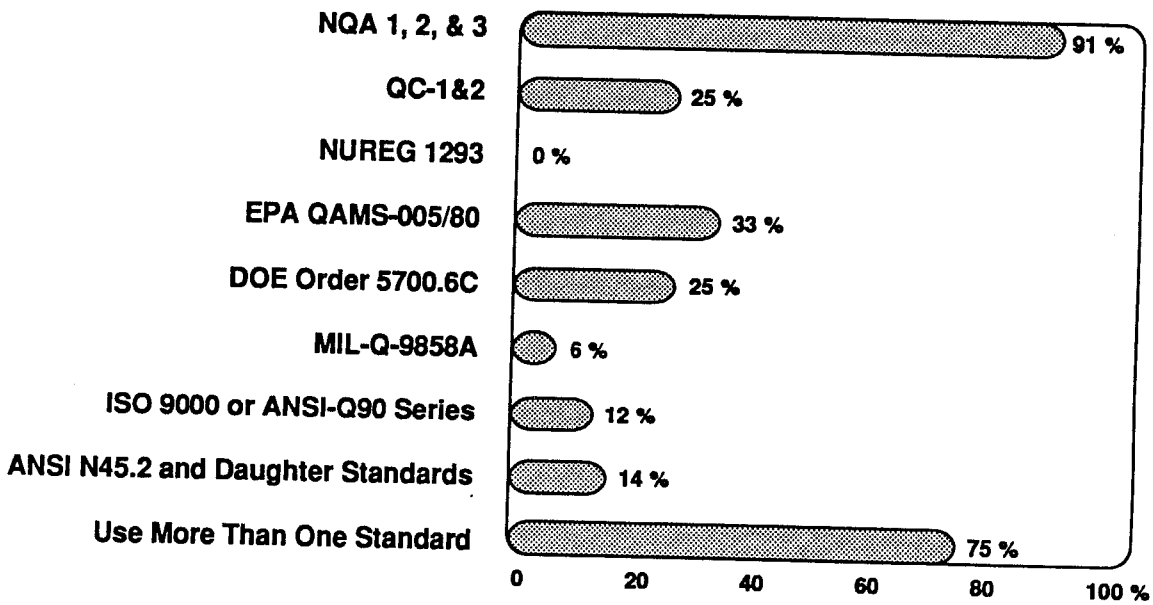
TYPES OF READINESS REVIEWS



The respondents, for the most part, are just starting to develop graded approach programs at their facilities. They felt the need to have a graded approach program, but reported that they need guidance on how to get started and how to proceed with some of their existing programs. The general consensus is that there is a need for guidance in developing and implementing a graded approach program.

Of the 48 responses, 44, or 91 percent, use NQA 1, 2, or 3 (NQA 1, 2 or 3 was listed as one standard in the questionnaire. NQA 1, 2, 3 was referred to as one standard. Twelve or 25 percent use DOE Order 5700.6C or QC-1, 2 as their basic QA standard. Sixteen, or 33 percent use EPA QAMS-005/80. Only 3, or 6 percent, use MIL-Q-9858A. Six, or 12 percent use ISO 9000 or ANSI/ASQC Q90 series. Seven, or 14 percent use ANSI N45.2 and its daughter standards. Out of the 48 responses, 36, or 75 percent, use more than one guideline or standard to develop their quality assurance program.

INDUSTRIAL QUALITY ASSURANCE STANDARDS USED AT RESPONDING FACILITIES



RESEARCH AND DEVELOPMENT PROGRAMS

BASIC RESEARCH PROGRAMS

Eighteen basic research facilities responded to the survey. Most of the basic research facilities use the NQA 1, 2, or 3 standard in combination with other standards. Half of the facilities use QC 1, 2 or use it in combination with ISO 9000 or ANSI/ASQC Q90, EPA QAMS-005/80, or ANSI N45.2. Six facilities use DOE Order 5700.6C or 5700.6C in combination with other standards.

When asked about applying quality assurance controls to work, about one-third of the research facilities replied that they do not apply requirements to any item or activities until specifically identified. Only three facilities apply requirements to all items or activities. Two apply all requirements unless exempted. Most of the facilities apply the requirements according to the amount of risk.

Over half of the facilities use a formal mechanism to determine the degree of quality assurance programmatic controls. Half of the facilities have an informal mechanism that is commonly practiced to determine the degree of quality assurance programmatic controls.

Most of the responding facilities use both quantitative and qualitative methods of grading. Only two facilities use qualitative methods alone. Most of the basic research facilities use regulations in combination with one or more of the following: risk, nuclear safety, environmental impact, administrative, complex or unique design, public relations impact, mission-based, health physics, or data quality objectives. The majority of the respondents use both assessment of the probability of failure and the assessment of the consequence of failure.

The personnel usually responsible for risk assessment for the purpose of applying the graded approach are the line managers. Some line managers do the risk assessments with input from the ES&H group or subject-matter experts. The personnel within the basic research facilities who are responsible for determining the degree of quality assurance program controls are the line managers, with input from the quality assurance organization or from work teams.

When two organizations within the facilities need to interface to perform risk assessments, they usually implement a team concept with management negotiating agreements to arrive at mutual satisfactory controls.

Some of the aspects of a successful graded approach program include the following:

- Teams are well trained to make decisions
- The consequence of failure is used as a base, rather than a numeric system
- ES&H controls are included, productivity is usually improved
- When management is involved
- Uniform application across the organization.

Aspects of graded approach programs that indicate less success include the following:

- Guidance is lacking
- The programs are forced to fit by uninformed staff
- Difficulty in applying programs to basic research because of DOE orders applying to nuclear facilities
- Fewer controls than needed have been added to avoid cost/schedule increases
- Criteria are not yet specific.

Tips given for quality assurance professionals just starting their graded approach program include:

- Think through what exists
- Keep simple and trust the judgment of your best people
- Involve staff in planning
- Involve line management to enforce classification
- Identify the customer
- Define requirements
- Assess the significance of the risk
- Conduct management review to define levels of risk
- Encourage good judgment to identify process.

The majority of the basic research facilities use readiness reviews for activities that present higher risk. The criteria these facilities use for determining the need for readiness reviews include:

- Perceived risk
- Criteria imposed by an external customer
- Internal management goals and external requirements
- Past performance and baseline checklists
- Initial start-up where operation includes safety analysis.

Most of the basic research facilities have a formal readiness review, and a few have both formal and informal readiness reviews.

Other lessons-learned comments given by the respondents include:

- Make sure the graded approach for quality assurance coordinates interface with ES&H
- Conduct of operations should be a single approach
- Success depends highly on the quality of the initial risk assessment and good judgment used to impose control.

NUCLEAR RESEARCH AND DEVELOPMENT (2nd generation fission/breeder/fusion) PROGRAMS

Ten nuclear research and development facilities responded. Most of the facilities use the NQA 1, 2, or 3 standard. Some use the NQA 1, 2, or 3 standard in combination with QC 1, 2, and ISO 9000. Only two facilities use DOE Order 5700.6C as their standard. The ten responding facilities are split as to what type of approach they use; one-third apply all requirements to all items or activities, one-third apply all requirements unless exempted, and one-third apply no requirements to any item or activity until specifically identified.

Most of the nuclear research and development facilities have a formal mechanism for determining the degree of quality assurance programmatic controls. Some facilities have an informal mechanism, with only about one-third of the facilities having no formal or informal mechanism in place for determining the degree of risk.

Most of these facilities use both quantitative and qualitative graded approach methods for determining risk. All the responding facilities use regulations as the criteria for grading quality assurance. Most facilities use risk, nuclear safety, environmental impact, administrative, complex or unique design, public relations impact, mission-based, data quality objectives, or health physics in conjunction with regulations as the criteria for grading. The grading applications of quality assurance programs based on risk are both the assessment of the probability of failure and the assessment of the consequence of failure.

The personnel and organization responsible for risk assessment for the purpose of grading are the line managers and quality assurance office for most of the facilities. Others responsible for risk assessment are statisticians and the ES&H group. The personnel responsible for determining the degree of controls are line managers in most facilities and the operating organization in a few facilities. When two organizations work together to perform risk assessment, the two organizations interface through the team concept or the coordination is done through the ES&H group.

Some of the aspects of the grading process that have been successful are in the areas of productivity improvement and uniform application of the graded approach program process across the organization.

Areas that are not as successful in the graded approach program include:

- Development of formal grading with progress impact and documentation of decision.
- Graded initiatives for research and development are difficult
- Processes are not simple
- Grading criteria are not specific
- More effort is needed to reach clear grading criteria.

Some of the things facilities would have done differently in developing or applying a graded approach program include:

- Train staff for risk on their jobs, and remediate the graded approach program when necessary
- Define responsibilities for grading

- Better define and simplify research and development controls
- Extend the program to more situations
- Try to simplify to cut down the amount of numbers
- Break the graded approach out of the quality assurance program
- Develop a graded approach as a way to rank a system by risk, cost, and failure.

Some of the tips given for quality assurance professionals just starting to establish a graded approach program include:

- Keep it simple and trust the judgment of your best people
- Auditors need to recognize the validity of the graded approach
- Involve personnel to make the process work
- Involve technical people using the program during development
- Get the system operators involved in setting the graded approach, and quality assurance will follow.

All of the responding facilities use a readiness review for activities that present a higher risk. Some of the criteria for determining the need for a readiness review include:

- When restarting nuclear facilities
- Based upon perceiving risk
- Evaluation of risk by line managers
- Criteria imposed by external customers
- Past performance and baseline checklist

The majority of the facilities perform a formal readiness review, but several use a combination of formal and informal readiness reviews.

Additional comments given by the respondents are that DOE and auditors need to be convinced that the graded approach is valid and have a clear definition of what the graded approach program involves.

NON-NUCLEAR ENERGY RESEARCH AND DEVELOPMENT PROGRAMS

Twelve non-nuclear research and development facilities responded. All of the responding facilities use the NQA 1, 2, or 3 standard in combination with one other standards such as QC 1, 2; MIL-Q-9858A; ISO 9000; or EPA QAMS-005/80. Only one facility did not use NQA 1, 2, or 3. Four of the twelve facilities use DOE Order 5700.6C as their standard in conjunction with one or more of the standards listed above. The types of approach used in grading are split evenly among all requirements, all requirements apply to all items or work, and all requirements apply unless exempted. Most of the facilities also indicated that no requirements apply to any item or activity until specifically identified. The methods of grading used by the majority of the facilities are both quantitative and qualitative, with a few using only qualitative methods. Most of the facilities use risk, nuclear safety, regulations, environmental impact, administrative, complex or unique design, public relations impact, mission-based, data quality objectives, or health physics as the criteria for grading quality assurance. The majority of the facilities apply grading to quality assurance programs based on both the assessment of the probability of failure and the assessment of the consequence of failure. One facility based the grading process only on the consequence of failure.

The personnel responsible for risk assessment for the purpose of the graded approach are the line managers, with assistance from the ES&H quality organizations and subject-matter experts. Several stated that each individual organization is responsible for evaluation and assessment. The personnel within the facility who determine the degree of controls are the line managers, with input from quality engineers, consulting organizations, and quality assurance staff. When two organizations within a facility are involved, they interface through the team concept, through consensus, or through the health and safety division.

Some of the respondents credit their graded approach programs' success to the following:

- Having qualified technical staff
- Starting with a formal grading process
- Using the consequence of failure, rather than using a numeric system
- Showing an increase in productivity

- Integrating controls into work
- Accepting the controls associated with risk.

Several facilities reported that their programs are too new to give successes.

Some of the less successful graded approach aspects include:

- The program is external and is forced to fit by the uninformed
- Fewer controls are applied than needed to avoid cost and schedule increases
- Inadequate time and investigation are invested before implementing program.

Things that the facilities would do differently include:

- Train staff for graded approach program and remediate as needed
- Include experts in risk assessment and technical programmatic aspects to make a determination of level of quality controls
- Extend grading program to more situations
- Be sure line management is flexible enough to do the job right using good judgement in risk management
- Keep it simple
- Involve personnel
- Identify the customer
- Define requirements
- Assess the significance of risk with contemplated work
- Conduct management review to define levels of risk.

The criteria for determining the need for readiness reviews are based on past performance and the baseline checklist, the function of the facility, DOE Order 5000.3A, perceived risk, and external requirements. Half of the respondents have formal readiness reviews, and the other half have both formal and informal readiness reviews.

Another comment given about using the graded approach to apply quality assurance programmatic controls is that success depends highly on the quality of the initial risk assessment and good judgement used to impose control.

BIOLOGICAL RESEARCH AND DEVELOPMENT PROGRAMS

Ten biological research and development facilities responded to the survey. All of the respondents use NQA 1, 2, or 3 as standards of choice at their facilities. Most of the facilities use NQA 1, 2, or 3 in combination with other standard(s). The combinations include: QC 1, 2; MIL-Q-9858A; ISO 9000; EPA QAMS-005/80; and DOE Order 5700.6C. Only two of the responding facilities use DOE Order 5700.6C as their standard, and it is used in combination with EAP QAMS-005/80; NQA 1, 2, or 3; or QC 1, 2. The types of approach used for grading are split evenly among all requirements, all requirements apply to all items of work, and no requirements apply to any item or activity until specifically identified. Most of the facilities had a formal mechanism in place for grading, and about the same number have an informal grading mechanism in place. Most of the facilities use both quantitative and qualitative methods of grading. The criteria used by most facilities are risk, nuclear safety, regulations, environmental impact, administrative, public relations, mission-based, data quality objectives, and health physics. The grading application of the quality assurance program based on risk includes both the assessment of the probability of failure and the assessment of the consequence of failure.

The personnel responsible for doing risk assessments for the purpose of the graded approach are line managers eith alone or with input from statisticians, ES&H formal risk assessment, or with staff support and review. The personnel determining the degree of the graded approach controls are line managers with assistance from quality engineers, consulting organizations, and quality assurance staff support and concurrence. When two organizations interface to perform risk assessments and determine the graded approach controls, they are coordinated through the ES&H group charged with the institutional task or as a team consensus.

Aspects of the graded approach program that are successful include: the development of the consequences of failure, rather than a numeric system, productivity improvement, and the acceptance of set controls associated with risk. Most of the facilities' graded approach programs are too new to establish the successes at the time of the survey. Areas that are less successful include:

- Training to help staff understand the graded approach program
- Externally developed programs, forced to fit by the uniformed

- Inadequate time to investigate and develop
- Procurement levels
- Fewer controls than needed to avoid cost and scheduling.

Advice the responding facilities gave to facilities just starting their graded approach programs included:

- Train staff on graded approach program and follow up on the effectiveness of the training
- Use experts in risk assessment
- Develop technical program to make sure determination of level of controls is appropriate to obtain a high level of quality
- Extend the program to more situations
- Move toward determination based design classification
- Learning an effective graded approach is continuous improvement
- Line management must be flexible to do the job right and use good judgement in risk management
- Keep it simple and trust the judgement of your best people
- Inform and involve personnel, do not over proceduralized
- Give the designer/owner latitude to build quality
- Identify the customer
- Define requirements
- Assess the significance of risk with contemplated work
- Conduct a management review to define levels of risk.

The criteria for determining the need for readiness reviews are DOE Order 5000.3A, criteria imposed by an external customer, past performance, baseline checklist, complexity of system, testing, design, and the function of the facility. Half of the responding facilities use a formal readiness review and the other half use both formal and informal reviews.

Another comment made by the responding biological research and development facilities is that the success of a graded approach program depends highly on the quality of initial risk assessment and good judgement used to impose controls.

LASER/OPTICS RESEARCH AND DEVELOPMENT PROGRAMS

Twelve laser/optics research and development facilities responded to the survey. Ten of the respondents use NQA 1, 2, or 3 as quality assurance standards. They use NQA 1, 2, or 3 in combination with one or more of the following standards: QC 1, 2; MIL-Q-9858A; ISO 9000; DOE Order 5700.6C; or EPA QAMS-05/80. One facility uses only DOE Order 5700.6C as its standard for quality assurance. One respondent uses an informal method based on safety, risk, and programmatic importance. The approaches for applying the standard are evenly divided among all requirements applying to everything, all requirements applying unless exempted, and no requirements applying to any item or activity until specifically identified. The same number of facilities have a formal as well as an informal mechanism in place for determining the degree of quality assurance programmatic controls over work. The majority of facilities use both quantitative and qualitative graded approach methods of evaluation. The criteria used by most of the laser/optics research and development facilities are risk, nuclear safety, regulations, environmental impact, complex or unique design, mission based, public relations, data quality objectives, and health physics. Some sites do not use all of the above criteria, but most of the listed criteria are used by the responding facilities.

The organizations within the responding facilities that are responsible for risk assessment for the purpose of applying the graded approach are the quality assurance organization, with input from the line managers, ES&H, and experts. The personnel responsible for determining the degree of graded approach controls are the line managers, with input from the quality assurance organization or as a work team. When more than one organization is involved with performing risk assessments for determining the graded approach controls, the organizations work together as a team or coordinate with the ES&H group charged with the institutional task.

Most facilities thought it was too early in their graded approach program to say what the successes are. Areas they thought less successful included: The lack of guidance and programs forced to fit by the uninformed. Others thought it was too early in their program to say what is unsuccessful. Advice or tips that the responding facilities gave to organizations just starting their graded approach program included:

- Train staff on the graded approach program, and follow up on the effectiveness of the training

- Have staff contribute to team decisions
- Experts in risk assessment and technical programmatic aspects must be involved
- Extend the program to more situations
- Strive for continuous improvement for an effective graded approach
- Line management needs to have flexibility in using a graded approach program
- Keep it simple and trust the judgement of your best people
- Identify the customer
- Define requirements
- Assess the significance of risk with contemplated work
- Conduct management reviews to define levels of risk
- Encourage good judgement to identify process.

The criteria for determining the need for a readiness review include: the restart of a nuclear facility, based upon program managers perceived risk, criteria imposed by an external customer, past performance and baseline checklist, or are a function of the facility. Most of the responding facilities use formal and informal readiness reviews.

One additional comment was that success depends highly on the quality of the initial risk assessment and good judgement used to impose controls.

MATERIALS RESEARCH AND DEVELOPMENT PROGRAMS

Twelve materials research and development facilities responded to the survey. All of the responding facilities use NQA 1, 2, or 3. Half of the respondents use QC 1, 2 with NQA 1, 2, or 3. The standards that are used by one or more facilities include: ISO 9000; ANSI N45.2 and daughter standards; EPA QAMS-005/80; or DOE Order 5700.6C. Two facilities identified DOE Order 5700.6C as one of the standards they use in combination with NQA 1, 2, or 3. The majority of the respondents use the approach that no requirements apply to any item or activity until specifically identified. Most of the respondents have a formal mechanism in place for determining the degree of quality assurance programmatic controls over work. Only one-third have an informal mechanism for determining the degree of controls. Most facilities use both quantitative and qualitative graded approach methods of evaluation. The criteria used in

the quality assurance program grading methods are based on risk, nuclear safety, regulations, environmental impact, administrative, complex or unique design, and public relations impact.

When the grading of the quality assurance program is based upon risk, most of the facilities use both assessment of the probability of failure and the assessment of the consequence of failure. The main personnel responsible for risk assessment for the purpose of the grading are line management. The personnel responsible for determining the degree of graded approach controls are the line managers for most of the responding facilities, with input from the quality assurance organization. When two organizations are involved with performing risk assessment and determining graded approach controls, it is usually done by a team consensus.

Aspects of the graded approach program that are successful include:

- Teams are well trained to make decisions
- The consequence of failure is identified, rather than assigned a numeric value
- Areas of productivity improve
- Integrated work control programs are developed to perform maintenance
- Controls associated with risk are accepted
- Efforts are focused on important areas.

Several facilities felt it is too early in their program to give examples of success.

Aspects of the graded approach that are less successful include:

- There is little guidance for development and implementation
- There is inadequate time and investigation for development
- Line organizations have problems when quality assurance concepts are not understood
- Classification is not clearly defined which cause misapplication and sometimes cumbersome results
- Fewer controls than needed are applied to avoid cost scheduling
- The process is not simple.

Tips for quality assurance professionals when starting a graded approach program include:

- Provide more training to teams making decisions in implementing a graded approach program

- Extend the graded approach program to more situations
- Educate staff that an effective graded approach program is continuous improvement
- Line management flexibility is needed to do the job right, use good judgement in risk management
- Try to simplify to cut down the amount of numbers
- Think through what exists
- Keep it simple and trust the judgement of your best people
- Do not overproceduralize
- Give the designer/owner latitude to build quality
- Identify the customer
- Define requirements
- Assess the significance of risk with work
- Conduct management review to define levels of risk
- Involve the technical people who will be using the program during its development.

The criteria for determining the need for readiness reviews include DOE Order 5000.3A, criteria imposed by an external customer, past performance and baseline, complexity of system testing, design, function of the facility, risk of the evaluation, and, usually, external requirements. Most of the responding facilities have a formal readiness review.

ENVIRONMENTAL PROGRAMS

ENVIRONMENTAL HAZARDOUS/RADIOACTIVE/MIXED WASTE CLEANUP/REMEDIATION PROGRAMS

Thirty-one environmental hazardous/radioactive/mixed waste cleanup/remediation facilities responded. All of the responding facilitates use NQA 1, 2, or 3. Half of the facilities also use EPA QAMS-005/80, and about one-third use QC 1, 2 in combination with NQA 1, 2, or 3 or EPA QAMS-005/80. The majority of the respondents use the approach that no requirements apply to any item or activity until specifically identified. The other respondents were split between the responses on the questionnaire that all requirements apply to everything and all requirements apply unless exempted. Most of the facilities have a formal mechanism for determining the degree of quality assurance programmatic controls over work. About one-fourth of the respondents have an informal mechanism in place. Most of the facilities use both quantitative and qualitative approaches to grading. Most of the responding facilities use risk, nuclear safety, regulations, and environmental impact for their criteria for a quality assurance program. The grading application used in most responding facilities is based upon both the assessment of the probability of failure and the assessment of the consequence of failure.

The organization responsible for risk assessment for the purpose of a graded approach program is mainly the line organization. In some cases, it is the line organization in combination with engineering, quality assurance, or the ES&H group. The organization responsible for determining the degree of quality assurance program controls is usually the line managers or the line managers in combination with engineering, quality assurance, or other work teams. When two organizations interface for performing risk assessment and determining quality assurance program controls, the majority use the team concept to make the decisions.

Most of the respondents felt it is too early in their graded approach program to know what aspects are successful. The responding facilities that have had a graded approach program long enough to give success responses felt the aspects of a successful graded approach program include well-trained teams making decisions, the development of a productivity improvement integrated work control program to perform maintenance, less controls on lower-level requirements to reduce cost, and uniformity across the organization. Less successful aspects of their graded approach program are caused by little guidance, processes not being

documented, inadequate time and investigation before starting a graded approach program, difficulty of finding historical data on the graded process, too much reliance on quality assurance, management not allowing implementation of corrective actions, or the process is not simple to implement. Some lessons learned by the respondents in developing their graded approach programs include:

- Implement more training
- Start with developing a graded approach, rather than revising the present program
- Consider all risks
- Involve design engineers
- Revise as improvements are identified
- Apply program consistently across the organization
- Break the graded approach out of the overall quality assurance program
- Develop the graded approach as a way to rank a system by risk, cost, failure, and consequences
- Tie the graded approach program back to the quality assurance program after the graded system has been developed.

Tips suggested for quality assurance professionals just starting to establish a graded approach program include:

- Think through what exists
- Do not let the schedule prevail over good quality practice
- Integrate all approaches to use for all decisions
- Keep the system simple
- Find a proven system and mold it to your needs
- Look at all the risks
- Know regulations
- Identify the customer
- Define the requirements
- Assess the significance of the risk
- Conduct management reviews to define the levels of risk
- Encourage good judgement to identify the process
- Make sure safety functions are well defined before starting
- Involve the technical people who will be using the program during its development.

Most of the facilities use readiness reviews for activities that present higher risk. The criteria used to determine the need for readiness reviews are the customer, the site safety committee, safety systems, credibility risk, high negative environmental impact, importance of program, past performance, baseline checklists, degree of hazard, complexity of system, team assessments, problems of risk that could cause environmental health concerns, the function of the facility, and the field activities. Most of the facilities use formal readiness reviews.

Other suggestions reported for implementing a successful grading process include: obtain quality engineering consensus to use a graded approach, success depends highly on the quality of the initial risk assessment and good judgement used to impose control, and have a clear definition of the grading process.

ENVIRONMENTAL RESEARCH AND DEVELOPMENT PROGRAMS

Seventeen environmental research and development facilities responded. All of the respondents use the NQA 1, 2, or 3 standards, either alone or in combination with QC-1, 2; ISO 9000; ANSI N45.2; EPA QMS-005/80; DOE Order 5700.6C; or MIL-Q-9858A. Only one facility uses DOE Order 5700.6C in combination with NQA 1, 2, or 3 and EPA QAMS-005/80. The types of graded approach used are evenly split between requirements applying to all items or work and requirements applying to any item or activity specifically identified. The majority of the facilities use both quantitative and qualitative methods of grading. The criteria used by the facilities varies and no specific trend is established in what criteria are used other than a few: risk, nuclear safety, regulations, environmental impact, administrative, complex or unique design, public relations impact, mission-based, data quality objectives, and health physics. The only criteria identified in the survey that are not used by a majority of the respondents are data quality objectives.

The majority of the facilities use both the assessment of the probability of failure and the assessment of the consequence of failure. The personnel in most responding facilities responsible for risk assessment for the purpose of grading are the line managers. The personnel responsible for determining the degree of quality assurance program controls are the line managers, with assistance from quality engineers, consulting organizations, quality

assurance, and safety and health. When two organizations interface to perform risk assessments and determine controls, they accomplish this through the health and safety division or as a team consensus.

Some of the reasons graded approach programs have been successful include:

- Facility uses a very qualified technical staff
- The facility uses the consequence of failure, rather than a numeric system
- Productivity improves noticably
- There is an integrated work control program to perform maintenance
- Operational people are involved
- Employees accept set controls associated with risk
- There is reduction in effort where a graded approach program is implemented
- Efforts are focused on important areas.

Most of the facilities thought it was too early in their program to share their successes. Aspects that are less successful include:

- Development of a workable deployment
- Implementation
- Forced to fit by the uninformed
- Inadequate time and investigation
- Procurement levels
- Criteria not specific
- More effort needed to reach clear grading criteria.

Advice that the respondents would give to facilities just starting to develop a graded approach program includes:

- Do not mix applications
- Make quality more centralized
- Provide more training on using and understanding the graded approach program
- Expert risk assessment and technical programmatic aspects must be involved to make determination of the level of controls
- Extend the program to more situations
- Move toward a determination-based design classification

- Establish a regular, more consistent type of graded approach with follow-up on all areas needing correction
- Be consistent across the organization
- Encourage continuous improvement
- Line management needs the flexibility to do the job right, using good judgement in risk management
- Try to simplify to cut down on the amount of numbers
- Focus attention during development
- Do not let schedule prevail over good quality practice
- Know regulations
- Keep regulations updated
- Establish friendships with the organization and people you audit
- Identify the customer
- Assess the significance of risk with contemplated work
- Define levels of risk.

The criteria for determining the need for a readiness review include vital safety systems and key safety systems, DOE Order 5000.3A, management decisions to decide the need for a readiness review, criteria imposed by an external customer, past performance and baseline checklists, complexity of system, testing, design, function of the facility, and risk of evolution. Most of the facilities use a formal readiness review, with a few using both formal and informal readiness reviews.

WEAPONS PROGRAMS

NUCLEAR WEAPONS DESIGN/FABRICATION PROGRAMS

There were 17 responses from nuclear weapons design/fabrication facilities. The majority, or 71 percent, of the facilities responding use NQA 1, 2, or 3 or QC 1, 2 as their base standards. Other standards used by the other facilities are EPA QAMS-005/80, ISO 9000, ANSI/ASQC Q90 series, ANSI N45.2 and daughter standards, or DOE Order 5700.6C. The majority of the respondents apply basic minimum requirements for developing a quality assurance program and increase the requirements as the risk increases. Half of the facilities have formal mechanisms for determining the degree of quality assurance controls. The other half have no formal mechanism in place to measure the degree of controls. The majority of respondents have informal mechanisms to determine the degree of quality assurance controls. Fifty-three percent of the facilities have both quantitative and qualitative graded approach methods in place. Forty-one percent have only qualitative methods. The other six percent did not respond or only have quantitative graded approach methods. The majority of the facilities use the risk method of grading quality assurance. An equal number of the facilities use nuclear safety methods, regulations, and environmental impact. The majority of the facilities grade the application of their quality assurance program based upon risk by both the assessment of the probability of failure and the assessment of the consequence of failure. The majority of the facilities use both qualitative and quantitative evaluations to grade the application of the quality assurance program.

The organization within the nuclear weapons design/fabrication facilities that performs most of the risk assessments for the graded approach program is the line organization/management. The majority of the responding facilities determine the degree of quality assurance program controls by line management, with assistance from other supporting groups such as quality engineers, consulting organization designers, requisitioners, and quality assurance coordinators. Most of the facilities interface for performing risk assessment and determining quality assurance program controls by developing an organizational work team. Others use an informational system dependent on the ES&H group that has been charged with the institutional task, as well as procedure controls.

For nuclear weapons design/fabrication programs, most of the graded approach programs are too new to judge success. The ones that have measurements of success attribute the success to teams trained to make decisions, not rushing into a graded approach program, and personnel having more exposure to graded quality assurance. Graded approach programs that are less successful relate the lack of success to little guidance, lack of training, or programs developed by uninformed personnel that were forced to fit causing cumbersome results. Respondents suggested the way to make the graded approach program successful would be to provide more training in assessing risk; to start with a graded approach, rather than revising existing programs; and to use experts in risk assessment and technical programmatic aspects to determine the level of quality. Other suggestions given to facilities that have not started a graded approach program include:

- Get up to speed on ES&H application
- Do not let schedule prevail over good quality practice
- Establish and communicate the criteria for determining the degree of required controls
- Keep the program simple
- Trust the judgement of your best people.

Most of the responding facilities use readiness reviews for activities with higher risk. The criteria these facilities use for determining the need for a readiness review include: an external customer, the site safety committee, restart of a nuclear facility, vital safety systems, key safety systems, maturity of design, facility preparation, production readiness, and past performance and baseline checklist. Most of the facilities use formal readiness reviews.

OTHER TYPES OF FACILITIES

NUCLEAR POWER GENERATION PROGRAMS

Two nuclear power generation facilities responded to the survey. There were not enough responses in the nuclear power generation category to see a trend or pattern in implementing a graded approach program for quality. In the two facilities that responded, one uses NQA 1, 2, or 3 exclusively, while the other uses a combination of NQA 1, 2, or 3; EPA QAMS-005/80; and ANSI N45.2 and daughter standards. One facility uses all requirements applied unless exempted, and the other one has all items and activities fall under the quality assurance program, with specific requirements determined based upon risk. One facility uses formal and informal mechanisms for determining the degree of quality assurance programmatic controls, and the other facility has only a formal mechanism for determining the degree of controls. One facility uses the qualitative approach to grade the application of the quality assurance program and the other uses both quantitative and qualitative methods. Both facilities base their grading processes on risk, nuclear safety, regulation, administrative costs and schedule, and data quality objectives. One also uses environmental impact and mission. One facility uses both the assessment of the probability of failure and the assessment of the consequence of failure.

The line organizations are responsible for performing risk assessments in one facility; and the other facility had no specific organization responsible. In one facility, the degree of quality assurance programmatic controls is set by the operating organization, with overall quality assurance responsibility by a central quality assurance program. When more than one organization is involved in performing risk assessment and determining quality assurance program controls, the user organization and support organization meet to determine the level of controls. They negotiate agreements to arrive at a mutual, satisfactory level of control at the facility.

One facility contributed its success to having a uniform graded approach program across the organization. The other facility had not been as successful, stating that the criteria for having a graded approach program are not specific, and needed more effort to reach clear grading criteria. The responding facilities recommended, when developing a graded approach program, breaking graded approach out of the quality assurance program and developing a way

to rank the items or activities requiring a graded approach by risk, cost, failure, and consequence. Suggestions given when trying to establish a graded approach program include: the controls must focus on the end product, it is important to get system operators involved in setting graded approach controls, and quality assurance will follow.

Both facilities use readiness reviews for activities that present a higher risk. In one facility, the criteria for determining the need for readiness reviews would be a major milestone in the design. The other facility uses DOE start-up and restart regulations as identified in SEN-16B-91. Both of the responding facilities have formal readiness reviews in place.

LIST OF QUESTIONNAIRE RESPONDENTS

We thank the following facilities for providing procedures and examples used in producing this working paper.

- AlliedSignal Aerospace Company, P.O. Box 419159, Kansas City, Missouri 64141-6159
- Argonne National Laboratory - West, P.O. Box 2528, Idaho Falls, Idaho 83403
- Battelle - Pacific Northwest Laboratories, P.O. Box 999, Richland, Washington 99352
- Brookhaven National Laboratory, Upton, New York 11973
- EG&G Energy Measurements, P.O. Box 1912, Las Vegas, Nevada 89125
- EG&G Mound Applied Technologies, P.O. Box 3000, Miamisburg, Ohio 45343-3000
- EG&G Rocky Flats Plant, P.O. Box 464, Golden, Colorado 80402-0464
- Kaiser Engineers Hanford Company, P.O. Box 888, Richland, Washington 99352
- Los Alamos National Laboratory, P.O. Box 1663, Los Alamos, New Mexico 87545
- Reynolds Electrical and Engineering Co., Inc., P.O. Box 98521, Las Vegas, Nevada 89193-8521
- Westinghouse Environmental Management Company of Ohio, P.O. Box 398704, Cincinnati, Ohio 45239-8704
- Westinghouse Hanford Company, P.O. Box 1970, Richland, Washington 99352
- Westinghouse Savannah River Company, P.O. Box 616, Aiken, South Carolina 29808-0001

REFERENCES

ANSI N45.2 and Daughter Standards
American National Standards Institute
1430 Broadway
New York, NY 10018

EPA QAMS-005/80
Office of Monitoring System and Quality Assurance
Office of Research and Development
U.S. Environmental Protection Agency
Washington, D.C. 20460
Note: This document will be replaced by QAMS R-5 currently in final reviews.

ISO 9000 or ANSI-Q90 Series
American National Standards Institute
1430 Broadway
New York, NY 10018

DOE Order 5700.6C
Contact your area DOE Operations Office

DOE Order 4330.4A
Contact your area DOE Operations Office

DOE-ER-STD-601-92
Contact your area DOE Operations Office

DOE Notice-Graded Approach, November 4, 1993
Contact your area DOE Operations Office

NQA 1, 2, 3
American Society of Mechanical Engineers
United Engineering Center
345 East 47th St.
New York, NY 10017

NUREG 1293
Office of Information Resources Management
Distribution Section
U.S. NRC
Washington, D.C. 20555
or
Superintendent of Documents
U.S. Government Printing Office
P.O. Box 37082
Washington, D.C. 20013-7082

APPENDIX A

GRADED APPROACH QUESTIONNAIRE

Please check the appropriate boxes below and provide information as requested. Use the back of the page or attach additional sheets of paper if additional space is needed for your answers.

1. What industry quality assurance standards does your organization currently use?

- ❑ NQA 1, 2, & 3
- ❑ QC-1 & 2
- ❑ NUREG 1293
- ❑ EPA QAMS-005/80
- ❑ DOE Order 5700.6C
- ❑ MIL-Q-9858A
- ❑ ISO 9000 or ANSI-Q90 Series
- ❑ ANSI N45.2 and Daughter Standards
- ❑ Other (Please list below.)

2. To what type of work is your Quality Assurance Program applicable?

- ❑ Nuclear power generation
- ❑ Nuclear weapons design/fabrications
- ❑ Environmental haz/rad/mixed waste clean up/remediation
- ❑ Basic research
- ❑ R&D nuclear (2nd gen. fission/breeder/fusion)
- ❑ R&D Non-nuclear energy
- ❑ R&D Environmental
  - o R&D Biological
  - o R&D Laser/optics
  - o R&D Materials
- ❑ Other (Please list below.)

3. Several guidelines exist on the application of quality assurance controls to work. Some of the choices presented by NQA-1, NUREG 1293, and others are listed below. Which approach does your organization use?

- ❑ All requirements apply to everything.
- ❑ All requirements apply unless exempted.
- ❑ No requirements apply to any item or activity until specifically identified.
- ❑ Other (Please list below.)

4. Does your facility have a formal mechanism for determining the degree of quality assurance programmatic controls over work? If yes, please attach a copy of the implementing procedure(s).

- ❑ Yes
- ❑ No

5. Does your facility have an informal mechanism that is commonly practiced for determining the degree of quality assurance programmatic controls over work? If yes, please explain below.

   ❑ Yes
   ❑ No

6. Is your graded approach method:

   ❑ Quantitative
   ❑ Qualitative
   ❑ Both
   ❑ Other (Please explain below)

7. On which of the following criteria is your method of grading quality assurance programs based?

   ❑ Risk (general)
   ❑ Nuclear safety
   ❑ Regulations
   ❑ Environmental impact
   ❑ Administrative
      ❑ Cost
      ❑ Schedule
   ❑ Complex or unique design
   ❑ Public relations impact
   ❑ Mission based (project or facility mission success dependent)
   ❑ Data quality objectives (DQO) (environmental projects only)
   ❑ Health physics
      ❑ Contamination control
      ❑ External radiation dose
      ❑ Internal deposition
   ❑ Other (Please list below.)

8. If you grade the application of your QA program based upon risk, which of the following considerations are used?

   ❑ Probability of failure
   ❑ Consequence of failure
   ❑ Both probability and consequence
   ❑ Other (Please explain the method below.)

9. If you grade the application of your QA program, is the method a qualitative evaluation (such as subjective guesses, historical experience, etc.) or a quantitative evaluation (statistical approach such as probability risk assessment)?

   ❑ Qualitative
   ❑ Quantitative

   Please explain the method used.

10. What organization within your facility is responsible for performing quantitative and/or qualitative risk assessments for the purpose of quality assurance programs?

11. What organization within your facility is responsible for determining the degree of quality assurance programmatic controls required?

12. If two different organizations are responsible for performing risk assessments and determining quality assurance programmatic controls, how does the interface work between the two organizations?

13. What aspects of your graded approach program do you feel are very successful?

14. What aspects of your graded approach program do you feel are less than successful?

15. In your experience of developing or applying a graded approach program, what would you do differently?

16. What tips or points can you provide to quality assurance professionals just now trying to establish a graded approach program for their organization or facility?

17. Does your facility use a "readiness review" for activities which present a higher risk?

18. What are the criteria for determining the need for readiness reviews?

19. Are your readiness reviews

    ❑ Formal
    ❑ Informal

20. Please include any additional comments you would like to make regarding the graded approach to applying quality assurance programmatic controls.