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Secretary of the Commission
Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Subject: NRC Initiatives - Improving Quality Assurance

News Release No. 83-35 invited public comments on how the quality of nuclear power plant construction might be improved. Mr. Tom Bishop of Region V made the same point during the ASQC Western Regional Energy Conference in Richland, WA this week. He discussed a larger number of initiatives than those covered in the News Release.

There may be a way by which the involvement of senior management in quality assurance matters might be stimulated; further, this idea may help promote another NRC initiative. There appears to be increasing numbers of Audit Committees, usually comprised of independent Directors, reported in Notices of Annual Meetings (proxy statements) issued by many companies. These Audit Committees meet with and review the reports of external auditors; more and more are meeting with internal auditors as well. The Meeting Notices typically state that Audit Committees: "...review with the ... auditors their findings and recommendations, ... and review the principal accounting policies of the Company and other pertinent matters, either at the initiative of the Committee or at the request of the auditors." These matters are clearly similar for quality assurance programs ("quality" versus "financial" health of the organization).

I suggest that the Securities and Exchange Commission be asked how Boards of Directors Audit Committees came into being. If this was the result of persuasion, whether by the SEC or by industry's initiative, I believe a similar approach would be far preferable to use of regulations. In any event, if the concept were implemented, the initiative of increased use of independent auditors (and independent design reviewers) should also be reinforced - but the main thrust of my suggestion is to achieve a better understanding of QA matters by Chief Executive and/or Chief Operating Officers of licensees and their contractors.

DS09
add: Terry Harpster
305 EW/5

4/26/83 PD

The enclosed paper, presented in the same ASQC Conference, was a contributory factor to this idea. You may be interested in some of my remarks, not only those directly pertaining to the Commission.

If you think this suggestion has merit, I would be pleased to assist in developing and carrying out an appropriate action plan.

Very truly yours,

Daniel L. Garland

Daniel L. Garland

Enclosure

cc: H. Harty - PNL

T. Bishop - Chief, Reactor Project Branch, Region V

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ABSTRACT

RESPONSIBILITY FOR ASSURING QUALITY

Some considerations are presented for establishing responsibilities for attaining and assuring quality. Although responsibility assignments within an organization are emphasized, delegations to other organizations and the roles of enforcement and regulatory bodies are discussed to a limited extent. This review is meant to stimulate thinking about how best to assign responsibilities. No panaceas or prescriptive approaches are intended.

This paper is dedicated to Al Squire and Admiral H. G. Rickover. Each of them greatly influenced my career, and my life. If any useful ideas are noted, they — and countless others whose brains I picked over the years — deserve most of the credit.

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Do you recognize this quotation?

> *"'Twas brillig, and the slithy toves*
> *Did gyre and gimble in the wabe;"*

More to the point — do you understand the words?

Alice, the girl who first visited "Wonderland," found it in a book after she went "Through the Looking Glass." Humpty Dumpty told her the meaning of these words, then:

> *"When I use a word," Humpty Dumpty said, " it means just what I choose it to mean — neither more nor less."*
>
> *"The question is," said Alice, "whether you can make words mean so many things."*

And with that introduction,

My topic is:

RESPONSIBILITY FOR ASSURING QUALITY

I will discuss the first word, which frequently appears in regulations, codes, standards and specifications for Quality Assurance. This word often means different things to different people.

My objective is to encourage you to think about what "responsibility" means — and what it implies. I hope that you and your co-workers will discuss this, in order to reach a clear and uniform understanding of the roles of individuals and groups in your organization. I cannot recommend, let alone prescribe, meanings or usages, or assignments of responsibility, that are sure to be suitable for all organizations, or for all people.

I will start by discussing responsibility in one organizational group. Then how the word may apply to an entire organization, and also to interfacing multiple organizations. Finally, I will have a few comments on responsibilities related to regulatory and enforcement bodies. My remarks will apply to nuclear Quality Assurance — but they should be relevant for other fields where it is important that quality be assured, such as in aerospace, drug, food, and defense industries.

SEMANTICS

Let us begin with definitions.

RESPONSIBILITY

- The state or fact of being responsible
- A charge, trust, or duty, for which one is responsible

These definitions lead us to:

RESPONSIBLE

- Answerable, accountable (to another for something); liable to be called to account.
- Answerable to a charge
- Capable of fulfilling an obligation or trust; reliable, trustworthy; of good credit and repute.

There are other definitions of "responsibility" and "responsible." We could continue by looking up "answerable," "accountable," and so forth. This is not necessary for our present purpose. To sharpen up our understanding, however:

> "Responsibility, in order to be reasonable, must be limited to objects within the power of the responsible party."
>
> Alexander Hamilton, The Federalist

This suggests that responsibility should not be assigned or delegated to someone incapable of handling it. A corollary would be that responsibility should not be accepted, if you have any doubt about your qualifications to handle it.

> "It is only when the conception of the individual has been reached, that the idea of responsibility begins."
>
> Archibald Sayce, The Principles of Comparative Philology

Responsibility, in this sense, is a frequently abused word. We've heard, too often, that "We are all responsible for quality." This means nothing unless specific responsibilities are identified for individuals or groups — whether by name, title, or position. Otherwise, there is a collective sharing of responsibility, with a lot of finger pointing if things go wrong. For example:

> The Project Manager is responsible for....(just about everything but quality assurance)

You bet! If anything does go wrong, he (or she) may get it in the neck -- but does the Project Manager do all the work? Isn't it SOP for specific tasks to be assigned — and don't these carry responsibilities? While it is common to include such statements in a Quality Assurance Manual or other top-level documents, there is a high potential for misunderstanding unless procedures, instructions, job descriptions — or some written documents — clearly spell out the functions, tasks, and the like, that are assigned to organizations, groups, or individuals, as well as the associated responsibilities.

INDIVIDUALS AND GROUPS WITHIN AN ORGANIZATION

Let's begin with a small group, which has been assigned (delegated) certain work under the Quality Assurance program. You, as the manager, have a responsibility to see that such work is done properly — even though ultimate responsibility for this and other work activities is retained by higher management.

Alexander Hamilton's quotation is particularly relevant.

You parcel out the tasks to your subordinates, and you take account of their capabilities. You check up on them, at decreasing frequency as you gain confidence in their performance, to be reasonably certain they carry out their assigned responsibilities.

Before proceeding to the next area of interest, what does a signature mean? Did the inspector mean that the set-up, performance, and results of a hydrostatic test were acceptable — or only that one or more weld joints did not leak? Assuming the latter meaning, does the signature mean that the inspector personally examined the entire length or circumference of each weld for seepage? Similar

questions could be raised about signatures on control room logs, design drawings, and so on. I think it is important to carefully consider and establish — for each application — what a signature represents, at least in terms of assigned responsibility.

THE ENTIRE ORGANIZATION

When we review the responsibilities of different groups within an organization, things get more complicated. To begin with, many people believe that quality assurance is the responsibility of the Quality Assurance Department only. Worse, that quality is the responsibility of QA. If we fail to define, and document, the functions and responsibilities of all groups for planning, achieving, and verifying quality, there is a potential for things to go wrong.

When the Quality Assurance Manager descends from the mountain, carrying the tablets that delineate application of the 18 criteria, are they the entire QA program? Unfortunately, the QA Manual is so regarded by many people — in and out of the Quality Assurance Department.

In my view, the QA program also includes written procedures and instructions; and training which supports all these documents. After all, the Ten Commandments are only part of the entire Bible.

This concept can provide a rational basis for explaining to and persuading people in each organizational group, that almost everyone has one or more roles to play in the QA program. We can tell each person what his or her responsibilities for achieving and assuring quality really are.

- The planners — who prepare parts of the QA manual or other procedures and instructions — are responsible for doing this in a way that the rest of the organization can agree with, understand, and carry out.

- The doers — who produce a product — are responsible for doing so in accordance with established procedures, instructions, and training. In this connection, "product" includes a design drawing or specification; electricity or radioactive waste; and R&D or other data that may be used for improving designs or operations; as well as the obvious hardware.

- The verifiers — who check that specified quality has been attained, as well as that activities affecting quality have been performed correctly — are responsible for doing so in accordance with prescribed procedures, etc. Verification responsibilities should not be assigned only to QA personnel, for a variety of reasons. Verification may be accomplished by engineers and others involved in design reviews; by persons who make safety and fire inspections; or by those who evaluate performance of drills.

All such people — planners, doers and verifiers — are, in fact, performing quality assurance functions, regardless of their organizational affiliation; and everyone should understand the associated responsibilities.

Here are a few examples of what I am driving at:

1) How about verification of design adequacy? It is normal practice, when design adequacy is to be verified by design review, for Quality Assurance and other organizational groups to be assigned responsibilities. It is also SOP to require the participants in safety-related design reviews to be independent. Often neglected, however, is a clear identification of assigned responsibilities: e.g., for which design features is each group or person primarily responsible; who is responsible for documenting, resolving, and tracking any design deficiencies or other comments brought out in the review; and so forth.

2) How about verification that hardware meets design requirements? While Quality Control usually plays a major role, there is no specific requirement in NQA-1 or NRC Regulatory Guides that only QC personnel verify design characteristics. At least for non-safety-related items, you have some latitude in deciding who will be responsible for this. Verification may be assigned totally to QC; or inspection assigned to QC and testing to Engineering; or mainly to manufacturing/construction supervision, with first piece and periodic subsequent overchecks assigned to QC.

3) How about Stop-Work authority? Why is this responsibility usually assigned to the Quality Assurance Department? Why shouldn't line management be held responsible for controlling their work activities? Isn't that what they are paid to do? Wouldn't it make sense to assign line management the primary responsibility to stop work that may not be safe or otherwise satisfactory? And, if Quality Assurance — after pointing out unsafe or unsatisfactory conditions to line management — does stop work when a line manager fails to, has the line manager met his assigned responsibility?

4) Let's take another look at the NRC emphasis on Quality Assurance having Stop Work authority. Is it because QA is considered to be the only part of the organization that is responsible for independent verification? If not, should other "verifiers" also have the authority — and the heavy responsibility — to stop work?

In contrast to most of my other remarks, these questions take us to the responsibilities of those who establish the QA program, including the associated procedures and instructions. For example:

- Which groups or persons are responsible for assigning verification responsibilities?

- Which groups or persons are responsible for deciding the items or activities that are "important to safety?"

- For setting quality levels, and the associated decisions on which QA program requirements will be applied to items and activities?

Many more questions could be raised about responsibilities for planning. There is not enough time to get into them — but this area offers a lot of food for thought about responsibility. Not only for the initial assignments of responsibility, but also for review, concurrence, or approval of such assignments.

5) How about the "regular review of the status and adequacy of the QA program?" Does this mean that the Quality Assurance Manager will do this somehow? Or that, as NQA-1 states:

> *"Management of those organizations implementing the QA program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible....?"*

Carefully planned and carried out self-appraisals can be very useful, if well documented and followed up by prompt action to correct any observed deficiencies. It is surprising to see how often a General Manager will delegate this important task to the QA Manager. In contrast, ASME survey teams thoroughly evaluate the involvement of the most senior manager in the periodic assessments of an ASME Section III QA program.

6) Who is responsible for corrective action? A prevalent misconception is that the QA Department knows best, how to recommend corrective action, at least for "significant conditions adverse to quality." However, NQA-1 says:

> *"Persons or organizations responsible for....verifying that activities affecting quality have been correctly performed shall have sufficient authority....and organizational freedom to....(2) initiate, recommend, or provide solutions to quality problems...."*

The emphasis is added for this discussion.

In the first place, too many QA people are prone to abuse this perceived authority. It is bad enough when they make snap judgments about what really caused an observed problem, and not only recommend but insist upon their pet ideas as to how to resolve it.

If there is indeed a quality problem, think about the proposition that the manager or supervisor responsible for the activity has presumably been selected for his/her ability to do the whole job. This should include the corollary duties of investigating the reasons for perceived problems, with the assistance of others in the organization if necessary. If QA tells a manager what to do, or insists upon approving planned corrective actions in advance — does that not relieve the manager of responsibility?

I could go on with other comments on responsibility within an organization — but these should suffice for now.

MULTIPLE ORGANIZATIONS

Let's now look briefly at responsibilities delegated among multiple organizations.

> MULTIPLE ORGANIZATIONS - RESPONSIBILITY
>
> Where more than one organization is involved in the execution of activities covered by this standard, the responsibility and authority of each organization shall be clearly established and documented.

Some of the typical delegations to contractors and suppliers include responsibility to identify and obtain the purchaser's resolution of design conflicts or deficiencies; for qualification of personnel; and so forth.

Some contracts and purchase orders do not clearly establish responsibility for some activities. For example:

1) The basis for the purchaser's source surveillance and inspection activities is not made clear: That it is for meeting the purchaser's responsibilities, but not to relieve the supplier of his. Besides applying the logic discussed earlier for corrective actions, how about your audits? If the contractor or supplier is required to perform internal audits, do you do this for him? This mode of auditing relieves the supplier of a contractual responsibility, and you become his crutch. And, what is your role when your contractor audits subcontractors? If you become a member of the audit team, you at least partially relieve the contractor of a responsibility. Moreover, how can you meet <u>your</u> responsibility, to evaluate the performance of your contractor?

2) Some procurement documents, as well as purchaser practices, confine or restrict a contractor or supplier to such an extent that there may be a valid question about his ability to meet product design requirements. If procurement documents narrowly specify the processes and methods that may be used — or if the purchaser directs, by extensive comments,

content of procedures — is there not a question about the extent to which someone can legally be held responsible for the product? When, and if, we "micro-manage" our supplier or contractor, do we not become part of the problem if the end result is not satisfactory?

3) What can we learn about responsibility from the recent case, in which the Department of Justice found that a distributor was falsifying certified material test reports and mislabeling pipe? Obviously, the distributor abused his responsibility to supply acceptable material, and is being punished. However, pipe and other products were sold to many customers — it is not clear how many were engaged in nuclear work. I suggest that purchasers also failed to meet their responsibilities, since NQA-1 (and N45.2) requires the purchasing organization to verify the validity of supplier certificates and the effectiveness of the certification system, if certificates are used as the basis for acceptance. Considering the extent of falsifications in this case, it seems clear that many purchasers failed to carry out their responsibilities, but instead took comfort in pieces of paper!

ENFORCEMENT AND REGULATORY BODIES

Let's turn our attention to enforcement and regulatory bodies. What are their responsibilities?

According to the ASME Code, enforcement authorities are defined as:

ENFORCEMENT AUTHORITIES

1. States and municipalities....that have adopted or accepted one or more sections of the Boiler and Pressure Vessel Code, and

2. The National Board of Boiler and Pressure Vessel Inspectors

Although the Owner of a nuclear reactor plant and contractors must engage Authorized Inspectors to make the required inspections, the Authorized Inspectors are responsible to the Enforcement Authorities — and thus to the public. It is noteworthy that an Authorized Inspector's signature on a Code Data Form certifies only that:

"....*to the best of my knowledge and belief, the Owner* (or other Certificate Holder) *has performed examinations and taken corrective measures....in accordance with the Code.*" And, "*By signing this certificate neither the Inspector nor his employer makes any warranty....concerning the examinations....*"

In other words, Authorized Inspection Agencies and Enforcement Authorities do not represent Certificate Holders and cannot be held responsible for the quality of nuclear plants.

The Authorized Inspector's disclaimer on the Code Data Form means that each Certificate Holder is responsible for its activities and products. This includes complete performance of each verification. Remember the hydrostatic test inspector? When there are large pipes in congested areas, does your inspector crawl around to examine the full length and circumference of each weld under test? Or does he take the word of an Authorized Inspector who simultaneously witnessed the test, but will sign the Data Form disclaiming any responsibility?

How about Regulatory Authorities? Again, per the ASME Code:

> REGULATORY AUTHORITY
>
> A Federal Government Agency, such as the Nuclear Regulatory Commission, empowered to issue and enforce regulations concerning the design, construction, and operation of nuclear power plants.

Obviously, the scope of a Regulatory Authority is wider than that of an Enforcement Authority, since it encompasses operations. With regard to the NRC, we must keep in mind that its statutory responsibility is limited to public health and safety, and protection of the environment.

There are two key words: To issue, and enforce, regulations. The NRC's responsibility for ensuring the adequacy of regulations may be subject to interpretation. In my opinion, the NRC may have gone too far in issuing voluminous and very detailed regulations — just as a purchaser may be held responsible for the efforts of a supplier, who was allowed little if any freedom to choose how best to do the specified work. When combined with enforcement rigidity, by making it very difficult to use methods of control other than those provided in Regulatory Guides, it is not surprising that the Kemeny Commission concluded that the nuclear industry might reasonably have believed no additional controls were necessary. It is noteworthy that the NRC has recognized this problem, and is now very carefully reviewing proposed changes to its requirements so as not to increase unduly their total impact.

The Commissioners have made it clear that they hold Owners responsible for the quality of nuclear reactor plants, including operational quality. This is essentially the position taken by Enforcement Authorities. However, the NRC has a legal responsibility for safety to the public. Can these different responsibilities be sorted out?

This question has no easy answer. While the relationships are different from those of a Purchaser to its contractors and suppliers, the techniques and methods that may be used by the NRC to verify that quality is achieved will be similar to those used by the Owner. We may get a better understanding of the differences in responsibility between Owners and the NRC, when the courts rule on the GPU suit for $4 billion against the NRC.

WRAP-UP

The NRC Commissioners testified, a year and a half ago, in a House Subcommittee hearing on quality assurance in nuclear plant construction. When asked why many problems were not found earlier, the Commissioners and staff replied, in part, that licensees did not have sufficiently large or competent QA organizations. They made a passing reference to inadequate corrective action as a contributory factor.

It was those remarks which prompted me to write this paper. I do not agree that:

- A licensee needs to have a large QA organization
- The QA organization should do all the verifying
- Inadequate corrective action is only a contributory factor.

I am convinced that a basic cause of the "QA" problems is that many people did not understand responsibility concepts, or were not held accountable for living up to their responsibilities.

I strongly believe that responsibilities must be carefully assigned, not on any preconceived concepts. That delegated responsibilities must be subjected to oversight by the delegators. How this is done in each organization, or among organizations, we cannot say in generic terms — each Owner and other organization must think these matters out carefully for its own case, taking account of the capabilities of its people.

My parting question — which takes in another aspect of responsibility — is:

> What do you do when someone does not carry out an assigned responsibility?

Overlooking that, or acting as a crutch, or patching additional controls into the program, breeds disregard for carefully planned assignments of responsibility. It is the surest way for a Quality Assurance Program to become ineffective.