LEGIBILITY NOTICE

A major purpose of the Technical Information Center is to provide the broadest dissemination possible of information contained in DOE's Research and Development Reports to business, industry, the academic community, and federal, state and local governments.

Although a small portion of this report is not reproducible, it is being made available to expedite the availability of information on the research discussed herein.

LA-UR -89-2027

Los Alamos National Laboratory is operated by the University of California for the United States Department of Energy under contract W-7405-ENG-36

LA-UR--89-2027

DE89 014315

TITLE DIFFICULTIES IMPLEMENTING A QUALITY ASSURANCE PROGRAM AT A NATIONAL LABORATORY

AUTHOR(S) P. L. Bussolini, MEE-9

SUBMITTED TO American Society for Quality Control,
Fort Lauderdale, FL,
September 17-20, 1989

DISCLAIMER

Los Alamos National Laboratory
Los Alamos, New Mexico 87545

SIXTEENTH ANNUAL NATIONAL ENERGY DIVISION CONFERENCE

RESEARCH AND DEVELOPMENT QUALITY ASSURANCE

DIFFICULTIES INVOLVED IN IMPLEMENTING A QUALITY ASSURANCE PROGRAM AT A NATIONAL LABORATORY

Peter L. Bussolini
Group Leader

Los Alamos National Laboratory
MEE-9, MS G736 P. O. Box 1663
Los Alamos, New Mexico 87545

ABSTRACT

Personnel who perform scientific research are highly educated, highly motivated professionals who are often leaders in their fields. A recent survey of researchers at Los Alamos shows that they like freedom and peer recognition, and dislike red tape. Rigid, prescriptive quality assurance programs are often fail because they are perceived to limit freedom and peer recognition and enhance red tape.

This paper will present some of the reasons for research personnel to have rebelled against quality assurance programs and will offer suggestions for the development of a meaningful and successful quality program.

In recent years, funding agencies have been imposing the requirement of quality assurance programs for scientific research. The Department of Energy now requires that research work funded by them be conducted using a written quality assurance program. This program is to be developed using NQA-1 as the preferred standard

Attempts to implement quality assurance programs for research laboratories have, with a few notable exceptions, resulted in less than successful results Some of the reasons for nonacceptance often voiced by researchers include the following:

1. NQA-1 and other nuclear standards are too rigid, are hardware- and are nuclear-power plant oriented

2. High quality work was produced in the past as well without the need for a quality assurance program.

3. Quality assurance programs are costly and, therefore not affordable.

4. Quality assurance is appropriate for mass production work, but is not needed or wanted by research scientists.

These comments and other comments that you are no doubt familiar with should be analyzed, and quality assurance programs should be modified as much as possible.

There are also many good constructive reasons for implementing a meaningful quality assurance program for research. These may be used successfully in selling your quality assurance program. Some of the justification for a quality assurance program in research include

1. The growing concern for safety and environmental issues;

2. The growing concern about fraud..ent research; and

3. The avoidance of disasters (i.e . the O-ring situation).

It may be said that a well thoughtout quality assurance program for research could

1. Increase program effectiveness;

2. Provide a focus on job requirements;

3. Promote attention to quality; and

4. Give feedback to management.

I feel that two concepts are essential to the success of a quality assurance program for research. The first is that the jargon used must be that of the researcher, not the quality assurance professional I will give a few examples of this later in my talk. The second is that the quality assurance program must be meaningful to the research project and therefore needs the maximum amount of input from the researcher This will also result in the researcher developing a sense of ownership in the program

In fact, quality assurance for research is different from quality assurance for production, construction, or operation Research projects are often one of a kind, are highly technical

in nature, and have a high probability for "failure." Researchers have a high degree of expertise and education and work toward vastly different goals from those of most engineering and production professionals. Research projects are often funded at a low level. These differences need to be addressed in a research quality assurance program in order to give a reasonable chance for success.

In a recent survey, Los Alamos researchers were asked what they like or dislike about their jobs. The majority of the scientists agreed that they liked the freedom they were given to conduct research in their areas of expertise; they liked the peer recognition received, often through publications and presentations; and they all disliked the growing amount of red tape. Based on more than ten years of experience in the implementation of quality assurance programs for research at Los Alamos, some common fears the scientists voice are that quality assurance programs

1. Will limit their freedom;

2. Will restrict their ability to produce;

3. Will limit their ability to publish;

4. Are not necessary; and

5. Will involve too much paper work.

It is no wonder that they often oppose quality assurance programs.

I often feel that we, quality assurance professionals, selected the worst possible descriptive terms for our quality assurance programs, which are often referred to as "QA jargon." The following are some examples of terms which are not understood or accepted by most researchers:

CONTROL-As mentioned earlier, all scientists like freedom Control is thought to oppose freedom directly.

SURVEILLANCE-Surveillance is thought of as a cloak-and-dagger activity that has no possible use in research

QUALITY ASSURANCE PROGRAM-A quality assurance program is perceived to be directly related to paper work and uninformed people getting in the way and asking dumb questions. This inhibits freedom and produces red tape

NQA-1-NQA-1 is thought to be a hardware oriented standard that may be applicable to nuclear power plants but certainly not to research Scientists believe that their

work is anything but standard, and almost never is it hardware oriented.

AUDIT-An audit is perceived to be related to a painful scrutiny before people with preconceived conclusions, such as the IRS.

PERSONNEL CERTIFICATION-Personnel certification is a term that may have some meaning for technicians but certainly could not apply to a Ph.D. level scientist who often is a leader in his field.

DOCUMENTATION AND RECORDS-Documentation and records are thought to be red tape that is voluminous, restrictive, and, most likely, not applicable.

You probably can add many additional terms to this list.

There are similar terms that have become jargon in the research area and are understood and accepted by the researcher. The following are some terms that have useful meaning and should be considered for use in a research quality assurance program.

RESEARCH PROPOSAL OR PLAN-This term can often be used in lieu of the quality assurance program plan.

TECHNICAL PROGRAM REVIEW-This is an accepted term that could replace surveillance or inspection.

PEER REVIEW-Peer reviews are well understood and accepted by scientists and may be used in place of audit.

LABORATORY NOTEBOOK-Most researchers now use a laboratory notebook to document their research plan and to record all applicable data. With little or no revision, the existing laboratory notebook system can meet the quality assurance requirement for procedures, documents, and records.

Other terms that may be useful are good scientific practice or good laboratory practice; software validation; equipment maintenance and calibration; and confirmation of results. No doubt you can think of other terms that are equally useful and acceptable, some of which may be specific to your own organization.

In general, a quality assurance program that may be acceptable to a scientist should be understandable to the researcher; be written as much as possible by the researcher; use as much existing information as possible; and be designed so that it helps the scientist to meet his personal goals.

Quality assurance professionals do, in my opinion, have an important function in a research quality assurance program. However, care should be taken in the selection of these people. The quality assurance person should have as much technical education in the area of expertise as possible. Certainly, a person with no technical expertise should not be used. The short-term use of research personnel should be explored. They can often contribute greatly, are acceptable to other researchers, and have a good knowledge of quality assurance when they return to research. An excellent solution can often be found by using research personnel for long-term or career positions as quality assurance professionals. One of our very best quality assurance professionals is, in fact, a Ph.D. level astrophysicist with extensive research experience. I strongly suggest avoiding the usage of "compliance types," who probably are better suited to production programs.

My experience has shown that training is an essential ingredient to any quality program, especially one designed for a research program. Some training techniques are well documented, and I will not repeat them here. In addition to the standard techniques, each quality professional assigned to a research program should use every contact with research personnel as a training program. I find that this continual, less obstructive training, often on a one-to-one basis, can be very effective. Management training is also most important to the success of any research quality assurance program. Another unique method of training is the use of research scientists as audit team members on programs other than their own.

Finally I would like to present what, in my view, are the best ways to organize a research quality assurance program. A good way to start is to list some important goals for your quality assurance program. The following is a typical list of basic goals:

1. Ensure that adequate planning precedes major projects;
2. Assure that personnel with appropriate expertise or training are used;
3. Assure that proper materials, equipment, and processes are used and that operations are performed safely;
4. Assure that all pertinent data and information are properly recorded and can be retrieved, and
5. Provide confidence that results are valid, that products meet specifications, or that services are performed effectively and efficiently

Now, how would these goals be best formatted into a quality assurance program which could both meet the needs of the user and an outside compliance auditor? I suggest a program with headings such as the following be used:

1. Planning and Organization,
2. Qualification and Training of Personnel,
3. Control of Equipment and Materials,
4. Acquisition and Recording of Data,
5. Peer and Technical Review, and
6. Audits.

My experience has shown that this type of program can both be useful to the scientist and meet the requirements of a compliance auditor. In fact, I feel that this program meets the applicable requirements of NQA-1 or any existing compliance program.

In conclusion, because the application of quality assurance to research is a fairly new and unique experience, new and unique techniques must be used. The following are some innovative techniques that should be considered:

1. Use all applicable existing material as a base for the quality assurance program;
2. Use the jargon of the scientist, not that of the quality assurance professional;
3. Design the program to fit the goals and needs of the scientist;
4. Be flexible;
5. Help the user develop the actual program;
6. Take or make every opportunity to provide training; and
7. Let the quality assurance professional handle questions about quality assurance standards.

I feel that, by using these techniques a successful quality assurance program can be designed for a research application.

I hope that you find the information in this paper useful and good luck to those of you who are applying quality assurance to research activities. Please call on me if I can provide assistance.