THE IMPORTANCE OF A SUCCESSFUL QUALITY ASSURANCE (QA) PROGRAM FROM A RESEARCH MANAGER'S PERSPECTIVE

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Research Managers' Responsibilities for QA – One responsibility of research managers is to ensure that data from research projects are acquired, processed, reported, and used in accordance with the Quality Assurance (QA) requirements established by the organization. When management does not take QA seriously or when QA requirements are not fully implemented in an organization, the results can be embarrassing, damaging, or dangerous to the organization as well as its customers or clients. The literature and news media report often the results that occur when QA is not a priority or when QA requirements are not implemented properly.

Notable QA Failures – QA has uncounted successes, but our nature is to focus on its failures. Unfortunately, there is a long list of failures to consider. Three examples have been taken from this long list to reinforce the points I wish to make about QA from a research manager's perspective:

1. On December 3, 1999, Tamara Lytle, a staff writer for "The Orlando Sentinel," published an article which stated that an Air Force report concluded that five rocket launches, from August 1998 through May 1999, failed due to cutbacks in QA staff by the contractors, poor engineering and workmanship by the contractors, and lax monitoring by U.S. military managers. Further, it was reported that one contractor had reduced QA staff on the projects by more than 60% in the years preceding the failures. The five failures cost U.S. taxpayers more than \$3 billion and delayed the deployment of military payloads that were designed to help the U.S. catch terrorists as well as commercial payloads intended to enhance mobile communications capabilities.

2. The news media have provided extensive coverage of the conflicts between Ford Motor Company and the Firestone Company related to the failure of Firestone tires on Ford's Explorer Sport Utility Vehicle. Robert Polz wrote an article on tire failures in "Reliability Engineering" in which he critiqued and commented on an article entitled "Tire Failures, SUV Rollovers Put Quality on Trial," published in the December 2000 issue of American Society for Quality's *Quality Progress* magazine. Polz states that, if the failures are design-related, it is the province of reliability engineering to determine the root cause(s) of the failures. However, if the failures are production-related, then QA should spearhead the assessment. Since the cause is uncertain in the Ford/Firestone case, Polz concludes that both disciplines should work together as a team to determine the cause(s). Meanwhile, the National Highway Transportation Safety Administration (NHTSA) has already received more than 1400 complaints, with reports of 88 fatalities and 250 injuries. 3. On January 26, 1986, the Space Shuttle Challenger exploded during take-off. The first cousin of Mike Smith, the pilot of Challenger, at that time was a member of the NRMRL/APPCD staff. Today, more than 16 years later, I still have displayed in my office a decal commemorating the Challenger's crew and its mission. Investigations have identified the failure of o-rings in the external fuel tanks as the cause of the catastrophic explosion that doomed the Challenger and its crew. In the hours before launch, engineers familiar with the design of the external fuel tanks and their o-rings recommended and strongly urged that the Challenger not be launched on January 26, because the ambient temperature was less than the safe minimum temperature for the o-rings to function safely and effectively. Since the engineers took these actions in an attempt to delay the launch, it may be concluded that the QA requirements for safe launch and operation of the Challenger were known but not adhered to. The result was the loss of all of Challenger's crew members, and America's Space Shuttle program was put on hold for about 2 years.

The EPA QA Analogy – So, what analogy, if any, is there between these high visibility examples in which QA was not a priority or QA requirements were not followed and QA in EPA? To be sure, EPA does not design or build rockets that might explode on their launch pads, design or build consumer products that might injure or kill users, or provide QA for products, systems, or devices, such as those on the Space Shuttle, that could fail and injure or kill people. However, it could be argued that EPA does, in fact, have analogous QA responsibilities. The Agency is charged with the protection of public health and the environment, and meeting that responsibility requires extensive research programs which generate data. It is estimated that EPA and the regulated community spend about \$5 billion annually collecting environmental data. In addition to data, EPA generates information, software, and other tools which are ultimately used to justify, establish, and defend national and state standards for pollutant emissions and exposures. These emission and exposure limits are designed, first and foremost, to protect the health of the American public. If EPA had undertaken this mission and tried to see it through without adequate management and staff attention to QA, it is possible that regulatory decisions could have been made on the basis of flawed data and information and that public health and the environment might not be protected as well as they could have been.

Suggested Requirements for EPA Managers – To its credit, EPA has spent a lot of time and staff effort developing and putting in place an impressive Quality Management Plan (QMP) guidance document which delineates QA requirements for all Agency organizations involved in the acquisition, processing, and publication of research data and information. The guidance document is used by EPA's National Laboratories and Offices to prepare their QMPs. However, as indicated in the QA failure examples above, the effectiveness of any QMP is dependent on the commitment that management and research staff alike make to its implementation. From a management perspective, this commitment requires that research managers understand Agency QA requirements; establish an effective QA program to ensure that data are of known quality which is acceptable for the intended use of the data; and provide support, guidance, and oversight to principal investigators (PIs) in meeting QA requirements. It is also important that managers lead by example in the QA area:

- 1. Managers should make sure that other managers and PIs are aware that they view QA as an essential, integrated component of the research programs;
- 2. Managers should provide adequate resources (people and money) to support an effective QA program;
- 3. Managers should encourage collaborative, non-confrontational interactions between PIs and QA professionals; and
- 4. Managers should maintain oversight so that issues which have the potential for adversely affecting research and QA objectives can be negotiated and corrected quickly.

How QA Works in NRMRL/APPCD – The Air Pollution Prevention and Control Division has established a QA Team to support its four research branches. The QA Team is housed in the Technical Services Branch and consists of a team leader (who is a QA professional) and five team members (three of whom are QA professionals). The other two members are a professional who manages the QA contract for the team and a Senior Environmental Employee who assists the Team with QA data base management and reports preparation. The four QA professionals conduct all QA reviews and audits (with contractor assistance, as needed). QA Team members share QA work among themselves to maintain a reasonable balance of workloads. They also spend up to 30% of their time working directly with the research branches' PIs helping to plan, conduct, and oversee research projects. (Of course, no QA Team member is ever allowed to conduct QA reviews of research work in which he/she has been involved.) In FY 2001, the QA Team reviewed 63 QA planning documents/research products with an average turnaround time of 5.7 days. The Team members also reviewed 121 journal articles and reports in FY 2001. To date in FY 2002, the QA Team has completed the following reviews:

	Items Reviewed in FY 2002	Number Reviewed Through 3/19/02
1.	Journal articles and reports	32
2.	Test plans, QAPPs, Reports, Protocols	52
3.	Funding packages	20
4.	Responses to PIs' revisions	10
5.	SOPs	2
6.	QMPs	1

When QA Team members are involved to this extent with the PIs and their research activities, there is a high probability that differences of opinion will occur. Given that, I would like to emphasize the need for managers to lead by example, specifically item 3 under **Suggested Requirements for EPA Managers**, above: i.e., "Managers should encourage collaborative, non-confrontational interactions between PIs and QA professionals." The QA philosophy in NRMRL/APPCD is that the QA Team will aid the researchers in any way possible to produce a timely, high quality product. To implement this philosophy and avoid the counterproductive trap of being viewed as the "QA police," we have borrowed and employed the five "Basic Principles" from the Zenger-Miller team training course work:

- 1. Focus on the situation, issue, or behavior, not on the person.
- 2. Maintain the self-confidence and self-esteem of others.
- 3. Maintain constructive relationships.
- 4. Take initiative to make things better.
- 5. Lead by example.

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The use of these principles by the QA Team members in their interaction with PIs has resulted in the QA Team's maintaining the respect and cooperation of the PIs so that almost all interactions between them are positive and helpful. Infrequently, when QA Team members and PIs reach an impasse, the QA Team's Branch Chief and the PI's Branch Chief meet with the QA Team member and the PI involved in the dispute. In these meetings, it is essential that the same "Basic Principles" be employed. Using this philosophy and the "Basic Principles," only three or four meetings involving the Branch Chiefs have occurred in the last 7 years. During this time, no QA issue between a QA Team member and a PI has been elevated to the Division Director for resolution.

Conclusion – For the last 7 years, one of my responsibilities has been to supervise NRMRL/APPCD's QA Team. Through that experience, I have concluded that the collaborative, non-confrontational spirit exhibited by the members of the QA Team in their interactions with PIs and managers is a major component of a successful, productive QA program. As a research manager, I am very proud of the contributions the QA Team members make to the Division, the Laboratory, and the Agency. I consider it a privilege to be associated with them.

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Quality Assurance (QA) program and the appr- Division. The presentation is a technical requirements for and approach to QA in its include the design of the QA Team, the role technical aids provided by the QA Team to p Agency QA requirements, the interactions of tigators, and examples of effective conflic	oaches used to meet QA req manager's perspective of t research programs. The pr s of members of the QA Tea romote understanding of ar the QA Team members with t resolution.	uirements in the he Division's esentation will m, training and d adherence to principal inves-		
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