

NASA SP 6106



ISO 9001 Certification Government-Contractor Team Implementation Model Study

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Preface

The White Sands Test Facility (WSTF) government-contractor team began the International Organization for Standardization (ISO) 9001 implementation on October 3, 1994. The team of approximately 550 personnel then received a well-earned certification from the Det Norske Veritas (DNV) organization on October 20, 1995, approximately a year later. This was the first certification of both a National Aeronautics and Space Administration (NASA) installation and joint government-contractor partnership. The NASA Associate Administrator for Safety and Mission Assurance, Frederick Gregory, congratulated the NASA and site support contractor team for earning certification and indicated that WSTF was a benchmark for NASA. In recognition of this unique achievement, Vice President Al Gore's National Performance Review recognized WSTF for exceptional progress in reinventing government. National Performance Review Project Director Bob Stone presented the prestigious Hammer Award on March 4, 1996.

The ISO audit team had only five minor findings in contrast to the 20 to 30 that are usually associated with certification audits. Additionally, the quality system was put in place in a surprisingly short time, considering the magnitude of changes made to the documentation system.

Overall, certification of ISO 9001 emphasized WSTF's commitment to preeminence and demonstrated that the facility is well positioned to perform quality testing for domestic and international government and commercial entities.

This document is designed to encourage others to apply the ISO family of standards to their organizations and assist them in their efforts by providing the WSTF certification approach and lessons learned. ISO 9000 background information and WSTF post-certification survey data are included in the attachments. Other helpful references are included in the appendixes.

Acknowledgments

Many people made significant contributions to both the successful implementation of ISO 9001 and development of this document. The contributors include the WSTF test, evaluation, and maintenance (TEAM) contractors, NASA personnel, and contractor partners from Loral-Raytheon and Kelsey-Seybold who committed themselves to the certification effort and worked together at an unprecedented level of cooperation. The TEAM contractors include AlliedSignal Technical Services Corporation (ATSC) and subcontractors Rockwell Space Operations; L&M Technologies; Research Analysis and Maintenance; Unique Janitorial Services, Inc.; and SelRico Services, Inc.

Credit must be given to AlliedSignal Aerospace who provided knowledgeable consultants and dynamically supported the WSTF certification effort. Additionally, the Johnson Space Center Safety, Reliability, and Quality Assurance Office and NASA Headquarters Office of Safety and Mission Assurance must be acknowledged for providing necessary resources, guidance, and tireless advocacy of ISO principles.

Regor Saulsberry was assigned the responsibility of documenting the comprehensive WSTF ISO 9001 government-contractor certification to assist other NASA organizations. At the same time, this information was applicable to his New Mexico State University graduate study program. Therefore, this document is released under separate covers by the White Sands Test Facility and the New Mexico State University Mechanical Engineering Department. ISO 9000 overview, background, and references are included to increase the document's value to a more general audience.

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Acronyms

ANSI	American National Standardization Institute
ASCQ	American Society for Quality Control
ASFS	AlliedSignal Aerospace
ATSC	AlliedSignal Technical Services Corporation
C/PAR	corrective/preventive action report
DMP	detailed maintenance procedure
DNV	Det Norske Veritas
DR	discrepancy report
ISO	International Organization for Standardization
LJI	laboratory job instruction
M&TE	measuring and test equipment
NASA	National Aeronautics and Space Administration
OCP	operational checkout procedure
OMS	orbital maneuvering system
RAB	Registrar Accreditation Board
RAM	Research Analysis and Maintenance
RCS	reaction control subsystems
TEAM	test, evaluation, and maintenance
TPS	test preparation sheet
WJI	WSTF job instruction
WPD	WSTF policy directive
WSI	WSTF standard instruction
WSP	WSTF standard procedure
WSSH	White Sands Space Harbor
WSTF	White Sands Test Facility

White Sands Test Facility Overview

The National Aeronautics and Space Administration's (NASA) White Sands Test Facility (WSTF) was built in 1963 to support the national space program on a site near Las Cruces, New Mexico. The self-sufficient facilities have been upgraded and enhanced through the years to support the specific needs of programs. WSTF is currently operated by approximately 550 experienced engineers, scientists, and other support personnel. WSTF provided key support for the Apollo Manned Spacecraft, Viking, Skylab, Space Station, and the ongoing Space Shuttle programs. Before the lunar module *Eagle* carried men to the moon in July 1969, the engines that allowed them to go there, land, and return were tested at WSTF. Shuttle orbital maneuvering system (OMS), aft reaction control subsystem (RCS), and forward RCS component and system development and qualification testing were also supported at WSTF.

Today, flight-representative OMS and RCS ground test firings enhance the safety and reliability of the shuttle systems. Many problems are identified and corrected before they occur in flight, and other anomalies are investigated. Special shuttle processes and ground support equipment are also developed. WSTF is also a repair and acceptance test depot for shuttle components. These include hypergolic OMS and RCS rocket engines and components, and hydrogen and oxygen system components. Many other rocket engines and propulsion systems are also tested for NASA, the Department of Defense, other government agencies, and domestic and foreign commercial agencies.

Extensive material and component-level tests are performed in hazardous test media such as hypergolic propellants, high-pressure oxygen and hydrogen, and other explosive substances. Propellant explosive testing and material flammability testing are done on a continuous basis, which provides an in-depth knowledge base for hazard characterization. From this, propellant manuals and training materials are developed, and WSTF personnel conduct propellant safety classes on an international basis.

WSTF also operates the White Sands Space Harbor (WSSH), a landing and training facility on the White Sands Missile Range. Shuttle pilots frequently fly practice approaches to the runways in shuttle training aircraft that closely simulate shuttle handling characteristics. WSSH is also a contingency landing site for the Space Shuttle and supported the landing of STS-3 in 1982. Nearby areas are used for flight testing of single-stage-to-orbit technology vehicles and for surface vehicle tests.

WSTF facilities and test capabilities include:

- High Energy Explosion Test Facility
- Metal Alloy Development Facility
- Precision Cleaning Facility
- Hazardous Fluids and High-Pressure Test Facilities
- Materials Evaluation and Test Facilities
- WSSH and Flight Test Facilities
- Calibration Laboratory
- Vacuum and Environmental Laboratory
- Chemical and Analytical Laboratories
- Nondestructive Test Laboratories
- Modern Machine Shop
- Shuttle Component Repair Depot
- Eight rocket firing stands, five with altitude simulation
- Shuttle OMS/RCS test articles
- Three light gas hypervelocity guns capable of containing reactive and hazardous target materials

Project, facilities, and staffing are continually custom-designed to meet the research needs and testing requirements of projects that fall within the WSTF mission:

“The WSTF mission is to provide the expertise and infrastructure to test and evaluate spacecraft materials, component, and propulsion systems to enable safe human exploration and utilization of space.”

Objectives

We designed this document to encourage others to apply the ISO family of standards to their organizations and assist them in their efforts by sharing our experience. Major categories include:

- Why WSTF chose ISO 9001 certification
- The WSTF approach to ISO 9001 certification
- Lessons learned and recommended practices from the WSTF experience
- ISO background, if needed, and helpful references

Why ISO 9001 at WSTF

In 1992 WSTF issued *Preeminence -- The WSTF Strategy*, a long-term strategic plan for the future. The simple and efficient structure of ISO supported this vision of the future by offering further improvement to the existing high quality of service and additional recognition as a *world-class* organization. Perceived benefits of ISO 9001 certification were summarized as:

Streamlined Systems

Though WSTF has always worked to meet customer requirements and expectations, *the way we did business* often varied from one application to another. ISO 9001 provided a versatile model for a simpler, more consistent business structure to meet our customers' needs.

Simplified & Organized Documentation

WSTF's documentation had become top-heavy. Policy was too detailed, making management reviews time-consuming and inefficient. The ISO 9001 implementation effort provided an ideal opportunity for restructuring documents.

Improved Management Processes

ISO 9001 offered a model for management leadership, involvement, and organizational measurement.

Empowered Employees

WSTF had always provided leadership opportunity for its employees to excel; however, those opportunities were often limited to individual project applications. The ISO 9001 implementation effort would empower employees to take ownership of processes and design the *WSTF work environment*.

Team Building

The WSTF NASA contractor team approach to ISO 9001 implementation provided an excellent opportunity to optimize individual and organizational responsibility.

Strengthened Process Focus

ISO 9001 offered an excellent model for focusing on the processes and the need for consistency in work practices.

Continuous Improvement

ISO 9001 required continuous formal documentation of corrective and preventive action to establish an environment of continuous improvement in exceeding customer expectations.

Better Preparation for the Future

ISO 9001 certification provided an opportunity to increase visibility and effectiveness to meet even greater challenges in the future. WSTF's capabilities and expertise would be emphasized to the rest of NASA and to the aerospace industry.

The primary drawbacks were the effort, cost, and test business disruption associated with implementation of the ISO 9001 standard. This investment was significant because assessments indicated that large documentation system changes would need to be made. However, documentation improvements were long overdue, and other changes were needed to support an evolving business structure. Overall, drawbacks were short-term and benefits were seen as long-term. In the end, WSTF felt these benefits were truly achieved. (See Attachment 2, WSTF Post-Certification Survey Responses, Benefits of ISO Certification.)

Seeing ISO in action was also very inspirational. During the summer of 1994, the NASA Site Manager, his deputy, the AlliedSignal Technical Services Corporation (ATSC) Program Manager, and other support personnel visited AlliedSignal Fluid Systems in Tempe, Arizona. Earlier the same year, the facility had become the first AlliedSignal Aerospace (ASFS) business unit to be certified to ISO 9001. The WSTF contingency was very impressed with the self-assurance observed from top management to the floor employees. The Tempe employees knew their job, were proud of their work, and were better able to take charge of their future through pursuit of ISO. Seeing such a strong response was inspirational. With this in mind, WSTF went forward with the certification with the expectation expressed by the site quality policy:

“The White Sands Test Facility is committed to exceeding the expectations and needs of our customers through continuous improvement in the quality of the products we provide in the pursuit of our goal of preeminence.”

How WSTF Implemented ISO 9001

Introduction

The process of implementing ISO 9001 was highly successful, but there were many lessons learned that may be helpful in assisting similar certification at other locations. To facilitate a comprehensive collection of lessons learned, a post-certification survey was conducted. Approximately 550 WSTF employees were offered an opportunity to respond to the survey. From this, 161 forms were received, and the results were entered into a database. The survey provided feedback for developing this document.

Gap Assessment

It was necessary to assess the amount of change required before determining the implementation scope. At WSTF, quality system *gap assessment* performed by internal personnel and visiting consultants throughout late 1993 and early 1994 consistently identified major deficiencies related to the following ISO 9001 element categories: management responsibility, contract review, document and data control, corrective and preventive action, and internal quality auditing. Systems at WSTF existed to address most of the remaining ISO 9001 requirements but were not consistent. We thus determined that developing compliance would be a large effort.

Other organizations can anticipate less change and, consequently, lower ISO implementation cost if they are working in close compliance with other rigorous quality standards such as NHB 5300.4(1B), (1D-2), or MIL-Q-9858. Disciplined adherence to any of those standards could reduce the effort to simply indexing existing documentation and cross-referencing existing terminology. However, additional effort may be required to prepare an organization's quality system to meet the unique ISO aspects of management responsibility and internal auditing, ensuring that management has adequate access to, and control of, measurements associated with the quality system.

What is most difficult to measure is the organization's cultural attitude toward change and its willingness to work together as a cohesive team while respecting individual roles in providing a quality product or service. This factor significantly influences the cost and overall effort involved in ISO implementation.

Initial ISO 9001 Planning

Since NASA personnel played an integral role in WSTF project management, planning, and technical support, ISO 9001 registration was defined as applicable to the *facility* as a joint NASA and contractor supplier. Therefore, early NASA assessments and preplanning occurred. However, the WSTF test, evaluation, and maintenance contract was nearly complete, and detailed implementation planning could not occur until the new contractor was in place.

The new ATSC team contract became effective May 1, 1994. The team consisted of ATSC as prime contractor to five subcontractors: Rockwell Space Operations Company (Rockwell International Corporation); L&M Technologies, Inc.; Research Analysis and Maintenance, Inc.; SelRico Services, Inc.; and Unique Janitorial Service, Inc. As is the case with most implementations, this was a difficult time to begin. It required a significant commitment and conviction, considering the continuing contractor transition efforts that occurred under a high test-project load. This included urgent shuttle support commitments that could not be slipped. Personnel anticipating ISO 9001 implementation cannot simply wait for a *good time*. There may be some worse times to be avoided, but a *good time* will never come. Initiative has to be taken and the necessary commitment developed to move forward.

First, a WSTF ISO core team consisting of seven key NASA and contractor employees assembled to plan the implementation and document the approach. The WSTF core team was appointed from high in the organizational structure to ensure decisions would be implemented. Members needed to have necessary training, stay fully committed, and work effectively as a team.

The core team included:

- NASA and ATSC management representatives
- NASA and ATSC ISO coordinators
- Quality Management System element group leaders
- ISO documentation coordinator

The management representatives were the NASA Deputy Site Manager and his contractor counterpart, the Site Deputy Program Manager, who both reported directly to their respective site managers.

Planning the application of the standard to a research, development, and test-evaluation operation was difficult at first. Fortunately, ATSC brought corporate expertise that significantly assisted the effort. ASFS had received certification of its Fluid Systems facility in Tempe, Arizona and was at various stages of implementation at other business units across the country. As a result, they provided personnel with special expertise in various areas such as internal audits, consultants, extensive training material, *lessons learned*, and *best practices* from their corporate experience. This greatly aided planning and enhanced the overall implementation process.

The following list of *keys to success* includes 16 factors considered important to implementation success and was adapted from ATSC-supplied training material. The first 15 factors are shown in the relative order of importance established by the responses the participants had to the post-certification survey. As can be seen from the ranking bar chart in Attachment 2, Key 1, management commitment ranked the highest importance and is considered critical to certification success. Keys 2 through 9 were considered of high importance and keys 10 through 15 were of medium importance. Item 16, *effective teamwork and empowerment*, was not ranked in the survey but will be discussed because many individual comments were provided in that area. The specific order of importance to other organizations can be debated; however, each key should be carefully considered in most ISO 9001 certification efforts. These are shown in this ranking so the reader can refer to them in the following review of the WSTF Implementation Plan. Following this review, planning and lessons learned are summarized. The implementation timeline is then presented, and recommendations and lessons learned from the implementation period are discussed as they apply to each of the *keys to success*.

Importance

Keys to Success

Critical

1. Management commitment (all levels)

High

2. Effective internal audits and corrective action follow-up
3. Strong implementation organization
4. Well-organized documentation (by ISO element)
5. Defined work processes
6. ISO training (to lowest organizational levels)
7. Final audit readiness verification
8. Strong quality policy
9. Quality ownership transition

Medium

10. Detailed implementation plan
11. Project communications (effective and viable)
12. Customer consultation
13. Definition of terms (see Attachment 2)
14. Early question and answer session
15. Element books and checklist
16. Effective teamwork and empowerment (not ranked in the survey)

WSTF Implementation Plan Review

The WSTF core team developed an aggressive implementation plan to fit the unique WSTF environment. The plan defined purpose, scope, mission, goals and objectives, requirements and guidelines, team roles and responsibilities, personnel assignments, training, registration, budget allocations, and accounting.

To illustrate management commitment and to provide central focus on the task at hand, the implementation plan first provided a clear mission statement:

“The mission of the WSTF ISO 9001 implementation team is to develop and implement an efficient quality management system to achieve WSTF certification to ISO 9001. This system shall be dynamic and responsive to meet our varied customer requirements, yet disciplined and consistent to provide the best opportunity for success.”

An aggressive goal to attain ISO certification in one year (by October 1995) was made clear, and milestones were provided as shown in Table 1. It was critical to plan on building momentum quickly and maintaining momentum throughout the implementation process. Collateral objectives were also defined to target improved processes, buy-in, and participation.

Table 1
Plan Schedule Milestones

Target Date	Objective
09/26/94	element group teams and leaders
10/01/94	kickoff and training initiation
11/15/94	training
12/15/94	DNV question and answer
03/01/95	ISO implementing documentation
04/01/95	baseline audit
04/15/95	DNV registration assessments
05/01/95	baseline corrective action
06/01/95	DNV pre-assessment and initiate registration corrective actions
08/15/95	ATSC peer review
09/01/95	DNV registration audit
09/15/95	registration corrective actions

The overall WSTF ISO implementation team was defined as personnel involved directly in the planning, development, and implementation of the WSTF quality management system (Figure 1). The implementation team included the core team members, management, and element team group leaders and members. This involved a total of 60 NASA and contractor personnel from all organizations throughout WSTF. The size of the team was relatively large because of the government-contractor nature of the team and the magnitude of the overall effort. Additionally, all WSTF personnel were ultimately called upon to support the ISO implementation effort and its continuing maintenance.

Each of the core team members played a critical role. The overall effort may have been significantly hampered if any members had not accomplished their function. The management representatives had the authority to ensure lower organizations responded to the implementation team requests for action and had the necessary resources to do their job. The management representatives were also authorized to make the final decisions to resolve issues that could not be resolved at the lower level (barrier-busting). The balance of the core team had the job of coordinating all activities that supported the project. In addition to specific assignments, the core team had to become true ISO 9001 experts. They needed to know the requirements, the language, the details of the plan, all the people involved, what was working well, and what was not on a real-time basis. They had to facilitate communication among all elements of the project and do whatever was required to make the project a success. The specific responsibilities of each core team member are detailed as follows:

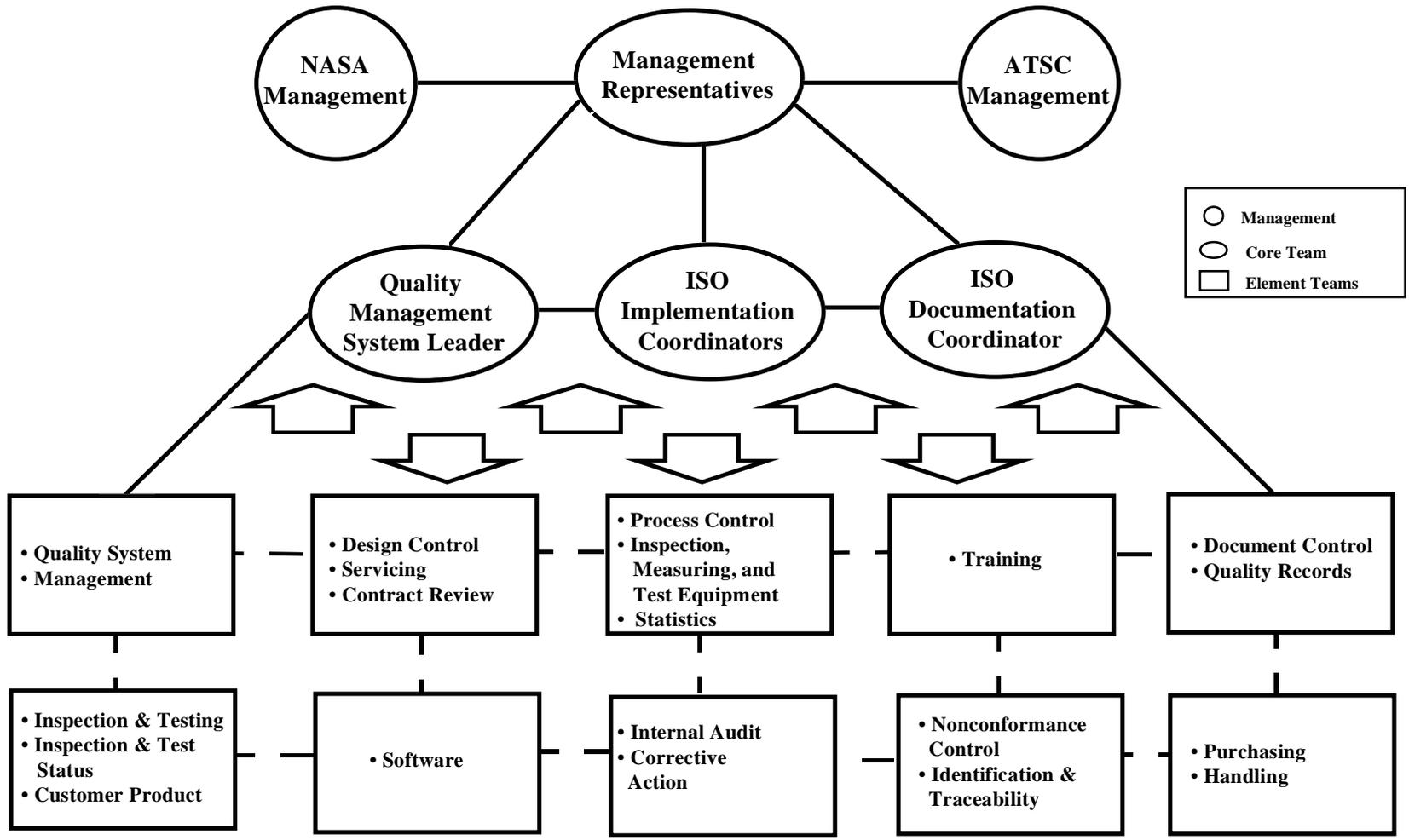


Figure 1
ISO 9001 Implementation Team

Core Team Responsibilities

NASA and ATSC ISO management representatives were responsible for:

- Ensuring the requirements of ISO 9001 were implemented and maintained
- Approving the ISO 9001 Implementation Plan including schedules, budgets, and major expenditures
- Developing and approving the scope and applicability of the ISO 9001 certification
- Coordinating with management on ISO issues and resource requirements
- Approving ISO system responsibilities assignments
- Developing the WSTF quality policy statement
- Supporting ISO implementation team empowerment

The ATSC ISO implementation coordinator was responsible for:

- Developing the ISO Implementation Plan
- Consulting with and integrating ISO element group teams
- Coordinating with the registrar and ATSC corporate representatives
- Interpreting ISO 9001 requirements
- Planning and coordinating certification and system assessment activities
- Assisting management representatives

The NASA ISO implementation coordinator was responsible for:

- Developing ISO implementation plans in coordination with ATSC
- Monitoring ISO system development, schedule, and cost for management representatives
- Assisting management representatives with development of certification scope, quality policy, and system responsibilities assignment
- Coordinating with NASA Headquarters, Johnson Space Center, and other federal ISO representatives
- Interpreting NASA ISO 9001 augmentation clauses
- Supporting ATSC coordinator and element group team activities

Quality Management System element group leaders were responsible for:

- Maintaining the WSTF Quality Policy and Procedures Matrix in support of the core team, and
- Ensuring consistency of policy publications with responsibilities associated with assigned ISO elements

The ISO documentation coordinator was responsible for:

- Developing WSTF document pyramid hierarchy
- Developing WSTF document format requirements
- Collecting and formatting draft ISO implementation documents
- Coordinating approval of ISO implementation documents
- Publishing and distributing approved ISO implementation documents

In addition to the core team, the balance of the implementation team included the ISO element group leaders and ten ISO element group teams. The element group leaders and element teams were formed to address the 20 elements of ISO 9001 as grouped to reflect organizational and functional considerations. The teams were the WSTF ISO authorities for their assigned elements. They analyzed processes and prepared a significant amount of documentation.

Specific ISO element group leaders responsibilities were:

- Planning element group team responsibilities and activities
- Identifying any additional resource or training requirements to ISO implementation coordinators
- Performing gap analysis for each assigned ISO element
- Performing system mapping (flowcharting)
- Preparing necessary documentation
- Conducting post-implementation baseline audit
- Planning and implementing corrective actions
- Providing assistance during peer and registrar assessments

Training

Training played a critical role in empowering the implementation process. ASFS provided initial ISO implementation training (Table 2). Individual element group leaders then provided specialized training as required. This required approval by the management representatives.

We later found that additional training was necessary. This included site-wide awareness training, several application workshops, and near-continuous training that was provided as new documentation was released.

Table 2
Initial Training

Training Module	Required Personnel ^a	Hours
Executive ISO 9000 Overview	NASA ATSC management, ^b core team	2
ISO 9001 Element Training	element group teams, core team	5
Auditing ISO 9001 Compliance	element group teams, core team	20
Root Cause and Corrective Action	NASA ATSC management, ^b element group teams, core team	4
Procedure Writing (Information Mapping)	element group leaders, core team	20
Process Mapping (TQ Speed)	element group leaders, core team	4

^a Additional personnel could participate in individual training modules upon request.

^b NASA office chiefs, ATSC department managers, and section supervisors/leads.

Implementation Challenges

After implementation kickoff, startup inertia had to be overcome. This involved learning terms and methods, understanding the *why's* (buy-in), dealing with reluctance to change (cultural inertia), and coming to grips with the necessary high degree of commitment (top to bottom). Many personnel, from management down, were also faced with the realization that they were going to have to get deeply involved at the detail level, and that it was going to take much of their available time.

As implementation progressed, the original milestone schedule was tracked, updated, and expanded as required during management review meetings, generally held weekly. Certification was accomplished with only a one-month slip (Table 3). However, it required more training, additional intervention, and the addition of a midpoint *Tiger Team* to keep the effort on target. Other changes such as those to the implementation scope were needed to better accommodate WSTF site needs.

Table 3
As-Implemented Milestones

Date	Milestones
10/03/94	Implementation kickoff
11/14-15/94	ATSC corporate implementation coordinator assessment
12/19-20/94	ATSC outside consultation visit
01/17/95	Root cause and corrective action training
01/19/95	DNV question and answer session
02/22/95	Management ISO policy review (slipped from 02/01)
03/13-17/95	Baseline Audit - vulnerability assessment
03/21-31/95	Baseline Audit - organizational
04/25/95	System procedures completed (slipped from 03/01)
04/25-28/95	DNV registration pre-assessment
05/04-15/95	Internal WSTF documentation system audit
06/12/95	Internal ISO <i>Tiger Team</i> established to assess change and recommend corrective measures
07/20-08/16/95	Application workshop
08/01/95	System procedure revisions completed
08/11/95	Orientation and question and answer session with new DNV lead auditor
08/21-24/95	ATSC peer review
09/21/95	Management representative survey completed
10/17-20/95	Successful DNV registration audit, certification date 10-20
10/20/95	Certification effective

Mid-Course Correction

Integrating ISO 9001 requirements with the way WSTF functioned was assigned to multi-disciplinary element teams of WSTF personnel. Because of lengthy effort and delays in developing the WSTF policy documentation, these teams were rushed to develop the associated procedural level documents to support a DNV pre-assessment. The pre-assessment was intended to establish a baseline for an internal WSTF preparedness review.

The April 1995 DNV pre-assessment shown in Table 3 revealed a significant gap between the newly implemented system and the processes that had been in practice. Most of the procedures had not been issued until very shortly before the pre-assessment audit, and many personnel, including key managers, were still unfamiliar with requirements. The element teams who were mapping processes and writing procedures had a fundamental understanding of the documentation changes necessary to be consistent with ISO, but middle management had not been sufficiently involved to fully appreciate the issues and direct team actions. The general assumption before the problem surfaced was that working-level personnel could bring about the necessary change themselves. As a result, the first set of site-wide procedures had significant problem areas. Middle management also had a belief that little actual documentation change was necessary. It was generally thought that the ISO requirements could be met simply by fitting existing documentation into the new hierarchy and documenting previously undocumented processes.

To expedite the plan, a *Tiger Team* made up of key middle managers and support personnel was established to assess the situation and make recommendations. The net results of the *Tiger Team's* efforts were that middle management would commit to spending 80% of its time in guiding the resource effort, would ensure that WSTF was ready for certification, and would receive no Category-1 finding (Attachment 1, Certification). To accommodate this commitment, the DNV registration assessment was delayed 30 days, and some impact to projects was accepted.

The *Tiger Team* effort led to several very positive results including unprecedented middle management commitment and cooperation, the development of a rapid and consistent document revision process, standardization of the implementation approach across the site, and definition of the critical schedule path for successful certification.

Evolution of Implementation Scope

The certification scope as stated in the Implementation Plan was to apply the international standard in principle throughout WSTF work practices. For the purpose of certification, the plan initially proposed the following:

“ISO 9001 certification is applicable to WSTF repair, test, analysis, and servicing of aerospace components, materials, and propulsion and power systems.”

Other support processes would then be considered for applicability during the course of implementation based upon the extent to which the candidate processes were available to external customers. As implementation progressed, it was evident that some WSTF activities would not be included within the scope of certification. These included support elements such as cafeteria and janitorial services because they were clearly not applicable to specific ISO 9001 compliance. Direct infrastructure supported activities such as administrative and accounting services, physical security, fire protection, and facility maintenance services. These activities were also generally exempted from specific certification scope. However, WSTF management gave a clear mandate to apply the general *ISO philosophy* to these as a *good way of doing business*.

Eventually, support activities *critical to project success*, such as precision cleaning, component (test systems) services, laboratory analysis, and calibration, were included with the primary test support capabilities to be within the scope of certification and referred to as *engineering and scientific services*. WSTF was officially certified for the following scope:

“Engineering and scientific services are provided by the White Sands Test Facility to external customers for test, evaluation and maintenance of materials, components, propulsion and power systems, and landing facilities.”

Safety should also be considered when developing the scope of ISO 9001 applicability. While compliance to safety codes and regulations is not specifically examined during the certification assessment, accommodation of safety within the context of ISO 9001 is key to an integrated management system. WSTF chose not to specifically address its entire safety system within the context of ISO 9001; however, significant safety requirements were integrated into customer agreement, design control processes, and documentation.

Summary of Planning and Lessons Learned

The lessons learned from the preceding sections are summarized as follows:

- Do not wait for a *good time* to start. *A good time* never comes.
- Formulate a well-thought-out plan before involving large numbers of personnel.
- Appoint the core team from high in the organizational structure to decisively *bust barriers* and ensure decisions will be implemented.
- Train the core team thoroughly in ISO basics and ensure they have the necessary tools such as detailed knowledge of organizational function and personnel resources.
- Perform a *gap assessment* before starting detailed planning to determine how big the effort will be. Without a realistic magnitude, planning, goals, and schedules will be flawed. This should start at least 60 days before the implementation kickoff.
- Use experts and consultants, training material, *lessons learned*, and *best practices* from similar certificates.
- Agree on a clearly detailed implementation scope, then include or exclude tasks based on their position inside or outside the scope.

- Focus on *needs* rather than *wants*. The effort will be large enough without creating excess change.
- Upper- and middle-level management should share in the selection of implementation workers. Select them from the best and brightest and *empower* them with training, adequate direction, and the authority to do their jobs.
- Encourage an environment of cooperation from the beginning.
- Lay out a milestone schedule that starts fast and maintains momentum throughout.
- Include middle management personnel who *get the job done* in review and authorization of the plan. Even lower-level review may provide benefit from worker insights and additional buy-in.
- Decide that it is going to be everyone's ISO system and be flexible enough to step outside your own views for the good of the organization.
- Minimize change where your systems are consistent and compliant with the standards.
- Do not underestimate the power of positive or negative thinking.

Keys to Success - Recommendations and Lessons Learned

1. Management Commitment (All Levels)

WSTF implementation participants felt that management commitment was at the top of their list of importance. Without management commitment little can happen, and without full management commitment the effort is not likely to be a success. Management commitment must be there during planning and must remain strong throughout the implementation process. Commitment must be demonstrated by word and deed at all levels.

The ISO certification process is full of management challenges, but management must stand true to the test. When conflicts occur between ISO certification and regular work projects, it must be made clear that the organization is expected to effectively manage both the quality system and regular business. ISO certification and regular business are of equal importance since both are critical to organizational success. These time conflicts were a challenge during the WSTF implementation. Priorities were evaluated on a case-by-case basis with the objective of minimizing impacts and ensuring success of both regular business and the certification effort. However, it was often necessary to contribute extra time. Tolerance of ISO work slippage should be absolutely minimized since it causes loss of momentum, disappointment, and increases the effort in the long run. Managers should also make it clear that a high level of ISO-related performance is expected. ISO contributions should become part of the employees' performance objectives and evaluation criteria. Budget will likely be a similar challenge, but management must somehow allocate the necessary resources.

Management must receive adequate training to demonstrate knowledge of ISO requirements and implementation status, and to make sound decisions. They need to be seen leading the way in knowledge and in full control of issues. When management participates in training of employees, down to the *lowest* levels, knowledge and commitment is demonstrated and buy-in is enhanced. Furthermore, management must commit to adequate training as the transition effort is launched. *Employees simply cannot be expected to accomplish what they are not trained to do.*

Similarly, management should encourage ownership at all levels. This includes management encouragement of involvement, positive feedback, recognition for participation, and employee visits at their level. WSTF site management held weekly management review meetings to maintain a broad understanding of the overall implementation process and was then frequently out in the field talking with workers at their various levels. Working-level employee interaction with site management was a benefit frequently indicated on the post-certification survey.

The overall effort requires a high level of management and supervisor interaction and support. Because of this, middle managers need to be heavily involved. They are generally the *movers and shakers* of organizations and it is extremely difficult to get the job done without their involvement. This was found to be crucial in the WSTF effort. Element group teams given the job of mapping processes and writing quality system documentation initially needed stronger support from middle management.

Management should make every effort to create buy-in through training, demonstration of high commitment, and assurances that the pros and cons of certification have been fully explored. Additionally, applicability of the standard should be assured. (*WSTF found that ISO elements could be applied to any task.*) After this, management needs to firmly move forward with an attitude of *we will do this*. Everyone cannot be sold on the idea. Dependence will be on people who will be responsible.

Management commitment lessons learned are summarized as follows:

- Management should be seen leading the way in knowledge and in full control of issues.
- Management should demonstrate commitment by word and deed at all levels.
- Management should be seen participating in training of employees down to the *lowest* levels to demonstrate both knowledge and commitment.
- Management should make ISO certification and regular business of equal importance because both are critical to organizational success.
- Management should clearly indicate that a high level of ISO-related performance is expected. Making ISO contributions a part of employees' performance objectives and evaluation criteria is a good way to do this.
- Management should absolutely minimize work slippage. This causes loss of momentum, disappointment, and increases the effort in the long run.
- Management must allocate the necessary resources even if budget is a challenge.

- Top management should stay deeply involved. Periodic management review meetings and frequent field trips to talk with workers at various levels are helpful.
- Management and supervision should provide strong support and be interactive. *It is an error to think that ISO technical details need only to be understood at the point of application.*
- Management should realize that everyone cannot be sold on ISO. They must make every effort to create buy-in, and then firmly move forward with an attitude of *we will do this*.
Dependence must be on people who will be responsible.

2. Effective Audit and Corrective Action Follow-Up

An effective internal audit and corrective action system must be developed to continually detect, document, track, and correct noncompliance problems. This is essential to successful certification and maintenance of a quality program. It is the primary tool for continually identifying and closing the multitude of gaps between where an organization is and where it needs to be. Additionally, it fulfills a basic requirement for certification, internal quality audits (Appendix A, ISO Element 4.17).

To meet this need, approximately 60 personnel received ISO internal auditor training at WSTF. This training taught auditors to be objective in their observations and fair in their descriptions of situations. Root cause analysis and corrective action training were also provided. Following this, internal audits were systematically accomplished.

It is also important that experienced auditors participate in the initial planning to chart the path and then return to assist with periodic assessments and provide internal audits. Ideally, these are auditors who will conduct the certification assessment. WSTF obtained an experienced full-time lead internal auditor from AlliedSignal Fluid Systems and had several others with significant auditing experience.

Internal audit and corrective action also go hand-in-hand with management reviews as required by Section 4.1 of the ISO 9001 standard. WSTF addressed processes site-wide by conducting in-depth internal audits almost continually. Corrective/preventive action reports (C/PARs) were then reviewed, acted on, and tracked during regular weekly management reviews. This brought critical processes into compliance. A sample internal audit check list is provided in Appendix B as a reference for other organizations.

An effective internal audit and corrective action system has the additional benefit of increasing customer confidence. The system develops objective evidence that can be shown to customers to demonstrate compliance both to the ISO standards and any special requirements they may have. This increased customer confidence should also decrease the need for their inspection or audit of your processes. A summary of benefits noted following the certification is listed under Benefits of Certification in Continuous Improvement in Attachment 2.

Effective audit and corrective action follow-up lessons learned are summarized below:

- Ensure experienced auditors participate in charting the initial path and then return to perform periodic assessment and internal auditor support.
- Place high overall emphasis on an effective internal audit and corrective action system.
- Complete auditor training and begin the auditing program very early.
- Use the internal audit and corrective action process extensively for positive change.
- Offer audit familiarization training to large numbers of potential internal auditor candidates. This will help in the selection of better internal auditors and will educate more personnel to the positive aspects of auditing.

3. Strong Implementation Infrastructure

As with most complex projects, the success of an ISO effort certification depends primarily on the effectiveness of overall project management. It requires an effective and committed organization empowered with the necessary training, resources, coordination, and communications. The project must be well defined with an effective internal audit/corrective action system to continually assess progress and bring about the required change. The implementation organization, training, and other elements of WSTF infrastructure are detailed under the previous Implementation Plan Review section.

WSTF had the wherewithal to make it happen in approximately one year as established by the test plan. However, this success was largely due to the ability of the infrastructure to determine and respond to needed changes (*Mid-Course Correction* discussion in the Implementation Challenges section).

Implementation infrastructure lessons learned are summarized below:

- Top management cannot achieve ISO certification without obtaining strong commitment from middle management and accepting some compromises.
- When top management decides to proceed with certification, the next management layer must be thoroughly involved in training. They then need to make fundamental decisions about adapting existing systems to the ISO standards from a fully informed basis and take system ownership at the initiation of change.
- Use middle management *movers and shakers* to get the job done.
- Fully empower management representatives to be *barrier busters*.
- Empower the implementation team with the necessary training, resources, coordination, and communications early in the process.
- Maintain a broad assessment capability and be ready to make major adjustments to the plan if required.

- Select responsible personnel at initiation, obtain commitment, and hold them accountable for support.

4. Well-Organized Documentation System

Restructuring the documentation system hierarchy and developing various levels of documents to meet interpretations of ISO requirements represented a large percentage of the total WSTF implementation effort. The effort resulted in development of a system which included a document relationship as shown in the WSTF document pyramid (Figure 2). The WSTF system deviated from the textbook model, three-tiered system and may not be the best for most organizations. The elements of the typical three-tiered system are described as follows:

Policy	Short, concise statements of the organization’s guiding principles.
Process or Procedure	Who does what; step-by-step written descriptions of the processes or procedures that implement the policy.
Work Instruction	How; provides detailed diagrams, checklists, forms, or other documents directing employee tasks and activities.

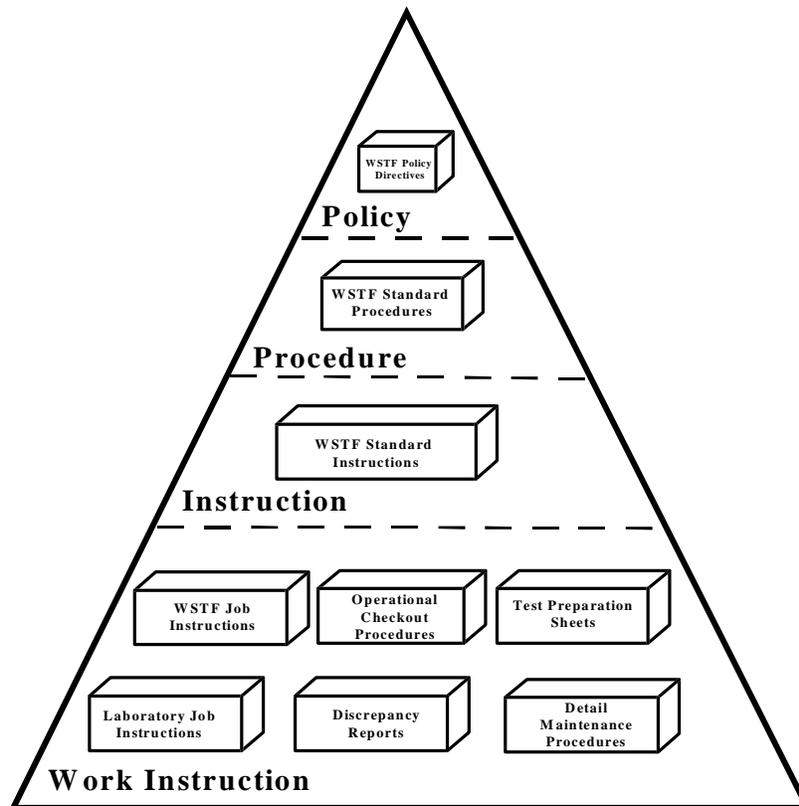


Figure 2
WSTF Document Pyramid

The WSTF four-tiered system split the instruction level. The system distinguishes between higher-level instructions and lower-level work instructions. Elements of the WSTF system are defined as follows:

- Policy** WSTF policy directives (WPDs) are grouped by ISO element number. They provide general requirements (*why and/or thou shalls*).
- Procedure** WSTF standard procedures (WSPs) describe activities, responsibilities, authorities, and relationships of personnel and/or organizations necessary to implement policies (*who and what*).
- Instruction** WSTF standard instructions (WSIs) are general directions on how to perform a type of job or task (*how*).
- Work Instruction** WSTF job instructions (WJIs) are step-by-step directions on how to perform a specific job or task. Test preparation sheets (TPSs), laboratory job instructions (LJIs), operational checkout procedures (OCPs), and discrepancy reports (DRs) also provide step-by-step directions. OCPs, LJIs, and detailed maintenance procedures (DMPs) are document types that perform a similar function, which will be transitioned to the WJI format over time.

The WSTF Documentation Development Effort

Determining the appropriate amount of change and developing a good approach was difficult. After trying other approaches, it was found that a policy-level strategic paraphrasing of the standard worked best for WPD development. The approach was carried down through the levels as was appropriate. This involved careful consideration of word swapping where appropriate, such as *customer agreement* rather than contract.

Second-level documentation consisted of 25 *ISO-related* WSPs involving an estimated 125 pages. At the third level, 90 *ISO-related* WSIs (28 site-wide, 62 departmental) consisted of an estimated 800 pages. Labor to generate, review, and approve these was roughly 5000 to 10,000 labor hours. The bulk of the effort was expended on the WSPs and site-wide WSIs because of interorganizational involvement. The departmental WSIs went faster, since they required much less coordination. The WSPs and WSIs took roughly three calendar months to get out the first time.

The site master index contains 800 WJIs, but only about 150 new instructions were needed. The *new* work instructions did not require as much effort to get in shape as the WSPs and WSIs. The documents were developed primarily within various departments, with little outside review. This represented approximately 2000 to 5000 labor hours and required approximately four to eight weeks to complete. The format of work instructions was not critical, but the content and purpose were very important. WSTF could have achieved certification without reformatting a single OCP, LJI, or DMP. WSTF could not have achieved certification without reworking the upper level WSTF management instructions and separating policy, **who and what and how, into separate documents.**

Although it has required a significant amount of effort, WSTF employees responded positively concerning the new documentation system in the post-certification survey. Pie charts (Attachment 2) show the percentage breakdown of all survey responses to questions concerning whether documentation is better understood, more applicable to WSTF test business, and supports doing quality work. The *agree* and *strongly agree response* is far larger than the disagree and strongly disagree response. Additionally, an extensive summary of benefits noted following the certification are also indicated under Improved Documentation (Attachment 2).

Documentation system lessons learned are summarized below:

- Set up the document system well in advance of new document development.
- Recognize up front that adopting a management system based on ISO 9000 will probably fundamentally change the existing management system.
- Keep your document control system simple. A basic three-tier documentation system should be used, if possible.
- Establish firm format requirements for policies and procedures, but allow flexibility on work instructions.
- Establish a centralized control system for policies and procedures. Distributed control is acceptable for control of instructions.
- Do not try to control external documents.
- Train the work force as soon as documents are approved.
- Use a simple approach organizing policy-level documentation. A strategic paraphrasing of the standard is a good direct approach.
- Provide strong middle management support for teams that develop documentation within their respective areas of process ownership.

5. Defined Work Processes

Process orientation is the path to simplification, consistency, efficiency, and cost reduction. If properly applied, it cuts across department boundaries and prevents redundancy. The typical approach to ISO implementation is to:

- Perform process mapping (flowcharting) of all the processes within the organization.
- Decide which processes are going to be certified.
- Map the ISO 9001 requirements for the identified processes.

The product that results from the detailed mapping of existing processes and modification of these process to comply with ISO 9001 requirements is a set of detailed process maps that can be used as a continuous process improvement initiative. Some uses are to:

- Evaluate redundant and nonvalue-added steps.
- Understand cycle time for each step of the process and make adjustments.
- Identify critical process characteristics and points of control.
- Evaluate adjustments for effectiveness.

WSTF initially tried this approach but found that it was not well adapted to the operational structure. The functions of a highly versatile test organization are more diverse and generic in nature than those in manufacturing. The ultimate compromise was to map a single generic WSTF work process adaptable to virtually any major project or capability at WSTF. Specific processes were then classified relative to the ISO 9001 elements and mapped and modified as necessary for compliance. This approach was also applied to several previously undocumented work processes.

This approach effectively demonstrated compliance to the standard. Although additional process definition and analysis would have produced greater benefit, appreciable improvement was realized at less cost using this approach. Better documented, standardized, repeatable, and dependable work processes resulted. These uniform and defined processes foster cross-functional cooperation and provide other benefits. The basis for process definition and control is in place for continued improvement. An extensive summary of benefits noted following the certification is indicated under Improved Work Processes (Attachment 2).

Work processes lessons learned are summarized below:

- Allowing *wants* to creep into process documentation is counterproductive and will require additional work to show objective evidence of those activities. Desirable *wants* will naturally be incorporated through the continuous improvement process.
- New processes should be in place a minimum of 60 days before the registration audit. This will allow time for changes if the process needs modifications. WSTF did not have some processes in place early enough. This made the efforts more intense at the end.

6. ISO Training (to Lowest Organizational Levels)

Training played a critical role in empowering the implementation process. Experienced personnel from ASFS provided initial ISO implementation training. Implementation personnel then provided additional training as required. Primary training is specified in Table 2. Additional awareness training was given to approximately 400 WSTF personnel, application workshops were provided, and continuous training was provided to site employees as new documentation was released.

Overall, the WSTF training continued through the implementation period and was ultimately very effective. Training was probably key to keeping the number of findings to five. However, it could have been planned and timed better. Benefits could have been gained from earlier and more in-depth core team and middle management training. Documentation development could have started earlier with better initial element team training. Earlier hourly personnel and technician training could have prevented gaps that had to be filled in the final weeks before certification.

Training lessons learned are summarized below:

- Provide adequate training before launching the transition effort. *Employees simply cannot be expected to accomplish what they are not trained to do.*
- Provide in-depth core team and middle management training as early as possible.
- Provide in-depth element team training before attempting documentation development.
- Slowly start technician and other hourly personnel training, then gradually and continually increase intensity as the registration audit approaches. The effort should be completed several weeks before the audit.
- Observe organizations that have successfully implemented ISO to see firsthand how the program works and how it affects the organization.

7. Final Audit Readiness Verification

Although progress should be tracked closely throughout the implementation, added audit readiness verification in the final weeks is well worth the effort. A significant amount of effort went into verifying WSTF was truly ready for the final audit. This involved a concentrated effort by the internal audit teams and by management. This ultimately resulted in a busy period of housecleaning and technician training but yielded excellent results.

Final audit readiness verification lesson learned is given below:

- Completing the planned implementation effort (i.e., new process implementation, training, and general housecleaning) 30 days before the final audit reduces pressure and allows for last-minute fine tuning.

8. Strong Quality Policy

The quality policy is the central focus for the overall quality system. It is critical to properly target the overall documentation system and mind-set of employees as they conduct their jobs and support customers. If the quality policy does not have the right focus, the balance of the system may be accordingly off target. Therefore, adequate time and energy must be placed on a strong quality policy. WSTF management defined the quality policy relevant to WSTF organizational goals and the expectations and needs of WSTF customers. WSTF was careful to make sure the site quality policy was properly focused and then made sure personnel understood the focus. The policy as shown below was on ISO badges provided to employees and posted on signs throughout the site.

“The White Sands Test Facility is committed to exceeding the expectations and needs of our customers through continuous improvement in the quality of the products we provide in the pursuit of our goal of preeminence.”

WSTF Management has the responsibility to ensure the policy is understood, implemented, and maintained at all levels of the organization. The quality policy along with the mission statement (WSTF Overview Section) present the ideal of preeminence which drives the WSTF values and commitment to quality. WSTF management reviews the overall quality system at defined intervals to ensure it continues to be appropriate and effective in satisfying the requirements of ISO 9001 and WSTF’s quality policy. Records of such reviews are maintained as formal ISO 9001 quality records. WSTF in turn prepares procedures consistent with the ISO requirements and the WSTF policy documents or WPDs.

WPDs are grouped by ISO element number to clearly show direct fulfillment of ISO 9001 requirements and further breaks down policies in the context of the quality policy. WSPs then describes activities, responsibilities, authorities, and interrelationships of personnel and/or organizations necessary to implement policies. The quality system documentation can be made available as guidelines to assist other similar organizations. An extensive summary of benefits noted following the certification is indicated under Improved Quality (Attachment 2).

The primary strong quality policy lesson learned is given below:

- Ensure a simple and direct quality policy with the correct focus is established and effectively communicated to all employees.

9. Quality Ownership Transition

The quality function responsibility for documentation and maintenance needs to be transitioned to the logical or natural process owners. **The challenge is to see that the right people assume ownership and responsibility.** Distribution of ownership is also a necessary tool to bring about buy-in. There was a perception of Quality Organization *empire building* during the early WSTF certification effort. However, as large segments of the work force were assigned document development responsibility on element teams, it became clear that the ownership distribution was going to be widespread. **The eventual transition of documentation review and approval**

responsibility to NASA Office Chiefs represented a refinement of the transition process where the natural owners were ultimately given the responsibility.

Quality ownership transition lessons learned are summarized below:

- Ensure the quality functional responsibility is transitioned to the logical or natural process owners.
- Ensure ultimate process owners (management) are involved with development, revision, and approval of documentation.

10. Detailed Implementation Plan (Scope and Magnitude of the Implementation Effort Well-Defined)

Good implementation planning is essential, and documentation of this in the form of a formal implementation plan is helpful. WSTF planning activities, implementation plan development, and plan evolution are discussed in *How WSTF Implemented ISO 9001. Planning and lessons learned* are also discussed at the end of that section.

11. Project Communications (Effective and Viable)

Communication must be adequately addressed during the ISO implementation process because so much is dependent on it. Initial communication is critical at all levels for buy-in, and continuous communication is critical to training and work coordination throughout the implementation. Continual horizontal and vertical communication is needed between core team members, element team members, various element teams, offices and departments, procedure reviewers, and the overall work force. The WSTF implementation project could be viewed as a large implementation machine with dozens of subsystems that needed to be smoothly coordinated at various levels of communication intensity. Communication levels included top management and the seven-member core team, the 60-member element teams and leaders, NASA middle managers, and their contractor department management counterparts. The middle managers also directed dozens of NASA project managers and contract supervisors who reviewed documentation and provided training. At the broadest level, virtually the entire work force of approximately 550 was involved in communication concerning processes or audit preparations.

WSTF communication methods included:

- Frequent memoranda issued jointly from the NASA/contractor top management
- Other written communication at all levels
- Special ISO newsletter
- ISO badges with WSTF's quality policy statement
- ISO buttons
- Special bulletins and posters
- Frequent use of the public address systems

Communication lessons learned are summarized below:

- Set up an effective communication system up front and start communicating plans to the lowest levels of the organization.
- Communicate the detailed implementation plan and periodically provide updated schedules of ISO events.
- Hold an early question and answer session with auditors.
- Encourage frequent management communication (during assemblies and in the field).
- Strictly avoid the trickle approach; it can be contradictory and create confusion.

12. Customer Consultation

The ISO standard leaves a good deal of flexibility on requirement fulfillment. This flexibility can be used to good advantage by allowing primary customers inputs into specific requirement fulfillment. WSTF had little formal consultation with customers. However, in compiling with contract review element 4.3, flexibility was built into the WSTF system to accommodate virtually any special customer requirements.

WSTF employees responded very positively concerning customer support in the post-certification survey. The pie chart in Attachment 2 shows the percentage breakdown of all survey responses to a question concerning whether we are better able to firm up requirements and better support our customers. The *agree* and *strongly agree responses* are far larger than the disagree and strongly disagree responses.

13. Definitions of Terms

Whenever communication must occur, it is critical to have a common language. ISO involves many special words or common words that are used in a special context. Therefore, it is important to spend the necessary time educating participants. This is especially important for the implementation teams but is also needed for the organization at large. Without common definitions, a significant number of misinterpretations will result. A number of personnel will either be confused or simply tune out portions of ISO communications.

WSTF created a glossary of ISO terms to ensure consistent definitions throughout the documentation system and for training purposes. Each quality system document also contains definitions of special terms used in that specific document. A brief version of this glossary can be found in Appendix D.

Primary definitions of terms lessons learned are summarized below:

- Provide early training on ISO terms to minimize confusion and improve buy-in.
- Maintain a common glossary of ISO terms for documentation development.

14. Early Question and Answer Session

Earlier question and answer sessions are a very important part of the training process, especially if they are done in association with the auditing agency. This provides detailed information necessary to target the effort and help alleviate the many concerns that naturally arise in people's minds. WSTF conducted a question and answer day with DNV in January 1995, following the October 1994 kickoff of the implementation effort. A second question and answer session was conducted in August 1995 when a new DNV lead auditor was brought in after the *Tiger Team* recommended schedule changes.

The primary early question and answer session lesson learned is listed below:

- Use an early question and answer session including auditors to familiarize personnel with implementation effort.

15. Element Books and Checklists

A good approach to quality system organization is to break the system into 20 sections that correspond to the 20 elements. This approach helps to show compliance clearly. This is the basic approach WSTF took. WPDs are grouped by ISO element number to clearly show direct fulfillment of ISO 9001 requirements. WSPs then describe activities, responsibilities, authorities, and interrelationships of personnel and/or organizations necessary to implement policies.

AlliedSignal Fluid Systems provided WSTF with 20 element books corresponding to the 20 elements as guidelines for WSTF. These books contained process lists, process maps, process descriptions, and an index to their process descriptions and detailed work instructions. The hard requirement or *thou shalls* for each element were also included as a checklist. Appendix A contains a list of *thou shalls* for reference. These can be very helpful in auditing compliance. When an organization can show objective evidence that each requirement is met, management can feel confident that the element is complied with.

WSTF did not recreate element books. Rather, WSTF chose to develop master lists for each category and provide *read only* access to the documents to all workers through the WSTF computer network. Each documentation type has a separate directory and associated master list. The top-level WSTF policy documents clearly indicate the associated ISO requirements in the opening portion of each document. **Next-lower documents indicate the relationship to the associated policy documents.** Process maps were used in document development phases but were not included on the network. This quality system documentation can be made available to assist similar organizations.

Primary element books and checklists lessons learned are summarized below:

- Simply organize the quality system, preferably into 20 sections that correspond to the 20 elements to clearly show compliance.
- Refer to element books from similar, successful certifications to assist documentation system planning.

16. Effective Teamwork and Empowerment

When the implementation teams are initially assembled, teamwork should be an important consideration. Not only do those chosen need to be the best and brightest, but they also need to be personnel who can work together effectively and willingly. Personalities need to be compatible, and their abilities need to be complementary. The team must have clearly defined common goals and objectives and must also be supportive and objective to ensure success. This means that members need to be open-minded and willing to make personal sacrifices for the success of the group. If hidden agendas become a problem, a means must be available to deal with this.

Once good teams are assembled, team empowerment is required. Adequate training and direction for the specific job at hand must be provided. The teams must be committed to the effort and, if possible, sold on the mission. ISO implementation will most likely occur during heavy workloads, so the team must be committed to the effort and realize that short-term sacrifice is necessary for long-term benefit. Management needs to provide the necessary direction, resources, time, to be willing to clear roadblocks, and to truly listen and get involved when problems occur. Decision-making also needs to be flowed down to the most appropriate level. Additionally, good horizontal and vertical communication is critical for team cross-functional effectiveness.

During WSTF certification preparation, unprecedented cooperation and coordination ultimately yielded success, but it was not planned perfectly from the beginning. Much of it was born from necessity and required more of management's time than would have been necessary if greater initial commitment was in place across the board and element teams were better empowered.

Effective teamwork and empowerment lessons learned are summarized below:

- Choose personnel who can work together effectively and willingly.
- Provide clearly defined common goals and objectives.
- Emphasize short-term sacrifice for long-term benefit.
- Flow decision-making down to the most appropriate level.

Certification Assessment

During October 17-20, 1995, quality registrar DNV conducted an audit of WSTF for initial certification to ISO 9001. The assessment was conducted by two auditors. Five category II findings (minor nonconformances, see Attachment 1, Certification) were noted:

- An outdated document in a work area and no cross-reference for a revised instruction (ISO 9001 element 5)
- Unapproved redlines in an instruction manual (ISO 9001 element 5)
- Incomplete work instructions for three individual machine shop fabrication tasks (ISO 9001 element 9)

- Incomplete traceability to national standards for thread plug gages and thread micrometers in the machine shop (ISO 9001 element 11)
- In-process inspection and test records for valve shop maintenance operations were not identified as quality records (ISO 9001 element 16)

Other minor concerns were evident during the assessment; however, a network of WSTF contacts was alerted to potential problem areas as the assessment progressed. In most cases, the contacts were able to provide necessary clarification or other mitigating data to dispel concerns and prevent their inclusion as findings. Information was always fully disclosed and offered in a helpful manner, thus cultivating a cooperative relationship with the auditors. The conceptual knowledge of objective evidence and helpful attitude exhibited by the WSTF contacts attested to the effectiveness of WSTF's awareness and internal audit training. Considering the amount of time and effort expended and previous frustrations exhibited, the assessment findings were relatively insignificant.

The assessment was consistently aimed at confirming the existence of quality system processes and demonstrated use of the system. The assessment was not detailed but was effective at confirming the existence and use of the quality system and acknowledged a high degree of readiness, coordination, and cooperation within the organization.

Certification assessment lessons learned are summarized below:

- Be prepared to show the existence and use of the quality system.
- Establish a network to resolve potential problems as they become evident during the assessment.
- Cultivate a cooperative attitude with the auditors.
- Train and prepare intensively, because it pays off.

Maintaining the Momentum

The systems that WSTF put in place are an effective way of doing business. They now have to be used, maintained, and continuously improved. Receiving certification to ISO 9001 is not crossing the finish line, but simply a first step. Considerable effort should be focused on both solidifying improvements made during the certification effort and on continuous improvement. This helps maintain certification and promotes preeminence. WSTF is implementing the following activities to keep the momentum:

- Frequent management reviews to heighten awareness and set priorities as the certification maintenance audit approaches
- Publicizing best practices and site status in newsletters
- Maintaining standard audit and corrective action metrics
- Quantifying and tracking financial advantages

- Creating a system for customer satisfaction feedback
- Publicizing certification and Hammer Award achievements through the media
- Recognizing employee contributions to certification with awards and departmental certifications
- Actively encouraging departmental and process self-appraisal
- Conducting advanced audits based on perceived weaknesses and maintenance audit objectives
- Establishing an improved preventive corrective action process to enhance early identification and corrective action of problem areas before they happen
- Creating a horizontal multi-functional communication system for cross-talk of suspected systematic problems potentially common to other functional areas

Attachment 1
ISO 9001 Overview and Background

ISO 9001 Standards
Certification
General Advantages to Business

ISO 9000 Standards

ISO 9000 is a set of standards and guidelines that form the basic foundation for a quality management system. They are applicable to virtually all manufacturing and service organizations and are the basic foundation of a total quality system. The standards were originally published in 1987 by the International Organization for Standardization (ISO), a group representing the standard bodies of over 90 countries. They were then revised in 1994. Since 1987, they have been adopted as national standards by most highly industrialized countries. In the United States, the ISO 9000 series was issued as the Q90 series by the American Society for Quality Control (ASQC) and endorsed by the American National Standardization Institute (ANSI). The Q90 series was then reissued as the Q9000 series with the 1994 revision. The ISO 9000 is identical to the ANSI/ASQC Q9000 series except for a few minor differences in spelling.

It is important to note that the standard series is not simply a European invention. The United States was involved in the development process through participation in ISO technical committees. Experts from the United States continue to contribute to updates and revisions of the standards.

The roots of ISO are found in the NATO alliance. The NATO countries needed a common standard for materials provided to their respective militaries. They started with the US MIL-Q-9858 as a model and made it more generic so it would apply to a much wider range of products and services. In more recent times, the primary driver behind the standard is promotion of international exchange of goods and services through the principle of standardization. Although acceptance of the standards has been debated, response has generally been very positive. “There’s been nothing like this (the ISO 9000 series) before, in terms of interest,” said Patricia Kopp, standards administrator at the ASQC. “Standards have not been the most glamorous area over the years. Yet, suddenly, it is seen as important—even exciting” (Spizizen 1992).

The series breaks down as follows:

- 9000** - A guide for the selection and use of quality management and quality assurance standards. This is a road map that explains how to select and use the appropriate standards in the series.
- 9001** - A model for the assurance of quality systems for design and development, production, installation, and servicing. This standard has the broadest scope and applies to organizations that design and manufacture their own products or develop and provide services.

- 9002** - A model for the assurance of quality systems for production and installation. This applies to those manufacturers or service organizations who do not do any in-house design or development but conform to specified production and installation requirements that need to be assured, such as when products are manufactured to specifications provided by outside contractors or other branch operations.
- 9003** - A model for the assurance of quality systems for final inspection and test. This has the smallest scope, requiring only that conformance in final test and inspection be assured.
- 9004** - Guidelines for quality management and quality system elements. This is used internally and not in contractual situations. It lists, in some detail, the essential elements that make up a complete quality assurance system, including the responsibilities of management, marketing, procurement, corrective action, human resources use, product safety, and use of statistical methods. Many of these are elaborations of concepts contained in the three preceding standards.

The most popular standards of the series are ISO 9001 and 9002. The discussion in this document was limited to the ISO 9001 standard implemented at WSTF. ISO 9001 was selected since it is the only series that is comprehensive enough to cover overall WSTF operations and services. WSTF did not desire to cover only a portion of site operations with ISO standards and then cover the balance with the old quality system.

The standard is simply structured yet effectively specifies what is required to ensure that a full quality management system is documented, demonstrated, effective, and maintained. Audit by third-party registrars helps to ensure this. Key points include process orientation and emphasis on the processes, not personnel. This encompasses all processes that affect the product and service quality. During implementation, processes become better defined and better procedures are generated. Often this produces process simplification, better documentation, greater consistency, and greater efficiency. Most agencies adopting ISO initially have many processes that are redundant, undocumented, or poorly documented, so significant improvement can be expected. The emphasis placed on internal audit, preventive/corrective action, and management responsibility generally results in positive changes to organizations. Emphasis is also placed on customer requirements through contract or agreement review, and customer problems are fed back into the corrective action programs. Personnel responsible for processes are given true quality ownership.

The ISO 9001 Standard requirements are arranged into 20 sections, commonly called elements, that are broad enough to encompass all operational activities. The hard requirement of the standard is shown summarized in Appendix A as *thou shalls*. The 20 elements with a simple overview of each section are listed as follows:

ISO 9001 - The Sections

Simple Overview

1. Management Responsibility	Define who's in charge
2. Quality System	Define quality system
3. Contract Review (Customer Agreement Review for government projects)	Agree on the job
4. Design Control	Describe/control the design
5. Document & Data Control	Make/keep instructions
6. Purchasing	Buy good material
7. Control of Customer-Supplied Product	Control customer material
8. Product Identification and Traceability	Identify the product
9. Process Control	Describe how the job is controlled
10. Inspection and Testing	Inspect and test material/products
11. Control of Inspection, Measuring, and Test Equipment	Control test tools
12. Inspection and Test Status	Show material and product status
13. Nonconformance Control	Deal with bad material and products
14. Corrective and Preventive Action	Fix bad processes/prevent recurrences
15. Handling, Storage, Packaging, Preservation, and Delivery	Protect and deliver goods, products, and materials
16. Control of Quality Records	Keep good job records
17. Internal Quality Audits	Check on how we are doing
18. Training	Train personnel and keep records
19. Servicing	Service what you did
20. Statistical Techniques	Analyze what you did

In the application of the sections, the standard requires that objective evidence be provided showing that the quality system works in each area. The compliance bottom line is to:

- Say It - Document what you say
- Do It - Do what is documented
- Prove It - Maintain records that prove it was done

Certification

Companies that are in compliance with an ISO 9001 quality system can have their system certified by an accredited third party. Such a body is called a *registrar* because it keeps a register of all companies that it has certified. Registrars are authorized by an accreditation body to perform assessments or audits to evaluate compliance of a quality system of ISO requirements. When compliance is verified, the registrar recommends certification to the accreditation body.

Participating countries have such an accreditation body administering ISO 9000 certifications. In the United States, the Registrar Accreditation Board (RAB) has this role, but is not a federal body as is the case with the majority of participating nations.

A company seeking ISO 9001 certification should select a registrar that has experience covering what the company does and ensure that the registrar's accreditation certification scheme is compatible. WSTF chose DNV as the registrar because AlliedSignal had an effective working relationship with them from similar certification efforts. DNV is accredited by their native Dutch RvA Accreditation Board and several others, including the RAB. Many other good registrars are also available as listed in Appendix C, Quality System Registrars (Rubach 1995).

The certification process involves review of the quality system documentation that describes a company's quality system. The registrar can also do a preassessment that will help identify those areas requiring additional refinement or modification before the official, formal assessment. The preassessment represents an additional cost, but it should determine if the implementation process is on target. Discrepancies should be expected and will need to be tracked and corrected. The registrar (and possibly other independent assessors) can be consulted incrementally to ensure needed changes are appropriately implemented. When necessary changes are complete, the registrar does a certification audit. If a major implementation breakdown occurs involving unsuccessful implementation of an overall element or systematic problems affect the overall organization (Major or Category I finding), the organization is not initially recommended for certification. Corrective action must be taken within 30 days, and the site is subject to additional verification and audit. If lesser discrepancies (Minor or Category II finding) are found, the organization is allowed to make the necessary changes, and the recommendation for certification continues without additional audits as long as the changes are successfully implemented.

This certification is valid for three years, but the organization is subjected to semiannual maintenance audits over the life of the certificate. The maintenance audit is tailored by the individual registrars depending upon their registration schemes and the agreements they have with the individual companies. The certification is renewed after the three-year period, barring any substantial problems.

General Advantages to Business

Current literature identifies numerous specific advantages gained from being certified to ISO standards. A survey of 1,679 companies accomplished by Deloitte & Touche indicated that the most important benefits of registration were

- Greater quality awareness,
- Positive *cultural* change, and
- Increased operational efficiency/productivity (Deloitte and Touche 1994).

As the number of worldwide ISO-certified organizations increases, having the certification will become critical to doing business in the world market. By October 1995, more than 100 countries had adopted ISO 9000 as the national standard. Nearly 75,000 European companies were registered (Dunn and Bradstreet 1995). ISO certifications have occurred much more slowly in the United States than in the rest of the world, but the competition is accelerating. In 1991, only 25 U.S. companies were certified; this grew to more than 6,000 by 1995 (McCormick 1994a), and projections range from 200,000 to 500,000 by the year 2000

(McCormick 1994b). An extensive list of benefits WSTF personnel noted on a post-certification survey is also indicated in Attachment 2. Survey responses are summarized into categories as follows:

- Increased business level and recognition
- Improved documentation
- Improved effectiveness
- Better teamwork
- Job rewards
- Improved workplace
- Better new employee orientation

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Spizizen, Gary. *The ISO 9000 Standards: Creating a Level Playing Field for International Quality*. National Productivity Review, Summer 1992.

Attachment 2
WSTF Post-Certification Survey Response

Benefits of ISO Certification
Ranking of 15 Keys to Success
Documentation and Customer Support Improvement
Conflicts and Resolution
Certification Surprises
Lessons Learned Summary

Benefits of ISO Certification

Summary of Responses by Category

Increased Business Level and Recognition

- More business opportunities through international recognition of the ISO quality standard.
- Certification shows our commitment to international standards compliance, supporting *international projects* like Space Station.
- WSTF capabilities, operations, and processes are better documented, understood, and known.
- A more professional image and organized approach is presented to customers.
- Increased customer satisfaction through better customer interface and agreements.
- Recognition by Vice President Al Gore for reinventing government.
- Recognition within NASA for successfully implementing a structured quality system and for being first among NASA installations.
- Seen as a preeminent world class organization.

Improved Documentation

- *Corporate knowledge* and undocumented procedures are finally being documented.
- Policies and procedures are universally available and easy to find on the WSTF computer network.
- Documentation is better defined, structured, organized, reviewed, more consistent, and cleaner across the site.
- Documentation structure, policies, and procedures are easier to follow.
- Procedure changes are easier and faster to make.
- There is a clearer distinction between policies and how to implement them.
- An understanding of work documentation importance was developed at all levels.
- Personnel are more cognizant of and comfortable with site documentation.
- Personnel are conscious record keepers and will try to stay standardized.
- Drawing and procedures are kept more current.
- Program managers are now willing to pay for good documentation on new systems.

Improved Quality

- The quality system is better structured, more consistent, and more effective.
- Quality awareness and focus are greater at every level of the workplace.
- Policies and procedures are implemented and followed, resulting in a better product.
- Documentation of undocumented processes increases consistency of the product.
- Traceability is increased across the board.
- The quality system better targets customer needs.
- Quality documentation of non-NASA work is now straightforward.
- Quality that was already present is better recognized and measured.

Continuous Improvement

- The internal audit system forces continuous improvement.
- Certification helped begin needed change in site cultural mind set.
- ISO certification produces a tangible result whereas programs like TQM and *Commitment to Excellence* have tended to die out after a while, producing little tangible result.

Improved Work Processes

- The WSTF mission is better understood, agreed upon, supported, and unified.
- More formal and defined process directions and guidelines increase product consistency and quality.
- Corporate knowledge and previously undocumented processes are being documented, thereby improving product consistency.
- Documented project management and project leader procedures result in smoother project coordination from beginning to end.
- Objective process documentation is readily available as a computer network resource to make writing new documentation easier.
- Better organized and written procedures make it easier to do our work.
- Site-wide standardization simplifies projects and improves efficiency.
- Overall site operations are better understood and personnel can see how their processes fit in.
- Documented jobs processes allow new people to be productive faster and others to step in when personnel are absent.

Improved Effectiveness

- Standardization between offices/departments reduces redundancy.

- Better organized and defined processes and better understood roles and responsibilities streamline the effort.
- Better performance improves our product and increases customer satisfaction.
- Better organized offices reduce wasted time.
- Training is more consistent and better tracked.
- Improved project planning ensures that customers get what they specify.

Better Teamwork

- The certification process broke down department barriers and taught us to work as a team.
- Personnel have a stake in the system now.
- Certification unraveled ingrained thinking which allowed improvement.
- Employees became better acquainted, especially with management.
- Certification made us more accountable for our work and more aware of others' jobs and responsibilities.

Job Rewards

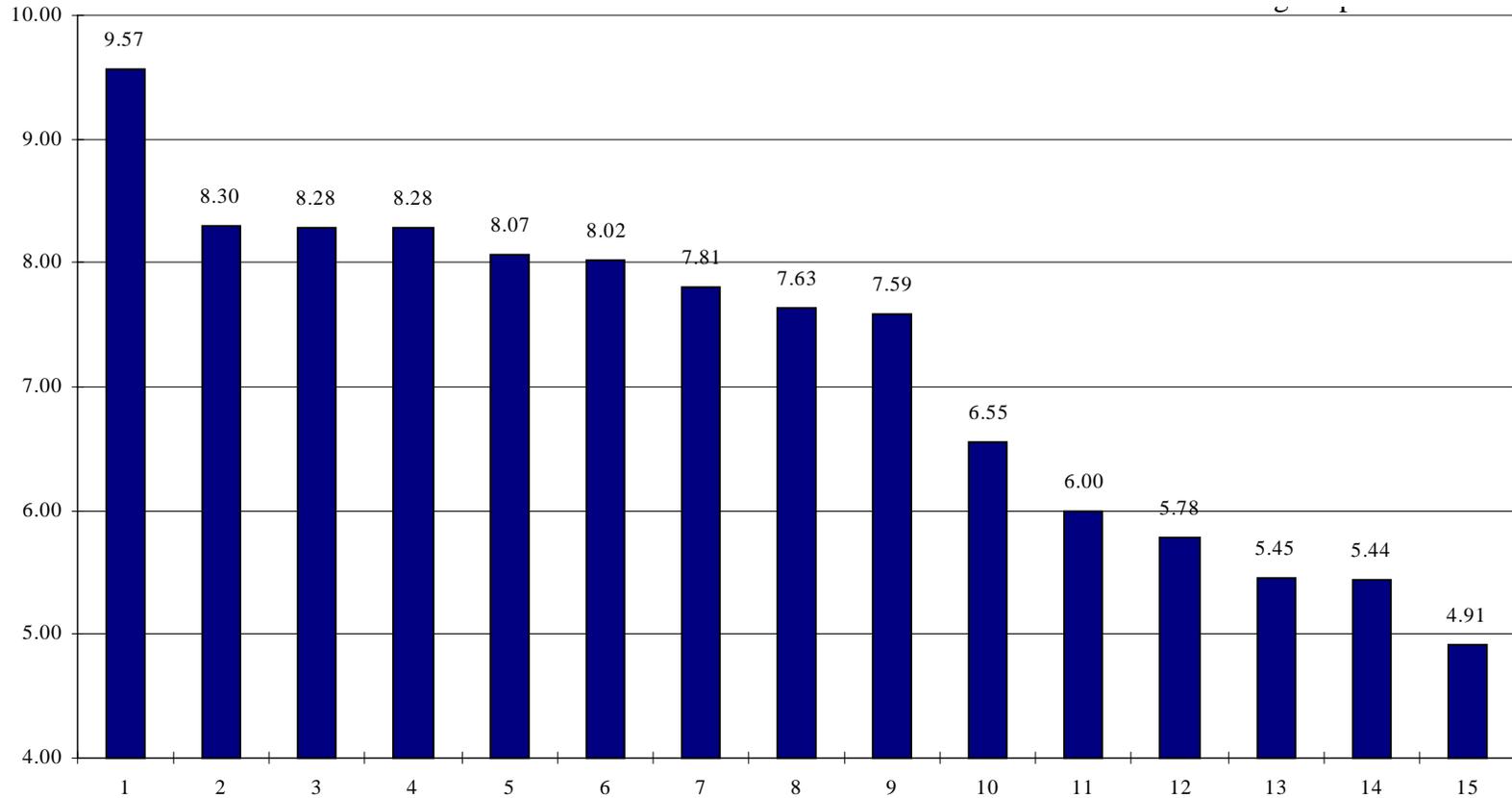
- Being recognized as doing quality world-class work is good for morale.
- Personnel have a stronger sense that our jobs make a difference.
- Personnel better understand the goals WSTF seeks to achieve.
- Personnel have increased team prestige; they view themselves as a winning team.
- Perceived preeminence is increased.

Improved Workplace

- Better site housekeeping, organization, and labeling.
- Better job security and morale.
- An organized work environment and better defined jobs help reduce stress.

Better New Employee Orientation

- Helps new personnel derive a better/quicker understanding of the site and its people.
- Job processes are better defined so new employees can pick up the effort with greater confidence.

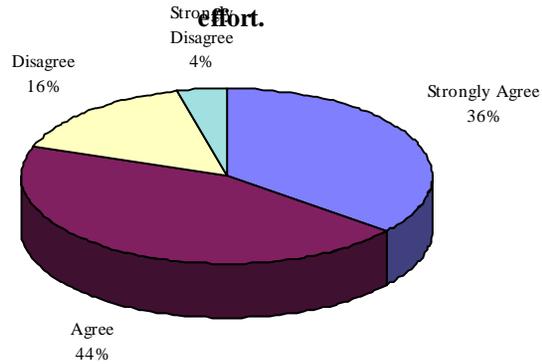


Respondents are NASA, ISO core team, management, and ISO team members

- | | | | | | |
|---|---|----|--|----|-----------------------------------|
| 1 | Management commitment | 6 | ISO training | 11 | Projection communications |
| 2 | Effective internal audits and corrective action follow-up | 7 | Final audit readiness verification | 12 | Customer consultation |
| 3 | Strong implementation organization | 8 | Strong quality policy | 13 | Definition of terms |
| 4 | Well-organized documentation (by ISO element) | 9 | Quality ownership transition (established areas of responsibility) | 14 | Early question and answer session |
| 5 | Defined work processes | 10 | Detailed implementation plan | 15 | ISO element books and checklist |

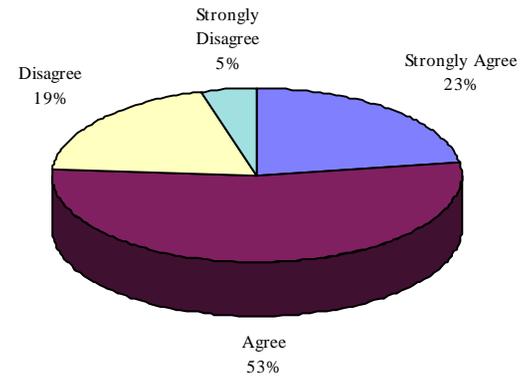
Ranking of 15 Keys to Success

Work Authorizing Documents are better understood as a result of the ISO certification effort.



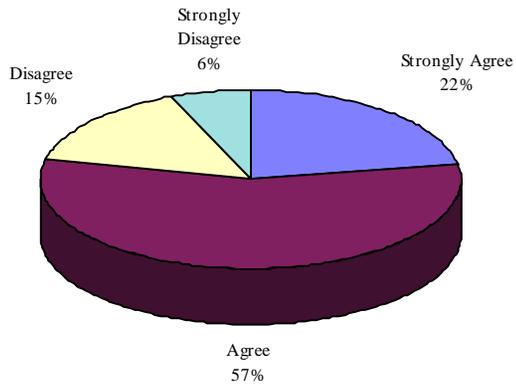
Information based on all responses to the ISO Survey.

The documentation structure now better supports doing quality work.



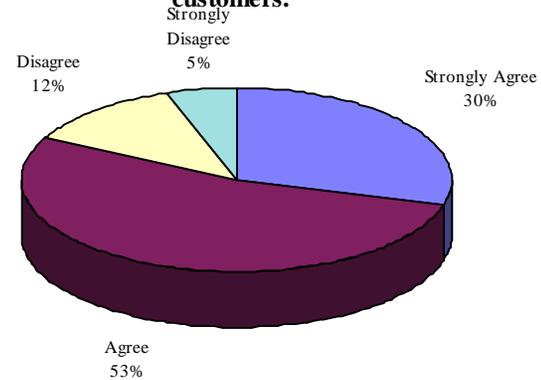
Information based on all responses to the ISO Survey.

The documentation structure has been made more applicable to WSTF testing business.



Information based on all responses to the ISO Survey.

We are now better able to firm-up requirements and better support our customers.



Information based on all responses to the ISO Survey.

Documentation and Customer Support Improvement

Conflicts and Resolution

Documentation Structure

Conflict: Element team members had significantly differing points of view concerning WSP/WSI (middle level documentation) content based on office/department viewpoints.

Resolution: Department management generally resolved issues, but a few issues were elevated to the management representative level for resolution.

Conflict: Addition of the WSI to the documentation pyramid vs. sitewide WJIs?

Resolution: Top management made a *thou shall* decision.

Interpretations

Conflict: Multiple understandings of what needed to be accomplished and what specific team responsibilities were.

Resolution: Processes were discussed and outlined in detail so that a common understanding was gained.

Conflict: Impasse over interpretations of general 9001 guidelines in application to specific WSTF processes.

Resolution: Documentation was turned over to a middle-management-led *Tiger Team* and was completed in a more orderly and timely fashion.

Resistance to Change

Conflict: Trying to change 30 years of *this is the way it has always been done* to ISO TQM team ideology in only 12 months.

Resolution: The *Tiger Team* forced *ownership*. More intense training to a lower level up front would have prepared more of the work force earlier and reduced resistance.

Conflict: Opposition to interdepartmental standardization of business processes.

Resolution: Office and department management was made accountable for process implementation.

Excessive Change

Conflict: Process documentation sometimes resulted in *how I want to start doing business* instead of *how we do business now*.

Resolution: Enforced application of *needs* not *wants*. Continuous improvement would allow feasible *wants* to be implemented in the future.

Resources

Conflict: ISO implementation vs. projects and other job assignments. The large amount of implementation effort at all levels caused serious issues to be raised.

Resolution: Management ultimately made real-time priority calls in an effort to minimize impacts to both sides. Additionally, most key personnel were supportive enough to put in significant extra time to make up for impacts. It also helped to streamline anywhere possible by doing such things as reducing the number of meetings.

Certification Surprises

Positive

- How together things were as we went from area to area with the auditors and how we got so few findings.
- How well previously undocumented standard processes can be documented.
- How unprecedented cooperation/coordination resulted when the chips were down.
- How smooth and effective the collaboration between NASA and the contractor became.
- How much personnel willingness, teamwork, and commitment most participants had.
- How much I enjoyed working with and meeting personnel I don't normally come in contact with.
- How willing most of the work force was to accommodate change, given a real opportunity.
- How well a test organization adapted to a guideline that was written primarily for manufacturing facilities.

Negative

- How much variance was found in our *long-established standard processes*.
- How a well-thought-out plan can turn into a crash effort at the end.
- How such a high percentage of some people's available time was required.
- How much training documentation was needed for certification.
- How much initial separation and divergence of goals existed between many key players.
- How some teams tended to influence the procedures to make their jobs easier.
- How some otherwise reasonable people react unreasonably to imposed change despite management's firm commitment.

Lessons Learned Summary

Planning

- Do not wait for a *good time* to start. A *good time* never comes.
- Formulate a well-thought-out plan before involving large numbers of personnel.
- Appoint the core team from high in the organizational structure to decisively *bust barriers* and ensure decisions will be implemented.
- Train the core team thoroughly in ISO basics and ensure they have the necessary tools such as detailed knowledge of organizational function and personnel resources.
- Perform a *gap assessment before* starting detailed planning to determine how big the effort will be. Without a realistic magnitude, planning, goals, and schedules will be flawed. This should start at least 60 days before the implementation kickoff.
- Use experts and consultants, training material, *lessons learned* and *best practices* from similar certificates.
- Agree on a clearly detailed implementation scope, then include or exclude tasks based on their position inside or outside the scope.
- Focus on *needs* rather than *wants*. The effort will be large enough without creating excess change.
- Upper- and middle-level management should share in the selection of implementation workers. Select them from the best and brightest and *empower* them with training, adequate direction, and the authority to do their jobs.
- Encourage an environment of cooperation from the beginning.
- Lay out a milestone schedule that starts fast and maintains momentum throughout.
- Include middle management personnel, who *get the job done*, in review and authorization of the plan. Even lower-level review may provide benefit from worker insights and additional buy-in.
- Decide that it is going to be everyone's ISO system and be flexible enough to step outside your own views for the good of the organization.
- Minimize change where your systems are consistent and compliant with the standards.
- Do not underestimate the power of *positive* or *negative* thinking.

Management Commitment

- Management should be seen leading the way in knowledge and in full control of issues.
- Management should demonstrate commitment by word and deed at all levels.
- Management should be seen participating in training of employees down to the *lowest* levels to demonstrate both knowledge and commitment.
- Management should make ISO certification and regular business of equal importance as both are critical to organizational success.
- Management should clearly indicate that a high level of ISO-related performance is expected. Making ISO contributions a part of employees' performance objectives and evaluation criteria is a good way to do this.
- Management should absolutely minimize work slippage. This slippage causes loss of momentum, disappointment, and increases the effort in the long run.
- Management must allocate the necessary resources even if budget is a challenge.
- Top management should stay deeply involved. Periodic management review meetings and frequent field trips to talk with workers at various levels are helpful.
- Management and supervision should provide strong support and be interactive. *It is an error to think that ISO technical details need only to be understood at the point of application.*
- Management should realize that everyone cannot be sold on ISO. They must make every effort to create buy-in then firmly move forward with an attitude of *we will do this*.
Dependence must be on people who will be responsible.

Effective Audit and Corrective Action Follow-Up

- Ensure experienced auditors participate in charting the initial path and then return to perform periodic assessment and internal auditor support.
- Place high overall emphasis on an effective internal audit and corrective action system.
- Complete auditor training and begin the auditing program very early.
- Use the internal audit and corrective action process extensively for positive change.
- Offer audit familiarization training to large numbers of potential internal auditor candidates. This will help in the selection of better internal auditors and will educate more personnel to the positive aspects of auditing.

Strong Implementation Infrastructure

- Top management cannot achieve ISO certification without obtaining strong commitment from middle management and accepting some compromises.
- When top management decides to proceed with certification, the next management layer must be thoroughly involved in training. They then need to make fundamental decisions about adapting existing systems to the ISO standards from a fully informed basis and take system ownership at the initiation of change.
- Use middle management *movers and shakers* to get the job done.
- Fully empower management representatives to be *barrier busters*.
- Empower the implementation team with the necessary training, resources, coordination, and communications early in the process.
- Maintain a broad assessment capability and be ready to make major adjustments to the plan if required.
- Select responsible personnel at initiation, obtain commitment, and hold them accountable for support.

Well-Organized Documentation System

- Set up the document system well in advance of new document development.
- Recognize up front that adopting a management system based on ISO 9000 will probably fundamentally change the existing management system.
- Keep your document control system simple. A basic three-tier documentation system should be used if possible.
- Establish firm format requirements for policies and procedures, but allow flexibility on work instructions.
- Establish a centralized control system for policies and procedures. Distributed control is acceptable for control of instructions.
- Do not try to control external documents.
- Train the work force as soon as documents are approved.
- Use a simple approach to organizing policy level documentation. A strategic paraphrasing of the standard is a good direct approach.
- Provide strong middle management support for teams that develop documentation within their respective areas of process ownership.

Defined Work Processes

- Allowing *wants* to creep into process documentation is counterproductive and will require additional work to show objective evidence of those activities. Desirable *wants* will naturally be incorporated through the continuous improvement process.
- New processes should be in place a minimum of 60 days before the registration audit. This will allow time for changes if the process needs modifications. WSTF did not have some processes in place early enough. This made the efforts more intense at the end.

ISO Training

- Provide adequate training before launching the transition effort. *Employees simply cannot be expected to accomplish what they are not trained to do.*
- Provide in-depth core team and middle management training as early as possible.
- Provide in-depth element team training before attempting documentation development.
- Slowly start technician and other hourly personnel training, then gradually and continuously increase intensity as the registration audit approaches. The effort should be completed several weeks before the audit.
- Observe organizations which have successfully implemented ISO to see firsthand how the program works and how it affects the organization.

Final Audit Readiness Verification

- Completing the planned implementation effort (i.e., new process implementation, training, and general house cleaning) 30 days before final audit reduces pressure and allows last-minute fine-tuning.

Strong Quality Policy

- Ensure a simple direct quality policy is established with the correct focus and is effectively communicated to all employees.

Quality Ownership Transition

- Ensure the quality functional responsibility is transitional to the logical or natural process owners.
- Ensure ultimate process owners (management) are involved with development, revision, and approval of documentation.

Project Communications

- Set up an effective communication system up front and start communicating plans to the lowest levels of the organization.
- Communicate the detailed implementation plan and periodically provide updated schedules of ISO events.
- Hold an early question and answer session with auditors.
- Encourage frequent management communication (during assemblies and in the field).
- Strictly avoid the trickle approach. It can be contradictory and create confusion.

Definitions of Terms

- Provide early training on ISO terms to minimize confusion and improve buy-in.
- Maintain a common glossary of ISO terms for documentation development.

Early Question and Answer Session

- Use an early question and answer session—including auditors—to familiarize personnel with implementation effort.

Element Books and Checklists

- Simply organize the quality system, preferably into 20 sections that correspond to the 20 elements to clearly show compliance.
- Refer to Element Books from similar successful certifications to assist documentation system planning.

Effective Teamwork and Empowerment

- Choose personnel that can work together effectively and willingly.
- Provide clearly defined common goals and objectives.
- Emphasize short-term sacrifice for long-term benefit.
- Decision-making also needs to be flowed down to the most appropriate level.

Appendix A
Thou Shall
ISO 9001 1994 Revision¹
(Hard Requirements)

¹ Adapted from original by: John Denman (602/893-5745), AlliedSignal Aerospace, P. O. Box 22200, M/S 1207-ISO, Tempe, AZ 85285.

NOTE: Many of the *thou shalls* are tempered by the use of modifiers (such as...*when applicable, as appropriate, to the extent, and where specified*). However, the presence of the modifier does not dismiss our responsibility to the requirement. The quality system must be able to adequately address each of these requirements.

[BEFORE EACH OF THE FOLLOWING STATEMENTS SAY, "THOU SHALL..."]

4.1 Management Responsibility

- Define and document our policy and objectives, and commitment to, quality.
- Ensure that the policy is relevant to our goals and the expectations and needs of the customers.
- Ensure this policy is understood, implemented, and maintained at **all** levels.
- Define and document the responsibility, authority, and the interrelation of **all** personnel who manage, perform, and verify work affecting quality.
- Identify in-house verification requirements, provide adequate resources, and assign trained personnel for verification activities.
- Appoint a management representative who is fully authorized and responsible for (1) ensuring that the requirements of this standard are established, implemented and maintained, and (2) report on the performance of management and use this report as a basis for improvement of the quality system.
- Review the quality system at defined intervals to ensure its continuing suitability and effectiveness.
- Keep records of these system reviews.

4.2 Quality System

- Establish, document, and maintain a quality system that ensures the product conforms to requirements.
- Define our quality system requirements in a quality manual.
- Include, or reference, the procedures in the quality manual and outline the structure of the documentation used in the quality system.
- Prepare procedures consistent with the ISO standard and our quality policy.
- Effectively implement the documented procedures and the quality system.
- Ensure that the degree of documentation required for the procedures is dependent on the methods used, skills needed, and training acquired by personnel.
- Define and document how the requirements for quality will be met.
- Ensure that quality planning is consistent with **all** other requirements and documented in a manner suitable to our operation.
- Give timely consideration, as appropriate, to **all** those activities necessary in meeting the specific requirements for products, projects, or contracts.

- Give appropriate considerations to quality plans, acquisition of needed resources, compatibility of design, inspection and test techniques, measuring and test equipment (M&TE) capabilities, suitable verification stages, and a clear and complete understanding of all features and requirements.

4.3 Contract Review

- Establish and maintain documented procedures for contract review and for the coordination of these activities.
- Review **each** accepted tender, contract, or order to ensure that:
 - Requirements are adequately defined and documented.
 - Order requirements are agreed upon before their acceptance.
 - Any contract or accepted order requirements differing from those in the tender are resolved.
 - The ability is there to meet contract or accepted order requirements.
- Identify how amendments to the contract are made and *flowed-down* to concerned functions.
- Maintain records of contract reviews.

4.4 Design Control

- Establish and maintain documented procedures to control and verify the design of the product.
- Prepare plans for **each** design and development activity and describe or reference these activities.
- Assign design and verification activities to qualified personnel equipped with adequate resources.
- Update the plans as the design evolves.
- Identify organizational and technical interfaces between the different groups and ensure that the necessary information is documented, transmitted, and reviewed regularly.
- Identify and document the design input requirements relating to the product and have them reviewed for adequacy.
- Resolve incomplete, ambiguous, or conflicting requirements with those responsible for imposing the requirements.
- Take into consideration, during design input, the results of **any** contract review activities.
- Document and express in terms of requirements the design output that can be verified.

- Ensure that design output (1) meets design input requirements, (2) contains, or references, acceptance criteria, and (3) identifies those characteristics *crucial* to the safe and proper functioning of the product.
- Review design-output documents before release.
- At appropriate stages, plan and conduct formal documented design reviews.
- Have present at each design review those representatives of **all** functions concerned with the design stage being reviewed.
- Keep records of design reviews.
- Perform design verification to ensure the design stage output meets the input requirements.
- Record design verification measurements.
- Perform design validation to ensure the product conforms to users' needs or requirements.
- Identify, document, review, and approve all changes and modifications by authorized personnel.

4.5 Document and Data Control

- Establish and maintain documented procedures to control **all** documents and data related to requirements of this standard.
- Review and approve for adequacy documents and data before issue.
- Establish and make readily available a master list or equivalent document control procedure that identifies the current revision status of documents.
- Ensure that pertinent issues of documents are (1) available at **all** locations where operations essential to the effective functioning of the quality system are performed, (2) ensure that obsolete documents are promptly removed from **all** points of issue or use, or otherwise insured against unintended use, and (3) identify **any** obsolete documents that are retained for legal or knowledge preservation purposes.
- Review and approve changes to documents with the same group that did the original review and approval.
- Ensure that access to pertinent background information is available to those who review and approve changes.
- Identify the nature of the change in the document or attachment.

4.6 Purchasing

- Establish and maintain documented procedures to ensure that purchased product conforms to requirements.
- Evaluate and select subcontractors on the basis of their ability to meet quality requirements.
- Define the type and extent of control exercised over the subcontractors based on the type of product, impact of this product on final product, and previously demonstrated capability and performance.
- Establish and maintain record of acceptable subcontractors.
- Ensure that purchasing documents contain data clearly describing the product ordered, including (1) type, class, style, grade, or other precise identification, (2) title and applicable issue of specification, drawing, process, inspection instruments, technical data, etc., and (3) title, number, and issue of quality standard applicable.
- Review and approve purchasing documents for adequacy before release.
- Specify verification arrangements, at subcontractor's level, and the method of product release in the purchasing documents.
- Afford the purchaser the right to verify at source or upon receipt that product conforms to requirements. However, verification by customer cannot be used by us as evidence of an effective quality by the subcontractor. Furthermore, this verification doesn't absolve us of providing acceptable product nor does it preclude subsequent rejection by the customer.

4.7 Control of Customer-Supplied Product

- Establish and maintain documented procedures for verification, storage, and maintenance of customer-supplied product provided for incorporation into the product.
- Record and report to the customer any product of his that is lost, damaged, or otherwise in an unsuitable condition.

4.8 Product Identification and Tractability

- Establish and maintain documented procedures for identifying the product by suitable means from receipt and during **all** stages of the production, delivery, and installation.
- Establish and maintain documented procedures for unique identification of individual product or batches.
- Record identification of traceable product.

4.9 Process Control

- Identify and plan the production and installation processes that directly affect quality and ensure that these processes are carried out under controlled conditions.
- For controlled conditions, observe the following:
 - Provide documented work instructions at locations where the absence of procedures could adversely affect quality.
 - Use suitable equipment in a suitable working environment.
 - Comply with reference standards/codes, plans, and documented procedures.
 - Monitor and control suitable process parameters and product characteristics.
 - Monitor approval of processes and equipment.
 - Maintain criteria for workmanship in the clearest practical manner, i.e., written standards, illustrations, or samples.
 - Maintain suitable equipment to ensure continuing process capability.
- Ensure that NDT-type processes are continuously monitored and controlled by qualified operators to ensure the product complies with requirements.
- Specify the requirements for **any** qualification of process operations (equipment and personnel).
- Keep records of qualified processes, equipment, and personnel.

4.10 Inspection and Testing

- Establish and maintain documented procedures for inspection and test activities to verify requirements.
- Document in the quality plan the required inspection, testing, and recording activities.
- Ensure that incoming product is not used or processed until inspected or otherwise verified as conforming to requirements.
- Verify requirements in accordance with the quality plan or documented procedures.
- Determine the amount of receiving inspection and testing required, based on the control exercised at the subcontractors and the recorded evidence of conformance provided.
- Only release incoming product for urgent production purposes if it is positively identified and recorded to permit recall and replacement in the event of nonconformance.
- Inspect and test the product to the quality plan or documented procedures.
- Hold product until required inspection and testing are completed or the necessary reports are received and verified, except when released under positive recall procedures.

- Carry out **all** final inspection and testing to the quality plan or documented procedures as evidence of conformance to requirements.
- Ensure that the quality plan or documented procedure requires that **all** inspections and tests are carried out and the results meet the requirements.
- Ensure that no product is dispatched until **all** activities of the quality plan or documented procedures have been satisfactorily completed and the necessary data and documentation is available and authorized.
- Establish and maintain records that provide evidence that the product has been inspected or tested.
- Show clearly whether the product passed or failed according to defined acceptance criteria.
- Ensure that when a product fails to pass **any** inspection or test, the procedures for control of nonconforming product are applied.
- Record the identity of the inspection authority that released the product.

4.11 Control of Inspection, Measuring, and Test Equipment

- Establish and maintain documented procedures to control, calibrate, and maintain inspection of M&TE (including test software) used to demonstrate the conformance of product to the requirements.
- Use M&TE in such a manner that measurement uncertainty is known and is consistent with the required measurement capability.
- Verify that test software/hardware are capable of performing the required task before release for use.
- Re-check the test software and hardware at prescribed intervals to ensure capability of product verification.
- Establish the extent and frequency of such checks and keep records as evidence of control.
- Make available technical data pertaining to the measurement devices to verify that the devices are functionally adequate.
- Control, calibrate, and maintain all M&TE. *(ISO 9001 mentions many things that we must do, but if we satisfy MIL-I-45662A, we will be in compliance with everything ISO 9001 requires of us. However, we advise you to **read Section 4.11.2** carefully and understand all requirements and nuances contained therein.)*

4.12 Inspection and Test Status

- Indicate the conformance or nonconformance of product with regard to inspection and test performed.
- Indicate and maintain the inspection and test status of product by means of markings, stamps, tags, labels, routing cards, records, software, physical location, etc., through production and installation of the product to ensure that only product that has passed the inspections and tests is dispatched, used, or installed.

4.13 Control of Nonconforming Product

- Establish and maintain documented procedures to ensure that a nonconforming product is not unintentionally used or installed.
- Control nonconforming product by identification, documentation, evaluation, segregation, disposition, and notification to the functions concerned.
- Define the responsibility for review and authority for disposition of nonconforming product.
- Review nonconforming product to ascertain if it *may* be:
 - Reworked to meet specifications,
 - Accepted with or without repair by concession,
 - Regraded for alternative applications, or
 - Rejected or scrapped.
- Report for concession the proposed use or repair to the purchaser or purchaser's representative, when required by contract.
- Describe the accepted nonconformity and, if repaired, record to denote the actual condition.
- Reinspect repaired and/or reworked product in accordance with a quality plan and/or documented procedures.

4.14 Corrective and Preventive Action

- Establish, document, and maintain documented procedures for implementing corrective and preventive action.
- Use *any* corrective or preventive action appropriate to the magnitude of the problems and commensurate to the risks encountered that will eliminate the causes of actual or potential nonconformances.
- Implement and record *any* changes in the documented procedures resulting from corrective or preventive action.
-

Have procedures for *corrective* actions that include:

- Effective handling of customer complaints and reports of nonconformities
 - Investigation of root causes of nonconformities and recording the results of the investigation
 - Determination of corrective action needed to eliminate the causes of the nonconformities
 - Applying controls to ensure that corrective action is taken and that it is effective
- Have procedures for *preventive* actions that include:
 - Using various and appropriate sources of information to detect, analyze, and eliminate potential causes of nonconformities
 - Determining the step needed to deal with any problems requiring preventive action
 - Initiating preventive action and applying controls to ensure it is effective
 - Ensuring that information on actions taken, including changes to procedures, is submitted for management review

4.15 Handling, Storage, Packaging, Preservation, and Delivery

- Establish, document, and maintain procedures for handling, storage, packaging, preservation, and delivery of product.
- Provide methods and means of handling that prevent damage or deterioration.
- Provide designated storage areas or stockrooms to prevent damage or deterioration of product, pending use or delivery.
- Provide appropriate methods for authorizing receipt and dispatch to and from designated storage areas.
- Check the condition of product stock at appropriate intervals to detect deterioration.
- Control packing, packaging, and marking processes to the extent necessary to ensure conformance to requirements.
- Take appropriate methods for preservation and segregation of product while it is under our control.
- Arrange for the protection of the quality of the product after final inspection and test, which may extend until product is delivered to destination.

4.16 Control of Quality Records

- Establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.
- Maintain all records that demonstrate conformance to specified requirements and the effective operation of the quality system.
- Extend protection to pertinent subcontractor quality records.
- Ensure that **all** quality records are legible and readily retrievable in a suitable environment that minimizes deterioration, damage, or loss.
- Establish and record the retention times of quality records.
- If contractually obligated, make quality records available to the customer or representative for an agreed-upon period.

4.17 Internal Quality Audits

- Establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the system.
- Base the audit schedule on the status and importance of the activity.
- Ensure that audits are carried out by persons independent of those having direct responsibility for the activity being audited.
- Ensure that results of audits are recorded and brought to the attention of the personnel having direct responsibility of the audited activity.
- Ensure that timely corrective action is taken on the deficiencies found during the audit.
- Perform the follow-up audit and record the implementation and effectiveness of the corrective action taken.

4.18 Training

- Establish and maintain documented procedures for identifying the training needs and provide the necessary training for **all** personnel performing activities affecting quality.
- Ensure that personnel performing specific tasks are qualified on the basis of appropriate education, training, and/or experience, as required.
- Maintain appropriate records.

4.19 Servicing (applies only when it is a specified requirement)

- Establish and maintain documented procedures for performing, reporting, and verifying that servicing meets the requirements.

4.20 Statistical Techniques

- Identify the need for statistical techniques required for establishing, controlling, and verifying process capabilities and product characteristics.
- Establish and maintain documented procedures to implement and control the application of the statistical techniques identified above.

Appendix B

Sample Internal Audit Checklist

TEST ORGANIZATION COMPOSITE CHECKLIST

Requirements _____

Audit No. _____

Audit Date(s) _____

Auditor _____

GENERAL QUESTIONS

- G1. What is your job? Do you have procedures for your job? Can I see them?
- G2. Do you follow the procedures?
- G3. Have you been trained in your job? Where are your training records?
- G4. How do you know that you are working to the latest revision on drawings, TPSs, WPDs, etc.?

4.1 MANAGEMENT RESPONSIBILITY

- a. Do you understand the quality policy? What are its main points?

4.2 QUALITY SYSTEM

- a. What is the Quality System? Are you familiar with WSTF's document pyramid?

4.3 CONTRACT REVIEW

- a. What is your role in customer agreement review?
- b. How is it ensured that requirements differing from original agreements are resolved?

4.4 DESIGN CONTROL

- a. How are design input requirements identified?
- b. How is compliance with specifications and customer requirements ensured?
- c. How is verification of design performed?
- d. What has been done to ensure design resources are suitable and available?

4.5 DOCUMENT AND DATA CONTROL

- a. How do you know you are using the latest issue of the document and not an obsolete one?
- b. When a document is revised, who is responsible for the revision?

4.6 PURCHASING

- a. Do purchase documents clearly describe the product being ordered?

4.7 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

- a. How is material identified and protected from unauthorized use or improper disposal?
- b. What is the procedure if the material is lost or damaged?
- c. How are special handling considerations identified?

4.8 PRODUCT IDENTIFICATION AND TRACEABILITY

- a. What system is used to identify and trace a product from the time it arrives on site to the time it is delivered to the customer?
- b. If a product is rejected, could its origins be traced?
- c. How and where are traceability records of your test reports maintained?

4.9 PROCESS CONTROL

- a. What documented work instructions exist, how are they controlled, and are they understood and available?
- b. What maintenance is required for test systems and support equipment?
- c. How are quality-sensitive areas identified and defined?
- d. How are special processes identified and controlled?

4.10 INSPECTION AND TESTING

- a. How is incoming product (test article) identified?
- b. How is it ensured that an incoming product or test article is checked to and conforms with specification (e.g., copy of order and specifications)?
- c. How is material identified if it is used for operations before inspection approval?
- d. What methods of in-process monitoring and control are in operation?
- e. How are inspection stages specified and documented?

- f. How are nonconformances identified, and are they removed from the process flow?
- g. Is the finished product subject to final inspection and testing?
- h. Is evidence of conformance to specification generated during the final inspection?
- i. How is the satisfactory completion of all testing and inspection recorded and verified?

4.11 CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

- a. How is test and measuring equipment controlled, calibrated, and maintained?
- b. How is it ensured that equipment used is suitable for the accuracy and type of measurement required in its application?
- c. How is the calibration status of equipment known?
- d. Who checks the validity of previous data if equipment is found out of calibration?
- e. How is accuracy and fitness of test equipment maintained?
- f. What precautions are taken to safeguard equipment subject to adjustment which would invalidate the calibration interval?
- g. How is equipment recalled for calibration or inactivation when its interval has expired?

4.12 INSPECTION AND TEST STATUS

- a. How is the inspection status of a product (test article or support equipment) identified?
- b. Can times and places of inspection/test be traced?

4.13 CONTROL OF NONCONFORMING PRODUCT

- a. How is a material identified as nonconforming prevented from inadvertent use?
- b. How are all nonconformities recorded?
- c. Who has the authority for dispositioning nonconformities?

4.14 CORRECTIVE AND PREVENTIVE ACTION

- a. How is the cause of nonconformity established?
- b. What action is taken to prevent recurrence?
- c. How are preventive actions implemented?

4.15 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

- a. Does documentation exist to cover handling, storage, packaging, preservation, and delivery?

4.16 CONTROL OF QUALITY RECORDS

- a. What records show objective evidence of inspection and test, process control, process qualification, maintenance, design verification, or training?
- b. What instructions are used for record retention? How long do you keep them?

4.18 TRAINING

- a. How are training requirements identified?
- b. What records are kept? Where are they kept?

4.20 STATISTICAL TECHNIQUES

- a. When are statistical techniques used?

4.21 SOFTWARE (AUGMENTATION)

- a. What type of work-authorizing document initiates software development and where is it located?
- b. Are design requirements reviewed before programming begins? By whom?
- c. How is software validated and verified before use?
- d. Describe your software configuration control process.
- e. Does software go through a final inspection? How is this documented?

Appendix C

Quality System Registrars

The following registrars have been accredited through the American Accreditation Program for Registrars of Quality Systems, a joint program of the American National Standards Institute (ANSI) and the Registrar Accreditation Board (RAB) (Rubach 1995).

ABS Quality Evaluations, Inc.

Dee Elliot
16855 Northchase Drive
Houston, TX 77060-6008
Telephone: 713-873-9400, Fax: 713-874-9564

A.G.A. Quality, A Service of International Approval Services

Daryl Parker
8501 E. Pleasant Valley Road
Cleveland, OH 44131
Telephone: 216-524-4990, Fax: 216-642-3463

American Association for Laboratory Accreditation

Peter S. Unger
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Gaithersburg, MD 20878-1409
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American Quality Assessors

Frank Degar
1200 Main Street, Suite M107
Columbia, SC 29201
Telephone: 803-779-8150, Fax: 803-779-8109

American Society of Mechanical Engineers

David A. Wizda
345 East 47th Street - 39W
New York, NY 10017
Telephone: 212-705-8590, Fax: 212-705-8599

AT&T Quality Registrar

John Malinauskas
650 Liberty Avenue
Union, NJ 07083
Telephone: 908-851-3058, Fax: 908-851-3360

AV Quallte

Ms. Terry Heaps
2900 Wilcrest, Suite 300
Houston, TX 77042
Telephone: 713-465-2850, Fax: 713-465-1182

Bellcore Quality Registration Services

Edward M. Barabas
6 Corporate Place
Piscataway, NJ 08854
Telephone: 908-699-3739, Fax: 908-336-2244

Bureau Veritas Quality International (NA) Inc.

Greg Swan
509 North Main Street
Jamestown, NY 14701
Telephone: 716-484-9002, Fax: 716-484-9003

Davy Registrar Services, Inc. (DRS)

Leroy W. Pfennigwerth
One Oliver Plaza
Pittsburgh, PA 15222-2604
Telephone: 412-566-3086, Fax: 412-566-5290

Det Norske Veritas Certification, Inc.

Yehuda Dror
16340 Park Ten Place, Suite 100
Houston, TX 77084
Telephone: 713-579-9003, Fax: 713-579-1360

DLS Quality Technology Associates, Inc.

Roco Lupo
Duane Dodge
108 Hallmore Drive
Camillus, NY 13031
Telephone: 315-468-5811, Fax: 315-468-5811

Entela, Inc., Q.S.R.D.

William Vosburg
3033 Madison, S.E.
Grand Rapids, MI 49548-1289
Telephone: 616-247-0515, Fax: 616-248-9690

Global Registrars, Inc.

(formerly Tri-Tech Services)
Joseph Fabian
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Pittsburgh, PA 15236
Telephone: 412-884-2290, Fax: 412-884-2268

HSB Registration Services

Jill Bellino
One State Street, P.O. Box 5024
Hartford, CT 06102-5024
Telephone: 203-722-5294, Fax: 203-722-5530

Inchcape Testing Services Intertek Services Corporation

James P. O'Neil
313 Speen Street, Suite 200
Natick, MA 01760
Telephone: 508-647-5147, Fax: 508-647-6714

KEMA-Registered Quality, Inc.

H. Pierre Salle
4379 County Line Road
Chalfont, PA 18914
Telephone: 215-822-4258, Fax: 215-822-4285

Kemper Registrar Services, Inc.

Bryce E. Carson, Sr.
Plaza One Building, Suite 305
1 State Hwy. 12
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Telephone: 908-806-7498 or 1-800-555-2928
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KPMG Quality Registrar

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Litton Systems Canada Limited Quality System Registrars

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OMNEX Automotive Quality Systems Registrar, Inc.

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Performance Review Institute Registrar

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Perry Johnson Registrars, Inc.

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SGS International Certification Services, Inc.

Lois O'Brien
Meadows Office Complex
301 Route 17 North
Rutherford, NJ 07070
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Fax: 201-935-4555

Steel Related Industries Quality System Registrar

Peter B. Lake
2000 Corporate Drive, Suite 330
Wexford, PA 15090
Telephone: 412-934-9000, Fax: 412-935-6825

TRA Certification, A Division of TR Arnold & Associates, Inc.

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Elkhart, IN 46515
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REFERENCE

Rubach, Laura and editorial staff. *Quality Progress Eighth Annual QA/QC Services*. Quality Progress, August 1995.

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Appendix D

Brief Glossary of Terms

The following is basic terminology related to ISO 9001. Specific WSTF documents expand on the definitions provided in this glossary.

Audit (ISO) - A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Auditee - An organization being edited.

Auditor - An individual trained and qualified to perform audits.

Certification - Documented proficiency to a recognized standard.

Conformity - The fulfillment of specified requirements.

Constraint - A state, quality, or event which will limit or restrict continued or future operations or testing.

Continuous Quality Improvement - The WSTF application of Total Quality Management principles.

Corrective Action - An action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation to prevent recurrence.

Customer Agreement - The documented agreement between WSTF and the customer establishing the requirements of the operations and the products to be supplied. This terminology is used rather than *customer contract* since the government generally does not enter into contracts to supply customers with a service.

Customer-Supplied Product - Product supplied by a customer for the purpose of fabrication, testing, storage, disposal, analysis, and/or refurbishment.

Design Review - A review focusing on the ability to meet customer and site requirements.

Design Validation - The process of confirming that the requirements for an activity have been fulfilled.

Design Verification - The process of confirming the customer design requirements for a process have been met.

Deviation - A documented departure from approved instructions. Deviations may be temporary or permanent.

Discrepancy - A nonconformance that prevents the item from meeting the required specification or performance requirement.

Disposition - Resolution directing a final action to correct or accept an anomaly or discrepancy.

Finding - A documented nonconformance identified during an audit and substantiated by objective evidence.

Management Review (ISO) - A formal evaluation by top management of the status and adequacy of the quality system in relation to quality policy and objectives.

Master List - An index maintained by a repository for a specific type of document; it will contain control information such as document numbers, issue versions or dates, and titles.

Nonconformance - A condition of a product in which one or more characteristics do not conform to requirements, including failures, discrepancies, defects, and malfunctions.

Objective Evidence - Information which can be proved based on facts obtained through observation, measurement, test, or other means.

Observation - An inference that a deviation from documented requirements has occurred or potentially will occur but for which there is no objective evidence at the time.

Preventive Action - An action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation to prevent occurrence.

Process - A set of interrelated resources and activities that transforms inputs into outputs.

Process Map - A schematic representation of a process or set of related processes.

Product - The intended result of activities or processes; products may include hardware, software, processed material, data, service, or a combination thereof.

Quality (ISO) - The totality of characteristics of an entity that bear on its stated ability and implied needs.

Quality Function - Review and oversight that ensures adequate product control of all product-related WSTF operations.

Quality Planning - The activities that establish the objectives and requirements for quality and for the application of quality system elements.

Quality Record - A record that demonstrates conformance to specified requirements and the effective operation of the quality system.

Quality System - The WSTF organizational structure, responsibilities, procedures, processes, and resources needed to implement quality management.

Quality System Manual - The document that provides WSTF quality policies and describes the WSTF quality system.

Record - A document that furnishes objective evidence of activities performed or results achieved.

Root Cause - The underlying reason for, or cause of, nonconformances that, when corrected, will prevent or reduce the chance of recurrence of nonconformances.

Special Processes - Processes with results that cannot be fully verified by subsequent inspection and testing of the product, and where processing deficiencies may become apparent only after the product is in use; i.e., crimping, soldering, and welding.

Traceability - The ability to trace the history, application, or location of an entity by means of recorded identifications.

Transition Document - An active document written in an obsolete format that will be used as is until revised.

Verification - Evidence that specified requirements have been met.

Waiver - A written authorization to use or release a product that does not conform to the specified requirements or deviates from documented policies or procedures.