Quality Assurance Program Plan

This Quality Assurance Program Plan provides an overview of the Laboratory's program to address the regulations contained in the most current revision of 10 *CFR* 830 Subpart A, *Quality Assurance.*

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1.0 REVISION/REVIEW LOG

This document will be reviewed annually.

Revision Number	Effective Date	Contact Person	Pages Affected	Description of Revision
0	10/01/01	Sordelet	All	Original
1	11/15/01	Sordelet	See Revision Description	G:\Doc&Recs\DCP\RevisionDescription\ plan10200.026QAP_rev1.doc
2	1/24/03	Sordelet	All	No Changes Required
3	1/24/04	Sordelet	All	No Changes Required
4	1/24/05	Sordelet	See Revision Description	G:\Doc&Recs\DCP\RevisionDescription\ plan10200.026QAP_rev4.doc
5	1/17/06	Sordelet	See Revision Description	G:\Doc&Recs\DCP\RevisionDescription\ plan10200.026QAP_rev5.doc

2.0 INTRODUCTION

The Laboratory's Quality Assurance Program (QAP) Plan describes how the quality assurance criteria of 10 CFR 830 Subpart A are addressed. The QAP is designed to be implemented in a manner that provides reasonable assurance of adequate protection of workers, the public, and the environment from adverse consequences, taking into account the work to be performed and the associated hazards. Section 3.0 of this QAP plan briefly describes the integration of quality assurance criteria with the Laboratory's Integrated Safety Management System (ISMS) and how the quality assurance criteria apply to the ISMS. The issue of applicability and use of voluntary consensus standards by the Laboratory's Quality Assurance Program is addressed in section 4.0. Section 5.0 describes Ames Laboratory's utilization of the graded approach concept. Section 6.0 presents the Laboratory's Quality Assurance Program implementation of the criteria in 10 CFR 830 Subpart A.

3.0 INTEGRATED SAFETY MANAGEMENT SYSTEM

The Ames Laboratory's Integrated Safety Management System is built upon processes and mechanisms designed according to the principles of quality assurance. Ames' ISMS is a fundamental Plan-Do-Check-Act cycle system. The primary mechanisms of the Laboratory's ISMS include Readiness Review, Needs Assessment Procedure, Training, Program/Department Walk Throughs, and Independent Walk Throughs. All of these mechanisms were developed as part of the Laboratory's quality assurance program and are fully integrated with the Laboratory's safety efforts. In addition, other processes and mechanisms supportive to the Laboratory's ISMS have been integrated with the functions and principles of ISM. All ISMS related processes and mechanisms are designed and reviewed to ensure that safety is considered as a quality component of the planning and performance of Ames Laboratory work. This Quality Assurance Program plan and the Laboratory's ISMS are consistent in their description of the function of the Laboratory's work processes and mechanisms.

4.0 VOLUNTARY CONSENSUS STANDARDS

The development of this QAP plan is based on the criteria as defined in 10 CFR 830 Subpart A. Where necessary and applicable the implementation of the QAP is supported by additional guidance as provided in DOE G 414.1-2A, and ANSI/ASQ Z1.13-1999.

5.0 GRADED APPROACH

The graded approach concept refers to the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with characteristics related to an activity. These characteristics include relative importance to safety, safeguards and security, magnitude of hazard involved, life cycle stage of a facility, programmatic mission of a facility, characteristics of a facility, relative importance of radiological and non-radiological hazards and other relevant factors.

Ames Laboratory utilizes the graded approach concept for the application of radiological requirements, standards and guidance due to the type and level of activities involving radiological hazards at the Laboratory. Ames Laboratory does not apply requirements uniformly across all activities. To do so would not necessarily add value or reduce risks and could be an ineffective allocation of resources.

Ames Laboratory has implemented a plan-do-check-act cycle based, Integrated Safety Management System (ISMS) mechanism known as the readiness review process, with participation from line management and safety, engineering and facility specialists, to determine the hazard level of activities. Three hazard levels of activities exist at Ames Laboratory. These levels are differentiated based on the magnitude (seriousness of potential harm) and scope (area of effect) of the hazard as well as the risk (realistic potential for the hazard to have an impact of a particular scope and magnitude) involved. Generally typical office activities are classified as Hazard Level I, and most experimental research activities and support activities are Hazard Level II. Very few Ames Laboratory activities are characterized as Hazard Level III. The readiness review process includes a determination of an activity's hazard level based on a hazard identification process. An activity's hazard level is used to determine the degree of formality, rigor and documentation of the requirements applied to the activity.

6.0 PROGRAM ELEMENTS – Quality Assurance Criteria

The Laboratory's Quality Assurance Plan addresses the following management, performance and assessment criteria.

6.1 Criterion 1 - Program

6.1.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
(2) Establish management processes, including planning, scheduling, and providing resources for the work.

6.1.2 Program Information

The Laboratory's organizational and management system is designed to accomplish its mission properly and safely. The mission and organizational structure are detailed in the Ames Laboratory Institutional Plan (http://www.ameslab.gov). Specific expectations are communicated through the U.S. D.O.E. Contract W-7405-ENG-82, including DOE Directives and Ames Laboratory Work Smart Standards Set. The following is a brief mission statement.

Ames Laboratory effectively focuses diverse fundamental and applied research strengths upon issues of national concern, cultivates tomorrow's research talent, and develops and transfers technologies to improve industrial competitiveness and enhance U.S. economic security. At the forefront of current materials research, high-performance computing, and environmental science and management efforts, the Laboratory seeks solutions to energy-related problems through the exploration of physics, chemistry, engineering, applied mathematics and materials sciences. All operations are conducted so as to maintain the health and safety of all workers, and with a genuine concern for the environment.

The Laboratory utilizes a distinct and unified management and organizational system, supplemented by documented requirements, to establish clear and defined roles, responsibilities and authorities. The organizational structure includes an Executive Council consisting of the Director, Deputy Director, Science and Technology Division Director, Technical and Administrative Services Division Director and the Industrial Outreach and Technology Administration Manager. Several independent offices, including the Internal Auditor and the Environment, Safety, Health and Assurance (ESH&A) office report to the directorate. The Technical and Administrative Services Division includes administrative and operations support departments. The Science and Technology Division includes all research program offices. Research programs are made-up of multiple research groups and administrative sections. Additional organizational reporting is primarily of the supervisory type.

Roles and responsibilities are primarily documented through position description and information questionnaires as part of the hiring process and additional definition of roles and responsibilities provided through process documentation. Every employee is responsible for achieving quality performance in her or his activities. Line management is accountable for work performance and implementation of the management system. Periodic performance evaluations are conducted to document individual performance. The Laboratory utilizes its management and organizational system, supplemented by formalized institutional planning, readiness review and budgeting processes to direct the planning, scheduling, resource allocation and performance of work at the Laboratory.

6.2 Criterion 2 - Personnel Training and Qualification

6.2.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Train and qualify personnel to be capable of performing their assigned work.
(2) Provide continuing training to personnel to maintain their job proficiency.

6.2.2 Program Information

The Laboratory's Hiring Process ensures that personnel are qualified to carry out their assigned duties. Qualifications for each job position are documented in a job description and further detail is listed in the position's Position Information Questionnaire or Position Description Questionnaire. The hiring supervisor is responsible for completing a Hazard Inventory (HI) and Job Task Analysis (JTA) for the open job. Candidates are required to furnish information on their education, professional experience and other credentials, which demonstrates their ability to perform the required duties and responsibilities. Interviews are conducted to verify competency and a candidate is selected which best matches the skills needed for the position. In addition, performance appraisals are conducted to ascertain if the employee would benefit from additional training to perform their current job activities. Training to improve the quality of work is considered when reviewing the individuals' Employee Training Profile (ETP) during the performance appraisal process.

The Laboratory's Training Program provides employees with the training necessary for the safe and productive completion of their work responsibilities. A primary emphasis is placed on the fulfillment of Environment, Safety, and Health (ES&H) training requirements. The foundation of the Training Program is the Needs Assessment Process, which identifies training requirements and needs for Laboratory employees. Subject Matter Experts (SMEs) provide training from various disciplines. Course evaluations are also obtained to continually improve the training elements. Employee training participation in relation to mandatory job requirements is tracked through the Ames Laboratory Training Records System (ALTRS).

The Training Program focuses on the following core activities: Needs Assessment Program; Institutional Training Modules; Module Development; Job (Activity) Specific Training; and Training Records Management.

<u>Needs Assessment Program</u>
The Needs Assessment Program is a joint effort between Human Resources, Occupational Medicine, and Environment, Safety, Health and Assurance (ESH&A). The Needs Assessment Program provides a mechanism to identify hazards, training needs, and job task elements. The identification of hazards and job task elements are identified on a Hazard Inventory/Job Task Analysis Packet. Once an employee is hired, their training needs are determined by the completion of a Training Needs Questionnaire (TNQ). The results of the TNQ are provided to the employee and their supervisor on an Employee Training Profile (ETP). To ensure that training needs are continuously addressed, ETPs are mailed to evaluating supervisors on an annual basis at performance appraisal time.

Institutional Training Modules

Institutional Training Modules are formally coordinated and tracked by the Laboratory's Training Office. Employees are triggered for certain institutional training based upon the activities that they will be performing. General Employee Training (GET) is a mandatory training module for new Ames Laboratory employees that provides employees with an understanding of the Laboratory's organization structure, policies and procedures, general safety policies and covers several other ES&H aspects.

Module Development

Institutional modules shall be presented by Subject Matter Experts (SME's) utilizing training lesson plans. Institutional modules have various formats including classroom instruction, video, examination and computer based training (CBT). Once a module has been reviewed and approved, an identification question is added to the TNQ to ascertain if the module is mandatory, suggested or elective for a particular employee or work position. Training modules are reviewed by incorporating feedback from trainees, updated regulations, and reviews of other agencies training materials.

Job (Activity) Specific Training

The employee's Program/Department and/or Group/Section shall provide Job (Activity) Specific Training based upon the employee's specific work. This training includes a review of the Group/Section's policies and procedures along with hands-on training for specialized equipment. It is not necessary that instruction be given according to formal lesson plans; however, the Group/Section Leader must maintain accurate operator aids, procedures, or manufacturer equipment manuals.

Training Records Management

Institutional training records are maintained both electronically and manually. The Ames Laboratory Training Records System (ALTRS) is utilized to keep training records electronically. ALTRS is accessed to continually review and delineate employees who are in need of an initial training or retraining. In addition to the electronic training records, hard copy attendance records are maintained in the employee's Official Personnel Training File.

6.3 Criterion 3 - Quality Improvement

6.3.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Establish and implement processes to detect and prevent quality problems.
(2) Identify, control, and correct items, services, and processes that do not meet established requirements.
(3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.
(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

6.3.2 Program Information

The Laboratory instituted many formal continuous improvement programs as a result of Tiger Team Corrective Action Plans and the implementation of the Quality Assurance Order (DOE Order 5700.6C) and the revised Quality Assurance Order 414.1C. All of the Laboratory's quality areas were strengthened including, Management Planning, Training, Design, Procurement, Inspection & Acceptance Testing, Documents and Records, and Assessments. The Laboratory continues to enhance many of its programs and systems to support the principles and core functions of Integrated Safety Management. Continuous Improvement efforts are discussed for the scientific process and for the Laboratory's operational areas.

Continuous Improvement within the Scientific Process

The steps to ensure the continuous improvement of research in a diverse research environment include selection of highly qualified and motivated people, the conduct of research, and the review of results by independent, competent peers. The primary mechanisms for assuring quality in research are discussed below.

Selection of the Researchers
Researchers are selected by conducting national searches, contacting references and performing comprehensive interviews. The candidate's education, experience and scientific expertise assure quality research. In addition, graduate students contribute significantly to the research efforts at the Laboratory. The University academic department screens these individuals as part of the admission process.

Conduct of Research
The primary responsibility for the proper conduct of the research lies with the Program Director and the Group Leader. They are responsible for planning and preparing the research proposal. The proposal includes a discussion of the experimental work, provides a historical overview, and describes the research methodology, resource requirements, scheduling milestones, and funding needs. In addition, the researcher utilizes several quality assurance mechanisms during this planning and preparation phase of the research. First, all researchers are critically knowledgeable of their particular research area. Attending conferences and meetings, as well as, collaborating on a continuous basis with peers internally and externally to the Ames Laboratory accomplishes this goal.

Second, the researcher will always perform an extensive literature search to keep abreast of what is known about a particular subject and what continues to be debated. Finally, a researcher may also decide to perform preliminary exploratory experiments to test a novel hypothesis prior to preparing the research proposal and performing a formal investigation.

Peer Review

The quality of research is assessed by the Peer Review Process and by oversight by the sponsoring organization. The research work is presented at national and international technical meetings. These presentations provide opportunity for feedback from individuals who have contributed to the body of knowledge within the technical discipline being discussed. In addition, a program review process is in place for most of the scientific programs. Generally, a group of external reviewers is selected by Laboratory management to conduct the review. Reviewers present their findings, both verbally and in writing, to the Program Director and Laboratory management. The nature of the input includes an evaluation of the correctness of the scientific approach, importance of the topic, and appropriateness to the character of the institution and the needs of the nation. An additional part of the review is the subject of new directions in which the Laboratory should extend its efforts to maintain a balanced program.

Continuous Improvement for Laboratory Operations

The continuous improvement activities discussed below, provide for continuous incremental improvements and support the philosophy of Integrated Safety Management.

Employee Concerns Program

Ames Laboratory requires employee involvement in the environment, safety & health program implementation. The Employee Concerns Program was implemented to encourage comments, opinions, and recommendations for the continuous improvement of Ames Laboratory work practices. ESH&A formally evaluates each concern and facilitates any corrective actions. Employee concerns are tracked and trended each year.

Lesson Learned

Internal and external Lesson Learned are distributed to all Ames Laboratory employees via the Laboratory's internal web page. This information is utilized to continuously review activities, including associated training, documentation, and the work process itself.

Safety Coordinator/Representative Program

Safety Coordinators and Safety Representatives represent the Program Directors/Department Managers and Group/Section Leaders at specialty training sessions and meetings in order to compliment the transfer of written information to the organizations and to serve as facilitators of safety related actions.

Readiness Review Process

All new or significantly modified activities shall undergo a Readiness Review. The review shall identify the hazards associated with the activity and a hazard management statement shall document how the hazards will be mitigated. The rigor of the Readiness Review shall be commensurate with

the degree of risk associated with the activity. Further information on this process is presented in section 6.5.

Needs Assessment Program

The Needs Assessment Program provides a mechanism to identify hazards, training needs, and job task elements. The program helps ensure that each employee has the physical capability of performing their job and identifies appropriate training modules so that they may perform the job safely and effectively. Employees and their supervisors formally review identified training (Employee Training Profile) on an annual basis. Further information on this program is presented in section 6.2.

Purchases/QA Inspection System

The Quality Assurance Inspection System is a process where purchased items with a higher associated risk are reviewed by a technical expert. The expert ensures that the goods meet the required specifications of the Laboratory and the requestor. To implement this process the Laboratory's Purchasing Office codes all purchased items. Items with selected codes (higher risk items) are then reviewed on a regular basis by the Engineering Services Group to ensure that safety & health issues are addressed. Coded items not reviewed by Engineering Services (except those exempted in section 6.72, see "Signature Approval Process") are reviewed by the requestor and must meet their established acceptance criteria.

Also, a physical review of purchases is performed by warehouse employees to prevent the acceptance or distribution of goods with any noticeable nonconformance from stated criteria, e.g., general item description, shortage, overage or damage. Such deliveries shall be held on-site until clarification/ authorization is received from the requestor. However, formal acceptance, according to required specifications is the responsibility of the end user and requestor of the goods.

Assessment Program

The Laboratory Assessment Program consists of Worker Observations, Program/Department Walk-Throughs, Independent Walk-Throughs, and external assessments. In addition, the Laboratory conducts a detailed Self-Assessment annually including Contract performance measures. All concerns that result from these assessments are tracked, closed-out, and verified in accordance with their assigned risk level. Further information on these assessment elements is presented in Sections 6.9 and 6.10.

6.4 Criterion 4 - Documents and Records

6.4.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
(2) Specify, prepare, review, approve, and maintain records.

6.4.2 Program Information

The Documents and Records Program provides for the creation, maintenance and use, and final disposition of all Laboratory records. The "creation" phase addresses the importance of a strong Document Control Program. The Document Control Program ensures that work-governing documents are approved, current, accurate, readily available, and document changes are properly reviewed, approved and disseminated. The "maintenance and use" phase requires that all inactive records are removed from high-cost office storage space and are indexed for easy retrieval. A successful program is founded on knowing what information is available and where it is located. Once records are electronically indexed, decisions can be made regarding the series disposition date, informational value, and how they can be managed until their final disposition. In the final phase, "disposition" records shall be secured and protected until they can be cleared for final destruction. The Documents and Records Program's core activities include the Document Control Program; the maintenance, storing, and protecting of inactive records; and a sound Vital Records Program.

Document Control Program
The Document Control Program utilizes Documentation Procedures to aid in the formalization and consistency of plans, policies, procedures, forms, handbooks, and guides that impact at the Laboratory level. Employees charged with drafting documentation receive assistance from Environment, Safety, Health and Assurance (ESH&A) on the proper formatting, approval, and registration actions needed to create Laboratory impacting documentation. ESH&A provides a document review function to ensure consistency and submits documents for final approval signatures. Documents are registered and tracked on a Document Control Program Database.

Maintenance, Storage, and Protection
Maintenance, storage, and protection of records are primarily accomplished by the use of an electronic database (Versatile) and storage within the Lab's Record Holding Area (RHA). Active records are adequately protected on-site by the Laboratory's Access Security Controls and Fire Protection Program. Inactive records are stored in the RHA, which was renovated to meet the requirements of 36 CFR 128.222 (Facility Standards for Record Centers). Records placed in the RHA are secured and access limited. All records of the Ames Laboratory are unclassified.

Vital Records Management Program
The Vital Records Management Program has been implemented to protect and access Emergency Operating Records and Rights and Interest Records. The Laboratory's personnel roster and financial information are protected on a daily backup tape. Research Notebooks issued after 1984, inactive Official Personnel Files after 1993 and all inactive employee medical records have been microfilmed.

6.5 Criterion 5 - Work Processes

6.5.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.
(2) Identify and control items to ensure their proper use.
(3) Maintain items to prevent their damage, loss, or deterioration.
(4) Calibrate and maintain equipment used for process monitoring or data collection.

6.5.2 Program Information

Ames Laboratory management identifies the space, activities, and personnel for which Programs/Departments have management responsibilities. Programs/Departments, in turn, have assigned responsibilities to Group/Section Leaders. The Group/Section Leaders monitor and manage the day-to-day performance of activities and therefore are best suited to identify and manage the hazards associated with the activities for which they are responsible.

Since each individual is responsible for the quality of her/his own work, she/he needs to have clearly assigned authorities, roles, and responsibilities. Group/Section Leaders utilize work instructions to clearly communicate the requirements and hazards associated with activities.

Readiness Review of Activities
The Ames Laboratory has developed a set of requirements, supported by procedures and assessed through independent review, to ensure that activities have achieved operational readiness. The level of independence of review and the rigor of application of the requirements for work processes are commensurate with the degree of risks associated with the activities.

The requirements detailed in the following paragraphs include the identification, hazard categorization, and readiness review of activities. Group/Section Leaders shall identify activities for which they have management responsibilities and clearly assign authorities, responsibilities, and accountabilities to other members of the Group/Section. An activity is one or several action(s), process(es), and/or equipment, coordinated to perform a task. Generally, it is recommended that an activity be defined to cover classes of actions, processes and/or equipment. An activity should include the most potentially hazardous conditions that could be encountered. The identification of ES&H hazards associated with activities is accomplished by utilizing a checklist of potential environmental, safety, and health concerns. A description of the identified hazards and the engineering, administrative and personal protective equipment controls associated with the management of the concerns shall be documented. All activities are categorized into one of three ES&H Hazard Levels.

Ames Laboratory activities are classified as Laboratory/Industrial Type and Office Type. Examples of Laboratory/Industrial Type Activities include: basic and applied experimental research, production, maintenance, fabrication, construction, hazardous waste handling, and warehouse

shipping and receiving activities. Examples of Office Type activities include theoretical research, computational, design, and administrative activities. All Laboratory/Industrial Type activities shall undergo Readiness Review by the Group/Section Leader, the Program Director/Department Manager, occupational medicine, facilities services, engineering services and the ESH&A office. Hazard Level II and Level III Activities require a final approval, which is granted by the Safety Review Committee (SRC).

Activities that undergo a modification are also subject to Readiness Review if the modification significantly alters the hazards associated with the activity or if the risk associated with a particular hazard is increased. An example of when the risk associated with a hazard has increased is the scale-up of an activity when larger quantities or a different class of hazardous chemical are to be used. Office Type Activities are not required to undergo Readiness Review in addition to reviews by the Group/Section Leader. Activities are also reviewed five (5) years after the last approval date via the Readiness Review procedure. On an annual basis, ESH&A provides Group/Section Leaders with a comprehensive listing of their existing activities so that it can be reviewed for accuracy and can be modified as needed.

Control of Items

Items are generally considered devices, tools and equipment; but can include hardware, samples, software, data or quality impacting consumables, e.g., chemicals, etc. Items should be identified and controlled to ensure their proper usage. The responsibility to prevent the usage of incorrect and defective items is assigned to the organizational unit with ownership or custodianship of the items.

Maintenance and Protection of Items and Equipment

The planning and performance of the maintenance and protection of items and equipment is the responsibility of the organizational unit with ownership or custodianship of the items or equipment. Facility infrastructure system items and equipment are maintained and protected through processes supported by Laboratory-wide services. Items and equipment utilized as part of specific group/section activities are maintained according to requirements of the item or equipment as interpreted by the specific group/section.

Calibration of Equipment

The Ames Laboratory Group/Section Leaders are charged with the responsibility of assuring that Measuring and Test Equipment is of proper type, accuracy, and tolerance to accomplish the specified requirements.

Items shall be calibrated and adjusted at specified periods to maintain accuracy within necessary limits and shall have known valid traceable relationships to nationally recognized standards or the documented procedure of an Ames Laboratory expert. Calibration standards shall be traceable to four levels: 1) calibrated and traceable to a National Institute of Standards and Technology (NIST) Standard; 2) calibrated and traceable to a Laboratory Standard; 3) calibrated and traceable to a comparable piece of equipment or instrumentation which is traceable to a NIST or Laboratory Standard; and, 4) calibrated to a known sample. The frequency of calibration shall be directly dependent upon the equipment's required accuracy, intended use, frequency of use, stability characteristics and how it influences the quality of an item's characteristics.

6.6 Criterion 6 - Design

6.6.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Design items and processes using sound engineering/scientific principles and appropriate standards.
(2) Incorporate applicable requirements and design bases in design work and design changes.
(3) Identify and control design interfaces.
(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.
(5) Verify or validate work before approval and implementation of the design.

6.6.2 Program Information

The design activities of the Ames Laboratory are primarily the responsibility of the Engineering Services, Facilities Services and Information Systems departments. Facilities Services engineers primarily perform design activities related to the Laboratory facilities. Design engineers and specialists are qualified by their educational degrees and/or experience and receive on-going professional development training as necessary.

The Design processes core activities include, Design Requirements, Design Standards, Design Verification, Design Approval and Validation, Documentation of Design and Design Changes.

Design Requirements
The requester establishes a set of functional design requirements. Generally, these requirements are specified on a Service Order Requisition (SOR). The SOR is utilized to control and document the planning and development of design and fabrication activities with the service departments. Complex SORs with significant hazards are reviewed by safety specialists and they are also reviewed for any potential safety impact for the requestor and/or the service provider. If the SOR describes a major engineering project requiring design then a Work Order (WO) or Job Order (JO) is prepared by Engineering Services. In addition, new or significantly modified activities require a formal Readiness Review. Simpler requests may just need to be reviewed by the requestor. The review process is commensurate with the scope of the activity and helps to ensure that all safety aspects are addressed prior to performance of the task.

Design Standards
The designer utilizes the functional design requirements outlined in the SOR and builds on this information. The qualified designer or drafter prepares a formal design utilizing national codes and standards. Under design control, the project engineer/designer assumes additional responsibilities including: generation of preliminary plans, specifications, initial cost estimates, and project description; assuring performance to specification of the final product; cost control on the work order/job order; timely procurement of all materials or parts; completion of the design; project scheduling, project status tracking, setup and delivery of the final product; and documentation/ generation of final as-built specification drawings. An electronic Computer Aided Design (CAD)

monitoring system rigidly enforces methodology by automatically tracking a project through the design CAD system in proper design sequence.

Design Verification

The Project Engineer/Designer is the staff member most knowledgeable about the particular project. Once the design package is prepared another Project Engineer/Designer provides an independent review and the rigor of the review is commensurate with the complexity or hazards associated with the system. If the project requires a team review then the team includes all the disciplines needed to accurately evaluate the design package. All projects requiring welding shall be reviewed to determine if the nature of the work requires that the welding must be performed as part of the Certified Welding Program. The review report either recommends approval of the design package or identifies issues to be resolved.

Design Approval and Validation

Final designs, field changes, and modifications shall be approved by the original design organization or a technically competent designee and shall be translated into specifications and drawings. Once the system is established in accordance with the approved design then the system is actually tested to ensure it conforms to all requester and design requirements.

Documentation of Design

A project file folder is created for each project requiring $2000 or more of service work effort. Design and fabrication project correspondence including copies of purchase orders for procured parts are contained or referenced in the project file. In addition, a Quality Assurance Document Record will be attached to each project folder to assure the proper routing of a project through design, fabrication, testing, and delivery. Design notes on any significant design and/or fabrication field changes, provides additional documentation in the project file folder.

Design Changes

The Project Engineer/Designer controls design changes. Simple changes may only require authorization from the Project Engineer. However, significant changes shall require a justification in writing and an analysis shall be made to ensure that the modified design meets the new design requirements. The Project Engineer is responsible for documenting changes via notes in the project file folder for future incorporation as needed into the as-built specifications and drawings.

6.7 Criterion 7 - Procurement

6.7.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Procure items and services that meet established requirements and perform as specified.
(2) Evaluate and select prospective suppliers on the basis of specified criteria.
(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

6.7.2 Program Information

The purpose of the procurement process is to procure material, equipment, and services consistent with sound, ethical business practices and applicable regulations and to provide timely, cost effective, quality products to Ames Laboratory customers. Materials and equipment with a nuclear safety concern shall have a procurement package that specifies the requirement for the inspection of records and materials along with a documented QA program.

The procurement processes core activities include procurement requests, sourcing/qualified suppliers, subcontractors, signature approval process, quality assurance inspection system, and receipt inspection.

Procurement Requests
Procurement activities shall be planned and documented to assure a systematic approach to the procurement process. Requestors prepare purchase requisitions that include suitable specifications, standards, and/or purchase descriptions that clearly and accurately describe the items that are being requested. Buyers assist in the preparation of specifications when assistance is needed. The purchase requisition shall contain a justification for the purchase of the item or service and shall contain a valid account code to cover the associated costs. The Purchasing Office also issues Purchasing Communication Tags as a way to request needed information from the requestor should there need to be any clarifications made during or after the purchasing process. In addition, employee may be issued a Government credit card to make purchases; however, they must complete the appropriate On-line DOE Credit Card Training prior to utilizing their card. To ensure the integrity of the Credit Card System, users are trained to input transaction onto the Credit Card Database and the Purchasing Office conducts random reviews of credit card transactions on a monthly basis. Furthermore, the Engineering Services Group reviews all credit card transactions to ensure the reliability and safety of the items purchased.

Sourcing/Qualified Suppliers
To promote acquisition of quality products and services at fair and reasonable costs, the Purchasing Office identifies capable and reliable vendors/subcontractors who provide the best value to the Ames Laboratory. A Vendor Resource Area is provided to requestors and Buyers are also helpful in suggesting vendor sources. The Purchasing Office continually evaluates vendor performance by issuing Quality Assurance Letters for Materials and Services that were recently purchased. The Purchasing Office tabulates requestor feedback and tracks receiving inspection information from Ames Laboratory warehouse personnel.

Subcontractors

The Purchasing Office assures that vendors/subcontractors are responsible and will provide quality products and services that are compliant with the terms of the subcontract. Awarding a subcontract or a purchase order based on lowest evaluated price alone can be a false economy if there is subsequent default, late delivery, or other unsatisfactory performance results in additional contractual or administrative costs. Therefore, while it is important that purchases be made at the lowest price, this shall not require an award to a vendor solely because that vendor submits the lowest bid. A prospective awardee must affirmatively demonstrate its ability to meet all the requirements of its proposal.

Signature Approval Process

Requisitions will not be processed by the Purchasing Office if the purchase requisition is missing any of the required signatures. The following signatures are required:

- Purchasing Office which, checks to see if equipment from the Laboratory pool can be utilized instead of purchasing a new item.
- Environment, Safety, Health and Assurance Office, which reviews any, purchases for chemicals, X-ray devices or radioactive materials and manages those purchases appropriately. Materials or services with a nuclear safety concern will require higher quality levels, which meet 10 CFR 830.122 requirements.
- Budget Office, which verifies the requestor's authorization to charge the cited account code.
- Accounting Office, which acknowledges the pending transaction.

Small purchases (less than $200) with local vendors do not require the above approval signatures; however, an employee must be authorized to use this purchasing option and still must provide the justification for the purchase. No Hazardous Materials can be purchased using a Local Small Order Form.

Quality Assurance Inspection System

The Quality Assurance Inspection System is a process where purchased items with a higher associated risk are reviewed by a technical expert. The expert ensures that the goods meet the required specifications of the Laboratory and the requestor. To implement this process the Laboratory's Purchasing Office codes all purchased items and forwards higher risk purchases on to the Engineering Services Group (ESG) for review to ensure that safety & health issues are addressed. ESG assigns an inspection rating or determines if an inspection is deemed unnecessary. Coded items not reviewed by Engineering Services (except those exempted in section 6.72, see "Signature Approval Process") are reviewed by the requestor and must meet their established acceptance criteria.

Control of Suspect and Counterfeit Items

Suspect and Counterfeit Items are reviewed utilizing the Quality Assurance Inspection System. The Procurement Quality Procedure (46200.003) assures that only correct and accepted items are used or installed. The procedure directs the quality procurement review and inspection activities performed

within the Ames Laboratory to review procured items for quality and safety concerns. It provides instructions for the identification and control of materials, parts, components, and partially fabricated assemblies during fabrication, installation, maintenance or modification. Procurement works in conjunction with Ames Laboratory's Engineering Services (ESG) Group regarding ordered materials; however, the main responsibility of this function is vested with the ESG due to its technical nature. ESG also provides training on the Procurement Quality Procedure for employees of ESG, Information Systems and the Procurement Office. Technical training on the specific electronic and mechanical review and inspection activities is conducted with the ESG- Electronics and ESG-Mechanical Sections.

Receipt Inspection

The Purchasing Office's warehouse personnel are charged with the responsibility of receiving, inspecting, temporarily warehousing, and delivering to the end user all incoming materials and equipment. They are also responsible for entering all pertinent receipt data in the Receiving Database. When special inspection is required, support services of such organizations as the Engineering Services or Facilities Services Departments are used to determine whether the received materials or equipment are in accordance with the subcontract. Procurement for services is verified by the requestor after the service has been rendered.

6.8 Criterion 8 - Inspection and Acceptance Testing

6.8.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.
(2) Calibrate and maintain equipment used for inspections and tests.

Program Information

Inspection and Acceptance Testing of specified items is conducted at the Ames Laboratory utilizing established procedures. The inspection process involves the real-time quality control examination and/or observation of activities or items in relation to approved acceptance criteria as demonstrated by procedures, specifications, checklists or drawings. Items found to be nonconforming are discarded, reworked, returned to the vendor, or otherwise controlled by segregation or tagging to prevent their inadvertent use.

The main Inspection and Acceptance Testing Areas are Procured Items, Measuring and Test Equipment, Welding, Hoisting and Rigging Equipment, and Safety Equipment.

Procured Items
A purchase requisition must be completed for every order that is processed through the Ames Laboratory Purchasing Office. The Buyer will place the order and will work along with the requestor to ensure that the vendor is offering items that conform to the specifications required. Purchase orders are coded to trigger a review by an Engineering Services Technical Specialist if it meets certain criteria. Based upon the review it is determined if the purchase requires a formal inspection by a specialist or by the Engineering Services Group. Once the item is received at the Ames Laboratory warehouse it is visually inspected for damage, matched against the purchase order and packing slip. The item is then routed to the requestor's specified delivery address by local transportation means. The requestor then inspects the goods for conformance with his/her specified requirements.

Calibration of Equipment
Inspection and testing is performed utilizing calibrated materials and testing equipment. The Ames Laboratory Groups/Departments are charged with the responsibility of assuring that Measuring and Test Equipment is of proper type, accuracy, and tolerance to accomplish the specified requirements. Items shall be calibrated and adjusted at specified periods to maintain accuracy within necessary limits and shall have known valid traceable relationships to nationally recognized standards or the documented procedure of an Ames Laboratory expert. The frequency of calibration shall be directly dependent upon the equipment's required accuracy, intended use, frequency of use, stability characteristics and how it influences the quality of an item's characteristics. Calibration verifications shall be documented and maintained by the appropriate Group/Department. Measuring and Test Equipment that is found out of calibration is identified and its impact is evaluated.

Welding
All welding (includes brazing and silver soldering but does not include soft soldering and does not include spot welding for research purposes, e.g., thermocouples and electronic contacts) at the Ames Laboratory shall be performed by the Engineering and Facilities Services Groups.

Hoisting and Rigging
Hoists and cranes shall undergo inspection and load tests when installed and after major modifications or replacement of major load carrying parts. The Laboratory's Engineering Services Group shall inspect hoists and cranes on an annual basis. A Hoist and Crane Inspection Label, which indicates the equipment's re-inspection date, shall be placed visibly on the equipment. The hoist or crane shall not be operated without a current inspection sticker in place.

All hoist and crane operators are required to attend the Laboratory's institutional training on Hosting and Rigging (AL-014). Participants review the current Hoisting and Rigging policy as outlined in the Environment, Safety, Health and Assurance Program Manual. In addition, a written training exercise is administered and the individual's Program/Department provides hands-on training. The verification of Hoist and Crane Training shall be maintained on the Ames Laboratory Training Records System (ALTRS), which also identifies the operator's three year re-train date.

The Environment, Safety, Health and Assurance Department shall maintain a Master Inventory of all hoists and crane equipment, which includes manufacture, model number, serial number, type, and capacity.

Safety Equipment
Ames Laboratory personnel conduct inspections of various types of equipment related to safety. These inspections are based on criteria, such as, the performance of the equipment and the performance of maintenance. The items are labeled to indicate physical inspection, test and/or the performance.

In-house Services
Ames Laboratory utilizes a several in-house services departments, i.e., Facilities Services, Engineering Services (Instrumentation Shop and Machine Shop), and Information Systems, to provide items, equipment and services. All of these departments have a quality assurance mechanism (form) in place, which documents a requestor's satisfaction with the worked performed.

6.9 Criterion 9 - Management Assessment

6.9.1 10 CFR 830 Subpart A – Quality Assurance Requirements

Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

6.9.2 Program Information

An important and effective process for identification and correction of process deficiencies is the observation of individual employees. Direct line supervisors provide individual work directions and each worker is accountable for performing quality work in a safe and productive manner. Employees are charged with the responsibility of continuously assessing their individual performances and their workspaces in order to prevent problems and to identify nonconforming conditions and opportunities for improvement. Ames Laboratory seeks to promptly address employee concerns in the workplace.

While each individual is responsible for the quality and safety of her/his work, Supervisors and Group/Section Leaders are accountable for oversight, direction, and guidance of work activities. Program Directors/Department Managers assess the allocation of resources and the management of hazards associated with the activities of the Groups/Sections within their organizations.

Workers shall assess their work and work environments in order to identify potential hazards and opportunities for improvement. Worker Observation Guides are available to assist workers in the observation of activities within office spaces and laboratory/shop spaces. Work deficiencies should be corrected as soon as possible by the workers involved with the activity. Workplace deficiencies should be reported to the first level of management as soon as possible. Resolution of concerns should occur at the level of line management most directly responsible for the activity. If the issue cannot be resolved at this level, the employee is directed to proceed within his/her line management structure or to report the concern to the Environment, Safety, Health and Assurance (ESH&A) office.

Group/Section Leaders should periodically review the work being conducted within their organization and correct any identified deficiencies. Formal documentation of this effort is not required, but unresolved concerns shall be presented to the appropriate Program Director/Department Manager or ESH&A. Programs/Departments shall conduct a walk-through at a frequency of approximately once per year. The Program/Department Walk-Throughs shall be documented and the issues addressed. Programs/Departments shall report the distribution of walk-through findings by type to the Environment, Safety, Health and Assurance Department for trend analysis.

6.10 Criterion 10 - Independent Assessment

6.10.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.
(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.
(3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

6.10.2 Program Information

The Laboratory has regulatory requirements to conduct independent assessments. These assessments provide objective reviews of the work place and implementation status of ES&H programs.

Independent Walk-Throughs
Independent Walk-Throughs shall be conducted under the direction of Environment, Safety, Health and Assurance (ESH&A) Office. A walk-through shall be performed on each Program and Department on an annual basis. The Independent Walk-Through Team shall consist of representatives from upper management, ESH&A, and appropriate safety specialists. ESH&A coordinates these walk-throughs and tracks corrective actions.

ESH&A Topical Appraisals
Environment, Safety, Health and Assurance (ESH&A) specialists shall perform topical appraisals of Ames Laboratory organizations in order to assist the Programs/Departments to fulfill their safety responsibilities and to fulfill the Laboratory's requirements to perform independent assessments. The ESH&A Office specialists, in agreement with the Ames Site Office, utilize a graded approach to determine applicability and frequency of specific topical appraisals.

Internal Audit Function
The Internal Audit office conducts a broad, comprehensive program of internal auditing within the Laboratory. The Internal Audit function examines and evaluates the adequacy and effectiveness of the systems of management control provided by the Laboratory to direct its activities toward the accomplishment of its objectives in accordance with Laboratory policies and plans and the DOE prime contract. The Internal Audit Office does not have authority or responsibility for the activities audited. The Internal Audit Office allocates audit resources in accordance with the estimated level of inherent risks associated with Laboratory functions or activities. The Internal Audit Office submits reports to the Director, and tracks associated corrective actions. The Contract provides for a direct reporting relationship to the Governing Board of the Contractor.