[assign a document number]
Revision: 0

[List University Name]

Quality Assurance
Program Description Document

[Date]

[List University Name]

Quality Assurance
Program Description Document

[Date]

[List University Name]
Quality Assurance Program Description Document

[Date]

Prepared by:

[List Name and Title of Preparer] Date

Concurrence by:

[List Name and Title of Personnel Concurring] Date

Approved by:

[List Name and Title of Personnel Approving] Date

[List Name and Title of Personnel Approving] Date

REVISION LOG

Rev.	Date	Revision Description
0	[List Date]	Initial Issue.

CONTENTS

FIGURES

TABLES

ACRONYMS

[List all acronyms used in the document]

1. INTRODUCTION

[Provide a brief introduction to the scope of work covered under the QAPD]

1.1 Purpose

[Example Purpose Statement – Include other information as applicable to the work scope] This Quality Assurance Program Description (QAPD) document defines the overall *quality assurance* (QA) (see def.) requirements for [LIST UNIVERSITY NAME] *activities* (see def.). The [LIST UNIVERSITY NAME] QAPD is developed, approved, and implemented to document quality responsibilities and authorities and describe the requirements for controlling the implementation, performance and the *assessment* (see def.) of *work* (see def.).

1.2 Scope

[Example Scope Statement – Include other consensus standards or QA standards as applicable to the work scope] The [LIST UNIVERSITY NAME] QAPD addresses each of the criteria in 10 CFR 830.122, "Quality Assurance Criteria," DOE Order 414.1, "Quality Assurance," and the requirements from ASME NQA-1-2008, and NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications" as shown on the crosswalk in Section 3.2.

The QA Program requirements are presented in Section 4, using the established criteria titles found in 10 CFR 830.122, supplemented with the requirements from DOE Order 414.1, and then clarified with the additional research requirements (such as *peer review* [see def.]). This QAPD also highlights additional QA requirements for activities that have progressed beyond R&D and addresses the application of QA requirements for [LIST UNIVERSITY NAME] Program activities.

1.3 Applicability

[Example Applicability Statement – Include other information as applicable to adequately define the applicability of the QAPD] The [LIST UNIVERSITY NAME] QAPD is applicable to all [LIST UNIVERSITY NAME] activities and participants and shall implemented using a *graded approach* (see def.), where the requirements specified are tailored to a level commensurate with the importance, significance and risks for each type of work scope being performed. Participants are not required to have in-place or establish an NQA-1 fully compliant program in order to meet the requirements of this QAPD. However, participants shall be able to demonstrate compliance to the applicable requirements for the work scope being performed for the [LIST UNIVERSITY NAME] QA Program.

2. [LIST UNIVERSITY NAME] ORGANIZATION AND RESPONSIBILITIES

The [LIST UNIVERSITY NAME] [Provide a narrative of the organization and roles and responsibilities]

[Insert Organization Chart Specific to the QA Program at the University}

Figure 1. [University Organization Chart].

[List all Titles and Roles and Responsibilities that apply]

2.1.1 Researchers [example position]

The researcher is responsible for the quality of the research and for implementing any applicable QA requirements applicable to the research activities.

- [List specific responsibilities]

2.1.2 Quality Assurance Manager [example position]

The QA manager is responsible for assisting in development, issuance, implementation, maintenance, and oversight of the QAPD, including the following:

- Perform oversight of QA Program implementation, including assessments or *audits* (see def.) of the activities.
- Revise the QAPD as necessary to address changes.
- Develop and provide QA training as necessary for participants.
- Assist participants in developing procedures to meet QAPD requirements.
- Disseminate lessons learned and quality alerts to communicate QA Program improvements.
- Plan, schedule, and perform or ensure performance of assessment activities of work activities.
- Provide feedback concerning QA performance issues.
- Ensure QA issues are effectively addressed.
- Coordinate QA required reviews at the university.

2.1.3 Participants [example position]

QA responsibilities for [LIST UNIVERSITY NAME] participants (e.g., other universities, subcontractors, suppliers, and others) include the following:

- Implement the QAPD requirements specified for their scope of work and ensure the quality of the work being performed.
- Develop and implement QA procedures and policies needed to properly execute the scope of work.

2.2 Interfaces

[List any interfaces necessary to execute the QAPD effectively]

3. SOURCE REQUIREMENTS

3.1 Regulatory and Consensus Standard Documentation

The following regulatory and consensus standard documentation serves as the basis for this QAPD: [example of potential applicable standards or regulatory documents] [List only those that are applicable]

- 10 CFR 830, Subpart A
- DOE Order 414.1D
- NQA-1-2008, Part I, "Requirements for Quality Assurance Programs for Nuclear Facilities"
- NQA-1-2008, Part II, "Quality Assurance Requirements for Nuclear Facility Applications"
- NQA-1-2008, Part IV, Subpart 4.2, "Guidance on Graded Application of Quality Assurance (QA) for Nuclear Related Research and Development"
- NQA-1a-2009, Addenda.

3.2 Comparison Crosswalk

[Example of a crosswalk for NQA-1-2000 to 10 CFR 830 and DOE Order 414.1D] [Provide a crosswalk if necessary for any standards used to other Orders, Rules, etc as applicable – Delete the section if not applicable] The following crosswalk (Table 1) identifies the requirements relationship between the criteria from 10 CFR 830.122 and DOE Order 414.1 to NQA-1-2008 and NQA-1a-2009 Addenda.

These requirements serve as the baseline for the [LIST UNIVERSITY NAME] QA Program implementation. They do not replace the universities QA Program or implementation of additional requirements imposed by contract, customer, or Federal or State requirements.

Table 1. Requirements crosswalk.

10 CFR 830.122/DOE Order 414.1		**NQA-1-2008 and NQA-1a-2009 Addenda**	
Criterion	**Title**	**Requirement**	**Title**
1	Program	1	Organization • Structure, Responsibilities, and Interfaces
2	Personnel Training and Qualification	2	Quality Assurance Program • Training, Qualification, and Certification
3	Quality Improvement	15 16	Control of Nonconforming Items Corrective Action

10 CFR 830.122/DOE Order 414.1		NQA-1-2008 and NQA-1a-2009 Addenda	
Criterion	**Title**	**Requirement**	**Title**
4	Documents and Records	6 17	Document Control Quality Assurance Records
5	Work Processes	5 8 9 13	Instructions, Procedures, and Drawings Identification and Control of Items Control of Special Processes Handling, Storage, and Shipping
6	Design	3	Design Control • See also Software Design Control
7	Procurement	4 7 2.14	Procurement Document Control Control of Purchased Items and Services • Commercial Grade Items, Subpart 2.14
8	Inspection and Acceptance Testing	10 11 12 14	Inspection Test Control • Computer Program Testing Control of Measuring and Test Equipment Inspection, Test, and Operating Status
9	Management Assessment	18	Audits
10	Independent Assessment	18	Audits
	Suspect/Counterfeit Items Prevention		Not included in NQA-1
	Software Quality Assurance	3 3 and 11 2.7	Software Design Control Computer Program Testing Computer Software, Subpart 2.7
	Peer Review	4.2	Peer Review, Subpart 4.2: Section 200

3.3 Resolution of Conflict Between Quality Requirements

In the event of a conflict between the [LIST UNIVERSITY NAME] QAPD and other [LIST UNIVERSITY NAME] quality assurance documents, the quality requirements specified in the [LIST UNIVERSITY NAME] QAPD shall take precedence. In the event of a conflict between the [LIST UNIVERSITY NAME] QAPD and applicable regulatory documents, the quality requirements specified in the regulatory documents shall take precedence. In the event of a conflict between the [LIST UNIVERSITY NAME] QAPD and the contractual requirements of participants, the conflict shall be elevated to the [List appropriate Position to elevate] to facilitate resolution with the contractual entity.

Upon discovery of any conflict between the [LIST UNIVERSITY NAME] QAPD and any other document, the affected participant shall notify the [LIST UNIVERSITY NAME] QA Manager to facilitate an acceptable resolution of the conflict.

4. QUALITY ASSURANCE PROGRAM REQUIREMENTS

In order to focus the research on the achievement of sustainable technologies, [LIST UNIVERSITY NAME] QA requirements shall be implemented through an established application of quality program requirements for all research and development work activities.

Application of the quality requirements by each [LIST UNIVERSITY NAME] participant shall be invoked by written contracts, policies, procedures, specifications, or other appropriate documents. It shall be noted that all the requirements of NQA-1, Part I and II, apply to R&D *support activities* (see def.) within the [LIST UNIVERSITY NAME] QA Program. In order to provide consistency of QAPD interpretation, the word *shall* or *will* denote a requirement; the word *should* or *may* denote guidance.

4.1 Quality Assurance Program

The graded approach is an essential element used in establishing quality requirements and is applied to *items* (see def.), activities, and *services* (see def.) at the earliest time consistent with the application of appropriate controls. This graded approach provides the researcher with increased agility and collaboration in determining and applying the requirements necessary to implement both the appropriate process controls and documentation for the achievement of *operational excellence* (see def.), based on the relative importance of a research activity, service, or item to the success of the [LIST UNIVERSITY NAME] Program.

[LIST UNIVERSITY NAME] participants shall demonstrate how the applicable quality assurance program requirements are implemented. Those performing the work shall comply with the requirements through implementation of work instructions, procedures, test plans, or other implementing documents.

The organization shall be defined to describe roles, responsibilities, authorities, interfaces, and relationships for the achievement of work and specific task objectives. Defining this organizational structure is performed by having discussions with university management and is dependent on the complexity of the research activity and the number of organizational interfaces. Documentation shall be maintained in the laboratory notebook, research work plan, or *project file* (see def.).

4.2 Personnel Training and Qualification

[LIST UNIVERSITY NAME] training and qualification requirements focus on providing researchers with the knowledge and skills necessary to perform tasks that meet acceptance and performance criteria. These requirements help personnel understand the safety conditions of tasks and processes; procedures needed to conduct tasks; quality, safety, and environmental requirements; systems terminology; and reasons for performing specific control functions to minimize process variability.

[LIST UNIVERSITY NAME] management shall define training, qualification, and certification requirements based on established regulatory requirements and position needs for selected job categories by considering the level of knowledge and skill required to perform the tasks. Implementing procedures shall describe personnel selection requirements and training, qualification, certification, and continued training processes. Objective evidence of training, qualification, and certification may be obtained through position descriptions, resumes, or other evidence of education and experience.

Personnel performing research activities shall be trained for those research activities to ensure work is being conducted properly to prevent rework or the production of unacceptable data. Training on processes, equipment, and procedures shall be performed and documented. The university shall maintain and control personnel training records.

As a minimum for the initial introduction of this QAPD, the following shall be trained. [List Positions Requiring Training including researchers, QA personnel, management, etc] These personnel shall document proficiency training to the current QAPD as accomplished via a classroom presentation or required reading. Training shall be documented.

4.3 Quality Improvement

Assessments, peer reviews, and researcher feedback are the primary methods used to identify performance initiatives, prevention measures, improvement opportunities, and corrective action issues as a part of an integrated quality improvement process.

4.3.1 Control of Nonconforming Items

The control of nonconforming items establishes the process for identification, documentation, evaluation, control, and disposition of items (e.g., hardware, material, or data) that do not conform to specified requirements in order to prevent their inadvertent installation or use. The documentation of nonconforming items shall be applied to support activities regardless of which research activity is being performed. The documentation of nonconforming items shall be identified and controlled as defined by the researcher for R&D activities. Corrective actions shall be specified and approved for nonconforming items.

The results of research activities are not expected to meet predetermined requirements. Therefore, obtaining unexpected research results does not constitute a nonconforming action within any of the three types of research. The point at which a nonconformance can be identified is the point where development research has transitioned into *design* (see def.), *fabrication* (see def.), or production of engineered items.

4.3.2 Corrective Action

Conditions adverse to quality (see def.) shall be identified promptly and corrected as soon as practicable. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management within the performing organization. Follow-up actions shall be taken to verify implementation and effectiveness of the corrective action in order to preclude recurrence.

4.4 Documents and Records

4.4.1 Document Management

The [LIST UNIVERSITY NAME] document management process shall include all activities involved in proposing, evaluating, planning, developing, reviewing, approving, releasing, distributing, managing, and canceling *controlled documents* (see def.). Documents shall be controlled to ensure the correct and current revision is being used and to provide assurance the record requirements are maintained.

Laboratory notebooks shall be controlled and maintained as QA records. Intellectual property documentation shall be subject to document control. Documents shall be prepared and controlled in accordance with the [LIST UNIVERSITY NAME] requirements or the participant's document control process.

4.4.2 Records Management

Records management provides controls to assure records accurately reflect completed work, facility conditions, and comply with statutory or contractual requirements. Records may be written or printed documents, microfilm, photographs, or electronic files. Computer hardware and software used to index, store, or access records shall be maintained and controlled to ensure record accountability, reproducibility, and protection from loss. Records shall be stored and maintained in a manner that minimizes the risk of damage, larceny, vandalism, or deterioration.

The notebook or journal of the researcher is a QA record. Other documents that provide evidence of the final research results may also be QA records. These documents/records shall be controlled in accordance with university documented procedure/process (e.g., maintain notebook as a controlled document and maintain copies of critical pages or access-controlled filing when not in use to preserve process repeatability and the QA record). If electronic media is used to record data it shall be subject to documented administrative controls for handling and storage of data. Records shall be managed and maintained by the university. Quality records shall be prepared, controlled and maintained.

Laboratory notebooks or journals of the researcher are QA records and shall be controlled in accordance with a documented process (e.g., maintain notebook as a controlled document and maintain copies of critical pages or access-controlled filing when not in use to preserve process repeatability and the QA record). Electronic media may be used to record data and shall be subject to documented administrative controls for handling and storage of data.

4.5 Work Processes

All [LIST UNIVERSITY NAME] research work shall be planned and funded. The funding and resources required to implement the applicable quality requirements shall be sufficient for the work being performed. The funding and resources for the QA personnel shall be sufficient for the work being performed and to provide adequate program independence, maintenance, and oversight of all [LIST UNIVERSITY NAME] QAPD activities.

Research work planning and authorization, including specifying the QA requirements and resources to support the requirements from this QAPD, shall be completed prior to the start of work.

QA requirements shall be flowed down to other participants or subcontractors through the appropriate contractual or work control process.

4.5.1 Instructions, Procedures, and Drawings

Work shall be performed under controlled conditions using work-controlling documents (such as approved procedures, drawings, instructions, work packages, or other appropriate means to ensure quality is integrated into the work process). Work directions shall provide a level of detail commensurate with the risk, complexity, importance and significance of the work.

[LIST UNIVERSITY NAME] research work shall be documented in reports, conceptual drawings, sketches, or notebooks, as appropriate. Protocols on generating and safeguarding data and process development shall be developed if needed for consistency of the research work.

Documentation of work processes and methods with complete and accurate results shall be maintained in a laboratory notebook, research work plan, or project file. The level of documentation shall be sufficient to ensure replication of the work and successfully passing a peer review.

4.5.2 Identification and Control of Items

Identification and control of items either manufactured or received provides for traceability and the necessary pedigree on the materials, items, or services, and prevents using incorrect or defective materials. The degree of application shall support the desired outcomes within the specified performance boundaries for the work. Specific identification and traceability requirements specified in codes, standards, or specifications shall be applied through work-controlling documents. Documentation for the identification of controlled items shall be maintained in a laboratory notebook, research work plan, or project file.

The methods for identifying and controlling items (e.g., batch, lot, component, part) shall be specified and materials or items shall be controlled per the methods specified to ensure that only correct and accepted items or materials are used. The item or material shall be identified and controlled from the initial receipt and or fabrication up through installation and use.

4.5.3 Control of Special Processes/Processes

Special processes are those for which the results are highly dependent on the control of the process or the skill of the operator and for which the quality of the product cannot be readily determined by *inspection* (see def.) or test. Special processes include activities such as welding, brazing, heat-treating, chemical cleaning, and nondestructive examinations. Only qualified personnel using qualified procedures shall perform special processes.

Documentation for control of special processes shall be maintained in a laboratory notebook, research work plan, or project file.

Control of a special process shall be contingent on the complexity of the research activity, the ability to duplicate the research if data were lost, and defined by the researcher’s instructions.

Work processes and supporting documentation shall be defined and work and operating procedures shall be developed and implemented with respect to safety considerations, quality, cost, schedule, and programmatic mission. Methods of implementation and training requirements shall be formally defined.

4.5.4 Handling, Storing, and Shipping

Work-controlling and procurement documents shall provide instructions for handling, storing, and shipping items. These activities include controls for cleaning, marking, packaging, and protecting items from deterioration, damage, or loss. Instructions or procedures shall be developed, approved, and issued for use in performing these activities. Documentation shall be maintained in a laboratory notebook, research work plan, or project file.

4.6 Design

Procedures shall provide the controls for preparing, reviewing, approving, and verifying documents of new designs and changes. Implementing procedures shall address the design input, development, analysis, *validation* (see def.), and output to ensure final designs of systems, facilities, and experiments comply with specified technical requirements, standards, and codes.

Design control shall be commensurate with the research activity and shall be used to support subsequent development work. Following transition to development work, design control shall support the input needs of the design process and shall be commensurate with the development research activity. In some cases, considerable importance may be placed on the development results to demonstrate the acceptability of the innovative design.

Experiment or prototype designs shall be approved by a university faculty or Technical Point of Contact and documented in the project files or laboratory notebook. Design review documentation shall include the following:

- Design criteria
- Applicable design input and output documentation
- Review criteria
- Actions and personnel assignments.

4.7 Procurement

Procurement activities shall be performed in accordance with approved procedures so design and operational requirements are integrated into corresponding purchase requirements. These procedures shall provide instructions for identifying, controlling, distributing, and approving procurement documents (including those provided by the supplier), specifying criteria for purchasing commercial-grade items, and preventing the purchase of suspect or counterfeit materials.

4.7.1 Procurement Document Control

Contracts, a memorandum purchase order, or other documents that serve as a procurement document between the university and other universities, subcontractors, suppliers, etc. shall flow down the applicable QA requirements.

All quality-affecting procurements (including calibration items), standards, and instruments calibrated by the manufacturer or supplier; calibration services; test materials; subcontracts; and other quality-affecting items and services that may affect data or its outcome shall specify the requirements in the procurement documentation.

University documented procurement document control procedures/processes shall be implemented if the pedigree of materials being used could influence the usefulness of the research work results. Procurement document specifications shall be controlled. The level of procurement document control shall be applied to support a design basis, i.e., engineering design system criteria.

The university shall provide for control of suspect/counterfeit items (S/CI).

Examples of procurement documents may include or reference the following criteria and information, as appropriate: a description of the item or service; procurement QA requirements; specifications, drawings, standards, design bases, and *acceptance criteria* (see def.); nonconformance reporting requirements; vendor data; documentation of personnel and materials qualification/certification, test, inspection, and review requirements; *calibration* (see def.) requirements; access requirements for monitoring supplier performance; and a statement of work.

4.7.2 Control of Purchased Items and Services

During research activities, procurement controls shall be implemented when the work results are expected or anticipated to be used for the next stage of research. Materials, items, or services that will influence the usefulness, objectives, and quality of the research results shall be controlled to ensure conformance with specified requirements. Requirements, commensurate with the graded approach and scope of the work being performed, shall be flowed down within procurement contracts.

Documentation of procurement controls and specifications concerning purchased materials, items, and services shall be maintained in a laboratory notebook, research work plan, procurement records, or in the project file.

Procured items and services shall be controlled to ensure conformance with specified requirements. Controls shall provide for the following as appropriate: source evaluation and selection, evaluation of the objective evidence of quality furnished by the supplier, and examination of items or services upon delivery or completion for conformance to procurement specifications.

4.8 Inspection and Acceptance Testing

4.8.1 Inspection and Test Control

Inspection and test control activities shall be planned and controlled in accordance with approved laboratory instructions, work orders, inspection plans, or other work controlling documents to verify conformance with specified requirements. Inspections for acceptance shall be performed by qualified individuals who have not performed or supervised the work being inspected or tested.

If the end use of the research product requires inspection to prove suitability for use, then inspection requirements shall be defined and documented in a laboratory notebook, research work plan, or project file. Documentation shall be developed to ensure replication of the work.

The researcher/developer shall document work methods and results in a complete and accurate manner. The level of documentation shall be sufficient to withstand a successful peer review. Protocols on generation and safeguarding of data and process development from research shall be developed for consistency of R&D work.

Laboratory notebooks shall be controlled by a documented procedure/process. Also, the process for development of intellectual property documentation shall be controlled under document control procedures/processes.

During development work, inspection criteria shall be established to provide the interface between development research and the design process needs for the next phase of the technology life cycle. Tests shall be planned, executed, documented, and evaluated. Characteristics to be tested and test methods shall be specified and the test results documented. The test results shall be evaluated to determine their conformance to documented acceptance criteria.

4.8.2 Control of Measuring and Test Equipment

Measuring and test equipment (M&TE) is defined as devices or systems used to calibrate, measure, gage, test, or inspect in order to control and validate acquired data and to verify conformance to specified requirements. The requirements for accuracy, precision, and repeatability of M&TE shall be specified and documented. Instrument selection shall be defined and all instruments used in data collection for published results shall be calibrated or *standardized* (see def.).

The researcher shall specify the requirements of accuracy, precision, and repeatability of measuring and test equipment. Depending on the need for accuracy, precision, and repeatability of the measuring and test equipment used in research, standard measuring and test equipment procedures shall be followed. Where standard measuring and test equipment procedures are not used, effects of the instrument's performance on the uncertainty of the measurements and tests shall be considered in the research. The measuring and test equipment shall be controlled. The degree of control shall be dependent on the application of the measurement. The university shall maintain calibration records documenting instrument calibration to a national standard. If requested by a funding organization the calibration records will be submitted as a deliverable product.

4.8.3 Inspection, Test, and Operating Status

The status of items and processes that have inspection and test requirements shall be specified by the researcher and shall be identified by indicators such as tags, markings, or other suitable means. The authority for application and removal of inspection and test identification shall be specified.

The status of inspection, test, and operating conditions for equipment and systems shall be identified either on the item or in documents traceable to the item. Status shall be maintained through indicators such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.

4.9 Assessment/Audit

All participants are subject to an assessment/audit of their QA Program implementation for their respective [LIST UNIVERSITY NAME] QA activities by [LIST UNIVERSITY NAME] QA management. Participants will be informed of any assessments at least 30 days in advance of the planned assessment. Participants also shall assess/audit implementation of the QAPD requirements consistent with the requirements of their own QA Program.

The participants shall ensure managers assess/audit their management processes and identify and correct problems that hinder the organization from achieving its objectives.

Assessments/audits shall be planned, scheduled and performed assessments and the results of these audits/assessments shall be documented. Follow-up actions shall be taken to verify implementation and effectiveness of corrective action.

4.10 Suspect/Counterfeit Items Prevention

The Suspect/Counterfeit Items (S/CIs) Prevention Program establishes the requirements for preventing the introduction and use of S/CIs. These requirements shall apply to development of procurement specifications; acquisition of material or equipment; inventory and storage, inspection and *testing* (see def.), replacement, maintenance, or modification of equipment; and the inspection, identification, evaluation, and disposition of S/CIs installed in all safety applications and other applications that create potential *hazards* (see def.).

Suppliers shall have sufficient procedural controls preventing the delivery of S/CI materials. However, if S/CIs are found currently installed or in inventory, they shall be identified and controlled. Corrective actions shall be taken based on risk and the consequence of failure; the identified S/CIs shall be reported.

4.11 Software Quality Assurance

Software quality assurance establishes the requirements for controlling the quality of computer *software* (see def.), because these requirements apply to development, procurement, modification, maintenance, operation, or retirement of software. Software quality assurance comprises a set of activities necessary to provide adequate confidence that a software item or product conforms to a set of technical requirements. The [LIST UNIVERSITY NAME] maintains a separate software quality assurance program plan to identify the requirements for R&D activities. When considering software in the R&D environment, there are two types of software efforts that may be undertaken: (1) the software effort is a tool used to perform the research activity or (2) the software is a deliverable of the activity.

During research, computer software management shall include the plans, procedures, and work processes used to establish and maintain control of software integrity. Procedures and work processes shall formulate a structured software methodology for software acquisition, development, change, maintenance, and disposition. Organizations using computer software, including associated data and databases, are responsible for the accuracy of computer data. Defining the software, its use, configuration management, and peer review shall be in a laboratory notebook, research work plan, or project file.

During research, if software is used to perform the research activity or is a deliverable, then software controls shall apply because these activities and products do have applications. Documentation of software requirements, controls, and modeling development shall be maintained in a laboratory notebook, research work plan, or project file. This documentation also shall include how the code was tested, the configuration control (revision number of the software), and how the validation of the input and output was performed. Software systems also require *verification* (see def.) to ensure functional requirements are met. The researcher shall ensure the systems and subsystems are operating properly and document both the testing performed and the test results.

4.11.1 Software Design Control

The nature of software design controls efforts, whether as a tool used to perform the research activity or as a software deliverable itself, benefit from documentation of the software development process. A software design review, performed by a competent individual other than whoever performed the design, shall be documented and shall verify requirements are met. After demonstration by testing that the hardware/software/equipment combination provides correct results, the configuration shall not be changed except for a cause that also is documented and approved.

This documentation provides a traceable process to aid in peer review, procurement, and corrective action, as appropriate, in support of the software effort. Software design control shall be commensurate with the applied research activity and shall be used to support subsequent development work.

NQA-1-2008, Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications," may provide additional requirements for the acquisition, development, operation, maintenance, and retirement of software, which should be considered during development work.

4.11.2 Computer Program Testing

Computer program testing is an activity where documentation shall be specified, documented, and provide a traceable process to aid in peer review. The researcher shall perform documented testing to demonstrate that the computer program testing requirements are met. The hardware, operating system, test problems, equipment or calibrations (as necessary), simulation models used (if any), and any deviations noted together with actions taken shall be documented.

4.12 Peer Review

A strong planning function is essential for the success of any peer review activity. The scope and content of the peer review activity shall be well defined to ensure an authoritative, independent, and fair evaluation is accomplished and to assemble the proper mix of expertise to cover the subject matter.

Peer reviews shall be performed and documented in accordance with journal peer review requirements or university peer review requirements. Peer reviews shall be maintained by the university.

The following attributes should be considered in peer review planning:

- The number of reviewers is commensurate with the complexity of the work to be reviewed, its importance to program objectives, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning issues under review.

- The collective technical expertise and qualifications of the reviewers should span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought.

- Peer review personnel should have extensive discipline/knowledge in the field of study to assess the underlying assumptions and logic associated with the research activity.

- The technical areas, central to the work to be reviewed, should receive appropriate proportional representation among the peer reviewers.

The supervisor, manager, or leader of the performer of the work shall select peer reviewers based on the complexity of the work being reviewed.

Peer reviewers shall be individuals who meet at least one of the following criteria as judged by the responsible manager:

- Have adequate academic education in the same technical discipline in which the work is performed or in a closely related field or have adequate work experience and technical activity in a related discipline.

- Have demonstrated evidence of proposing and solving engineering, experimental, or theoretical problems that are recognized as valid by the community of technical peers.

- Have contributed to the body of knowledge within a technical discipline such as publishing research results in the proceedings of scientific meetings or in professional journals.

Peer reviews shall be documented and the level of documentation should be commensurate with the level of peer review completed. The peer review report is an evaluation or critique used by the authors to improve the final product and should document the methodologies used and the results needed to verify the research success factors are achieved.

5. Quality Requirements Progressing Beyond Research and Development

[LIST UNIVERSITY NAME] work scope or program activities progressing beyond the quality requirements identified in Section 4 shall comply with the applicable requirements from Parts I and II of NQA-1-2008 and NQA-1a-2009, Addenda.

Additionally, specific work being conducted with the potential for future licensing decisions shall consider the requirements of 10 CFR 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.”

6. DEFINITIONS

Acceptance criteria. Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents. Source: American Society of Mechanical Engineers (ASME) NQA-1-2008 with NQA-1a-2009 Addenda.

Activity. A planned effort that spans a duration of time in order to accomplish a specific scope of work or milestone or deliverable. Source: Developed for program use.

Activities affecting quality. The actions that affect the quality of an item or service to meet or demonstrate compliance to requirements. Examples of activities affecting quality include: research and development, software management, siting, designing, procuring, calibrating, handling, shipping, receiving, storing,

cleaning, erecting, installing, inspecting, testing, operating, maintaining, refueling, modifying, and decommissioning. Source: Developed for program use.

Applied research. It is a process, the objective of which is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met. The process may involve basic research in selecting the best approach in accomplishing the applied research.

It is a proof of principle with more explicit objectives and warrants a set of milestones. This leads to the need for a records system that can protect patent rights by ensuring an orderly procedure for maintaining the necessary documentation. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Assessment. A review, evaluation, inspection, test, check, *surveillance* (see def.), or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. Source: DOE Order 414.1D.

Audit. A planned and documented activity performed to determine by investigation, examination, or evaluation of object evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Basic research. It is a process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward a process or products in mind. It is often conducted to acquire and disseminate new knowledge of a theoretical or experimental nature.

By its very nature, basic research is subject to the highest level of uncertainty and most is predicated on previous work and guided by hypothesis testing. However, even in basic research, work is broken down into a series of tasks with anticipated results and milestones. Good data and documentation are needed to ensure reproducibility of results as the researcher transitions to the next stage of the life cycle. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Calibration. The set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system and the corresponding standard or known values derived from the standard. Source: ANSI/NCSL Z540 and ISO-17025.

Conditions adverse to quality. An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and non-conformances. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Controlled documents. Any document, regardless of format, delivery method (i.e., paper or electronic), or type, for which distribution and status are to be kept current by the owner to ensure that users have available the most up-to-date version. Additionally, all versions of the document and related configuration management case files of ongoing record interest. Source: Developed for program use.

Deliverable. A document or product identified in a work package with a due date and work scope. Source: Developed for program use.

Design. Technical and management processes that commence with identification of design input and end with issuance of design output documents. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Development work. The systematic use of knowledge or understanding gained from research that is directed toward the creation of useful materials, devices, systems, or methods, including prototypes and processes. It also is the application of a proven theory and experimental results and their extension to an end use. Basic and applied research may be a direct input to development work. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Engineering. The creative application of scientific principles to design or develop structures, machines, apparatus, manufacturing processes, or works utilizing them singly or in combination; to construct or operate the same with full cognizance of their design; and to forecast their behavior under specific operating conditions; all as respects to an intended function, economics of operation, and safety to life and property. Source: Developed for program use.

Fabrication. The building of items, structures, machines, apparatus, and other equipment by cutting, shaping, and assembling components made from raw materials. Source: Developed for program use.

Graded approach. The process of ensuring the level of analyses, documentation, and actions used to comply with requirements are commensurate with the following:

- Relative importance to safety, safeguards, and security
- Magnitude of any hazard involved
- Life-cycle stage of a facility or item
- Programmatic mission of a facility
- Particular characteristics of a facility or item
- Relative importance to radiological and non-radiological hazards
- Any other relevant factors. Source: 10 CFR 830.

Hazard. A source of danger (e.g., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation). Source: 10 CFR 830.

Inspection. An examination or measurement to verify whether an item or activity conforms to specified requirements. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Item. An all-inclusive term used in place of appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, system, unit, or support systems. Source: 10 CFR 830.

Milestone. A document, product, or deliverable identified in a work package with a due date and work scope. Source: Developed for program use.

Operational excellence. A leadership driven, integrated approach to organizational performance management that results in the following:

- Alignment with strategy, vision, and values across the organization
- Improvement of overall organizational effectiveness, efficiency, and capabilities as demonstrated through results measured and expectations achieved
- Innovation through organizational and personal learning
- Delivery of ever-improving value to customer and stakeholders, contributing to organizational sustainability. Source: Developed for program use.

Participant. Any individual or organization performing work under the [LIST UNIVERSITY NAME] QA Program. Source: Developed for program use.

Peer review. A critical review of the research activity that is performed by one or more individuals who, collectively, have scientific expertise equal to or greater than those who performed the work. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Project file. Paper or electronic record that documents project information. The project file includes but is not limited to project requirements, milestones, tests, research results, research data, M&TE, design information, calculations, and procurement activities. Source: Developed for program use.

Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. Source: 10 CFR 830.

Quality assurance. All those actions providing confidence that quality is achieved. Source: 10 CFR 830.

Safety software. Software that includes the following:

1. **Safety System Software.** Software for a nuclear[a] facility that performs a safety function as part of a SSC and is cited in either (a) a DOE-approved documented safety analysis or (b) an approved hazard analysis per DOE Policy 450.4, "Safety Management System Policy," dated 10-15-96, and the DEAR (DOE Acquisition Regulation) clause.

2. **Safety and Hazard Analysis Software and Design Software.** Software that is used to classify, design, or analyze nuclear facilities. This software is not part of an SSC but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.

3. **Safety Management and Administrative Controls Software.** Software that performs a hazard control function in support of a nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating,

a. Per 10 CFR 830, quality assurance requirements apply to all DOE nuclear facilities, including radiological facilities (see 10 CFR 830, DOE-STD-1120, and the DEAR Integrated Safety Management System clause).

limiting, or mitigating nuclear hazards to the worker, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, "Occupational Radiation Protection," and the DEAR Integrated Safety Management System clause. Source: DOE Order 414.1D.

Scoping studies. A preliminary study used to further define the scope of a research activity. The intent of the scoping study is to assess the magnitude, seriousness, and intensity of a problem and the actions taken by the people concerned and affected by it. Scoping studies often focus on identifying the extent, nature, and range of research, testing (see def.), and analysis required to accomplish the following, as applicable:

- Ensure relevant research
- Identify concerns and issues
- Enable those responsible for the research to properly brief the research team on the following:
  - Alternatives and impacts to be considered at different levels of analysis
  - The assessment methods to be used
  - All affected interests
- Provide an opportunity for peer involvement in determining the factors to be assessed and facilitate early agreement on contentious issues
- Save time and money
- Establish terms of reference.

Scoping is not an isolated exercise. It may continue well into the project planning and design phase, depending on new issues that may arise. Various tools are available that may be used in scoping studies; historical profiles, problem trees, seasonal charts, discrimination profiles, and strength-weakness-opportunities-threats analysis are some examples. Source: Developed for program use.

Service. The performance of work, such as design, manufacturing, construction, fabrication, assembly, decontamination, environmental restoration, remediation, waste management, laboratory sample analyses, *safety software* (see def.) development/validation/testing, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, training, assessment, repair, and installation. Source: 10 CFR 830.

Software. Computer programs and associated documentation and data pertaining to the operation of a computer system. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Standardized. A process in which the value of a potential standard is fixed by a measurement made with respect to a standard whose value is known. Source: Developed for program use.

Structures, systems, or components. Structures are elements that provide support or enclosure, such as buildings, freestanding tanks, basins, dikes, and stacks. Systems are collections of components assembled to perform a function, such as heating, ventilating, and air conditioning systems, control systems, utility systems, reactor cooling systems, or fuel storage systems. Components are items of equipment (such as

pumps, valves, and relays) or elements of a larger array (such as computer software, lengths of pipe, elbows, or reducers). Source: Developed for program use.

Support activities. Those research activities that are conventional and secondary in nature to the advancement of knowledge or development of technology, but allow the primary purpose of the work to be accomplished in a credible manner. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Surveillance. The act of monitoring or observing to verify whether an item or activity conforms to specified requirements. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Testing. An element of verification used to determine the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions. Source: ASME NQA-1-2008 with NQA-1a-2009 Addenda.

Validation. The process of (a) evaluating a system or component during or at the end of the development process to determine whether it satisfies specified requirements; or (b) providing evidence that the software, and its associated products, satisfies system requirements allocated to software at the end of each life-cycle activity, solves the right problem (e.g., correctly models physical laws and uses the proper system assumptions), and satisfies the intended use and user needs. Source: ASME IEEE Standard 1012-2004.

Verification. The process of (a) evaluating a system or component to determine whether the products of a given development phase satisfy the conditions imposed at the start of that phase; or (b) providing objective evidence that the software and its associated products conforms to requirements (e.g., for correctness, completeness, consistency, and accuracy) for all life-cycle activities during each life-cycle process (e.g., acquisition, supply, development, operation, and maintenance); satisfies standards, practices, and conventions during life-cycle processes; and, successfully completes each life-cycle activity and satisfies all the criteria for initiating succeeding life-cycle activities (e.g., building the software correctly). Source: ASME IEEE Standard 1012-2004.

Work. A defined task or activity such as research and development; manufacturing; operations; environmental remediation; maintenance and repair; administration; software (including safety software) development, validation, testing, and use; inspection; safeguards and security; or data collection and analysis. Source: DOE Order 414.1D.