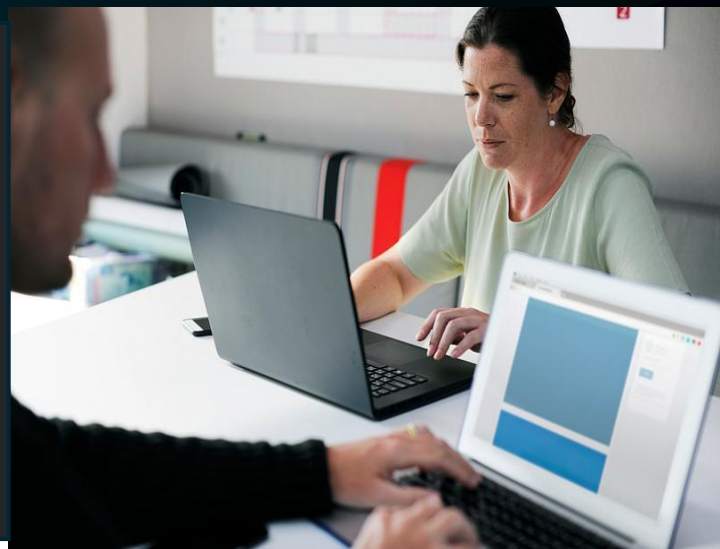
NQA-1

National Quality Assurance Level 1
Highest Nuclear QA Standard in the US

January 21, 2026



Timeline

- 1880 ASME is founded
- 1918 AESC formed, became ANSI 1969
- 1946 Atomic Energy Commission formed
- 1967 AEC issues10 CFR 50 Appendix A
  - Structures, Systems, & Components perform their safety functions
- May 1969 ANSI N45 committee forms the Ad Hoc committee on nuclear Quality Assurance Program Requirements

Timeline

- June 1970 AEC issues 10 CFR 50 Appendix B
  - 18 criteria – governs design procurement, construction, operation, maintenance & modification of nuclear facilities
- January 1971 the AEC becomes the NRC
  - Enhance safety & regulation of nuclear energy

Timeline

–1971 ANSI N45 Committee

- Issues N45.2-1971, the national consensus standard to meet the intent of Appendix B
- Translated the federal criteria into specific industry standards
- Structured method for controlling activities affecting quality

Timeline

- Alignment
  - ANSI N45.2 aligned closely with ASME's Section III of the Boiler and Pressure Vessel Code
  - 1975 ANSI formally transfers Stewardship of N45.2 to the American Society of Mechanical Engineers (ASME)
  - Administrative realignment

Timeline

– 1979 ANSI N45.2 becomes ASME NQA-1

- Combined safety codes for nuclear & Boiler and Pressure Vessel Code (BPVC)

– Covers nuclear facilities & companies (not just power plants)

Applicability

- Why is NQA-1 important?
  - Public Safety
  - It's the law
    - 10 CFR 50, Appendix B: Requirements for Quality Assurance Programs for Nuclear Facilities (not just power plants)
- Who enforces this law?
  - Nuclear Regulatory Commission (NRC) through Inspections (Routine or Reactive)

Applicability

– Who has to follow the NQA-1 rules?

Every employee who works on nuclear projects, and groups that support those projects (Configuration & Data Management, Facilities, Health Physics, Purchasing, Shipping/Receiving, etc.)

Nuclear QA Program / NQA-1

NQA-1 Culture: Quality is achieved by people possessing the competence, skills, knowledge, experience, training, resources, work ethic, and motivation to do the job right.

Nuclear QA Program / NQA-1

- NQA-1: Interprets and provides guidelines on how to implement a QA Program that complies with the requirements of 10 CFR 50 Appendix B
  - 4 Parts in NQA-1:
    - Part 1 – 18 Basic Requirements (Mandatory)
    - Part 2 – Additional Requirements (Some Mandatory)
    - Part 3 – Non-mandatory Guidance (Nice to do)
    - Part 4 – Non-mandatory Guidance (Helps and more stuff that's nice to do)

NQA-1 Requirements 1-10

- Req. 1 Organization – Who's Who & what do they do
- Req. 2 QA Program - QA & Training
- Req. 3 Design Control – Inputs, Process, Analysis, Verification
- Req. 4 Procurement Document Control - PO Requirements
- Req. 5 Instructions, Procedures, & Drawings
- Req. 6 Document Control – Procedures, Work Instructions
- Req. 7 Control of Purchased Items & Services – ASL, Nonconforming material, accepting product
- Req. 8 Identification & Control of Items - Tracking
- Req. 9 Control of Special Processes (Welding, NDE, etc.)
- Req. 10 Inspection – Source, Receiving, In-process, & Final

NQA-1 Requirements 11-18, Two Part 2 Subparts

- Req. 11 Test Control
- Req. 12 Control of Measurement & Test Equipment
- Req. 13 Handling, Storage, & Shipping
- Req. 14 Inspection, Test, & Operating Status
- Req. 15 Control of Nonconforming Items
- Req. 16 Corrective Action
- Req. 17 QA Records
- Req. 18 Audits
- Part 2, Subpart 7 Software Control
- Part 2, Subpart 2.14 Commercial Grade Dedication

Group-Specific Requirements

- Configuration. & Data Mgt. :
  - Req. 3 Design Control
  - Req. 5 Instructions, Procedures, & Drawings,
  - Req. 6 Document Control
  - Req.17 QA Records

Health Physics:

- Req. 4 Procurement Document Control
- Req. 6 Document Control
- Req. 7 Control of Purchased Items & Services
- Req. 13 Handling, Storage, & Shipping
- Req. 17 QA Records

Group-Specific Requirements

Purchasing:

- Req. 4 Procurement Document Control
- Req, 7 Control of Purchased Items & Services
- Req. 10 Inspection – Source, Rec., In-process, & Final
- Req. 17 QA Records

Shipping & Receiving:

- Req. 4 Procurement Document Control
- Req. 6 Document Control
- Req, 7 Control of Purchased Items & Services
- Req. 8 Identification & Control of Items
- Req.13 Handling, Storage, & Shipping
- Req.17 QA Records

Group-Specific Requirements

Nuclear R&D and Production Projects

All 18 criteria in Part 1, plus
Part 2, Subpart 2.7, Software Control and
Part 2, Subpart 2.14, Commercial Grade Dedication

NQA-1 Program - The Quality Assurance Levels

- The degree to which the NQA-1 requirements apply depends on the Quality Assurance level of the project and/or the customer's requirements.
- This is known as the Graded Approach or Graded Program
- There are 3 Quality Assurance levels for procedures that comply with NQA-1.
  - QAL I – Safety related
  - QAL II – Critical
  - QAL III – Noncritical, Off-the-Shelf

NQA-1 Program - The QAL definitions

- *Safety-Related:* equipment that is relied upon to remain functional during and after a Design Basis Event. Their function is critical to safely shutting down a nuclear reactor and maintaining it in a safe-shutdown condition to ensure that key regulatory criteria, such as levels of radioactivity released, are met.

NQA-1 Program - The QAL definitions

QAL I: Safety related - Applied to nuclear system, structure, subsystem, item, or design characteristic which prevents or mitigates the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

All engineered safety features fall within this level.

ANSI B31.1 items (piping) which contain or may contain radioactive materials shall be classified as QAL I.

NQA-1 Program - The QAL definitions

QAL II: Critical - Any nonsafety-related system, structure, subsystem, or item, which as a result of failure, could cause an unscheduled reduction in required performance, such as schedule, revenue, etc.

ANSI B31.1 items (piping) which do not contain radioactive materials is classified as QAL II.

Costs Time and/or money – remember time is money

NQA-1 Program - The QAL definitions

QAL III: Items for noncritical applications.

Basically, most off-the-shelf items

Two Exceptions:

- QAL III designs and procurements Include provisions for inspection and/or appropriate testing.

- Off-the-shelf-items things can be QAL I if they have a safety-related function

Definition

- *Graded approach:* the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement is commensurate with:
- a) the relative importance to safety, safeguards, and security
- b) the magnitude of any hazard involved
- c) the life-cycle stage of a facility or item
- d) the programmatic mission of a facility
- e) the particular characteristics of a facility or item
- f) the relative importance of radiological and non-radiological hazards

Graded Approach for R&D Levels

Basic Research

Applied Research

Development work

R&D Support Activities

Graded Approach for R&D Levels

Basic Research

- That phase of the research and development process that is subject to the greatest uncertainties
- Does not lend itself to predetermination of results

Graded Approach for R&D Levels

Applied Research

During applied research, grading is defined at the project or program level. Grading is minimal and is largely contingent upon the complexity of the research and the ability to duplicate the research if data were lost. The application of quality criteria may be minimal.

Applied research should be accompanied by documentation , such as research plans, testing, record keeping, and periodic reports commensurate with the scope of a given project may all be present.

Graded Approach for R&D Levels

Development and Support

All requirements of NQA-1 apply to R&D support activities.

Development activity entails the application of a proven theory and its extension to a practical situation. The plan that governs a developmental activity leads to a more structured management of the entire process.

Progress is measured against a predetermined set of results that appear to be appropriate at the outset.

NQA-1, Part I, Requirements	Basic	Applied	Development Work	Support Activities
1 Organization	Note (1)	Note (1)	Note (1)	Note (1)
2 Quality Assurance Program	Note (1)	Note (1)	Note (1)	Note (1)
3 Design Control	Note (2)	Note (3)	Note (1)	Note (1)
Software	Note (3)	Note (3)	Note (1)	Note (1)
4 Procurement Document Control	Note (1)	Note (1)	Note (1)	Note (1)
5 Instructions, Procedures, and Drawings	Note (3)	Note (3)	Note (3)	Note (1)
6 Document Control	Note (1)	Note (1)	Note (1)	Note (1)
7 Control of Purchased Materials, Items, and Services	Note (1)	Note (1)	Note (1)	Note (1)
8 Identification of Control Items	Note (1)	Note (1)	Note (1)	Note (1)
9 Control of Processes	Note (3)	Note (3)	Note (1)	Note (1)
10 Inspection	Note (2)	Note (2)	Note (3)	Note (1)
11 Test Control	Note (2)	Note (3)	Note (1)	Note (1)
Computer Program	Note (3)	Note (3)	Note (1)	Note (1)
12 Control of Measuring and Test Equipment	Note (3)	Note (3)	Note (1)	Note (1)
13 Handling, Storage, and Shipping	Note (1)	Note (1)	Note (1)	Note (1)
14 Inspection, Test, and Operating Status	Note (3)	Note (3)	Note (1)	Note (1)
15 Control of Nonconforming Items	Note (2)	Note (2)	Note (2)	Note (1)
16 Corrective Action	Note (3)	Note (3)	Note (1)	Note (1)
17 Quality Assurance Records	Note (1)	Note (1)	Note (1)	Note (1)
18 Audits	Note (3)	Note (3)	Note (1)	Note (1)

Requirement 1: Organization

Senior management:

- Defines policies and objectives
- Establishes and communicates expectations for quality and continual improvement
- Identifies and allocates resources to achieve expectation
- Specifies roles, responsibilities and authorities
- Ensures NQA-1 principles are understood, accepted and followed

Quality of work is:

- ✓ Achieved and maintained by performers
- ✓ Verified by those not directly responsible for performing the work

Requirement 2: Quality Assurance Program (QAP)

Management:

- Ensures proper development and implementation of the organization's QAP
- Ensures people are competent to perform their assigned quality-affecting work
- Provides training to achieve and maintain worker proficiency and qualifications
- Assesses the QAP and management systems to ensure compliancy, adequacy effectiveness and efficiency
- Seeks and uses relevant experience

Requirement 2: Quality Assurance Program (QAP)

- NQA-1, Requirement 2 requires indoctrination training
  - Personnel performing or managing activities affecting quality shall receive *indoctrination* in their job responsibilities and authority that includes general criteria, technical objectives, requirements of *applicable codes and standards*, *regulatory commitments*, company procedures, and *quality assurance program requirements*.

Requirement 3: Design Control

- Items are designed to requirements and documented in drawings and reports.
- Designs are analyzed and verified
- Changes to drawings and documents are controlled using sound engineering practices, analyzed, and verified
- Includes software control (also see Subpart 2.7) and hardware

Requirement 4: Procurement Document Control

- QAL I items are required to be purchased from QAL I Approved Suppliers on an Approved Suppliers List
- Projects have the prerogative of requiring QAL II suppliers be approved to purchase from, also. This is project-specific.

Requirement 4: Procurement Document Control

- Technical and quality assurance program requirements are specified on the procurement documents
- Receiving Inspection, Source Inspection, Technical Documents (Certificates of Conformance, Certificates of Calibration, Certificates of Analysis, etc.)
- Procurement documents shall specify the Supplier's requirement to report nonconformances

Requirement 4: Procurement Document Control

- Ensure that correct released drawings are provided as attachments
- Procurement documents shall be reviewed for accuracy prior to award
- Procurement document changes shall receive the same degree of control as the original documents
- QA requirements shall not to be waived by the buyer or the requestor without review and approval from QA

Requirement 4: Procurement Document Control

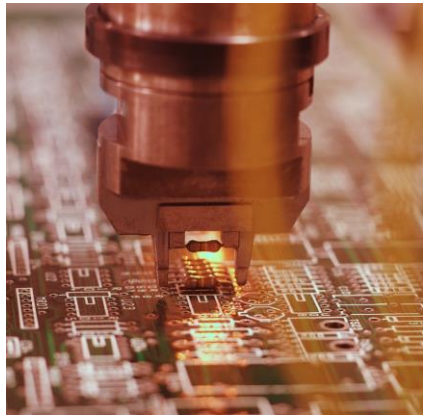
- Buyers need to make sure that the suppliers are aware of the QA requirements on the POs when placing the orders. QA is trying to jumpstart that awareness by including the QA requirements on IRs
- Vendors often state they did not see the QA requirements or ignore them outright
- The QA requirements (such as Certificates of Calibration) often causes the cost of a PO to increase if the supplier does not bid the job based on these requirements

Requirement 4: Procurement Document Control

- Biggest problem QA has is getting the Certificates of Conformance, Certificates of Calibration, and test reports from suppliers.
- Not getting these items holds up payment of the invoices. QA cannot approve invoices if there is missing paperwork.

Requirement 5: Instructions, Procedures and Drawings

- Work processes are planned and controlled
- Activities are performed in accordance with prescribed documentation
- Management ensures the right people have the right information at the right time



Requirement 6: Document Control

- Controlled documents shall be identified
- The distribution of controlled documents shall be specified
- Individuals responsible for preparation, approval and distribution shall be identified
- Controlled documents shall be reviewed for adequacy, completeness, and approval prior to distribution
- Changes to documents shall be reviewed by the same organizations and levels of personnel that reviewed the original document

Requirement 7: Control of Purchased Items and Services

- Suppliers will be evaluated and selected based on their capability to provide the items or services in accordance with requirements
- QAL II suppliers are qualified via a desk audit
- QAL I suppliers require a desk audit and an on-site QA audit prior to award of the PO (contract)
- Methods of acceptance shall be specified
  - Certificates of Conformance, Source inspections, Receiving inspections, etc.
- Methods for control and disposition of supplier nonconformances shall be documented

Requirement 8: Identification & Control of Items

- Items shall be identified from initial receipt or fabrication through, and including, installation and use
- Age sensitive items shall be identified and controlled to preclude use after shelf or operating life has expired

Requirement 9: Control of Special Processes

- Requirement 9, Special processes for achieving quality shall be performed under controlled conditions using qualified personnel, equipment, and processes
  - Use of correct materials, tools and processes and control changes is assured
  - Welding, NDE, Soldering, Cleaning of PWAs

Requirement 10: Inspection

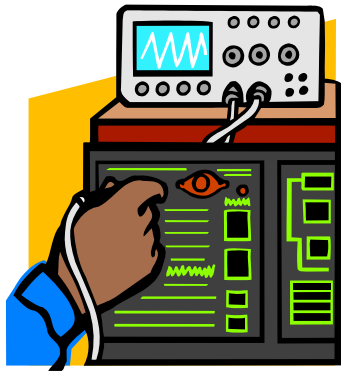
- In-process, final, and receiving inspection methods used to verify conformance shall be planned and documented

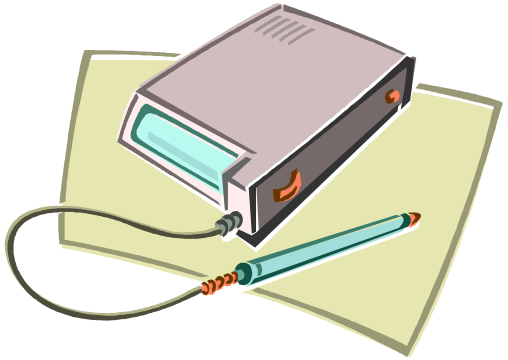
Requirement 11: Test Control

- Test requirements and acceptance criteria shall be specified
- Computer program test procedures shall demonstrate adherence of the program to documented requirements (also see Subpart 2.7)
- Test results shall be documented and maintained

Requirement 12: Control of Measuring and Test Equipment

- Tools, gages, instruments and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.
- Equipment shall be traceable to its application and use





Requirement 13: Handling, Storage, and Shipping

- Items are identified and controlled during shipping, handling, installation or use to assure their quality and prevent damage, loss or deterioration

Requirement 14: Inspection, Test, and Operating Status

- The status of inspection and test activities shall be Identified either on the items or in documents traceable to the items

Requirement 15: Control of Nonconforming Items

- Items that do not conform to specified requirements shall be identified and controlled to prevent inadvertent installation or use
  - Nonconforming items shall be segregated
  - Personnel performing evaluations to determine a disposition shall have demonstrated competence (AKA: MRB)
  - Technical justification for an item dispositioned as use-as-is or repair shall be documented
  - Does the nonconforming item meet the 10 CFR 21 reporting requirement?

10 CFR Part 21 (a.k.a. “Part 21”)

- 10 CFR Part 21: If the existence of a defect or deviation potentially associated with a substantial safety hazard is identified, it must be reported to management.
- Once reported, an internal investigation will occur to determine if the defective item/problem needs to be reported to the NRC
- Failure to report has substantial penalties
  - Fines and/or
  - Jail time

10 CFR Part 21 (a.k.a. “Part 21”)

- Purpose of the regulation is to notify the Commission (NRC) of a defect in a *Basic Component*
  - Basic Component
    - Items that have been design and manufactured under 10 CFR 50 Appendix B, or
    - Commercial Grade Items that have successfully completed the dedication process
- The process consists of:
  - Discovery
  - Evaluation
  - Notification

Definitions

- *Basic Component:* structure, system, or component, or part thereof that affects a NPPs safety function necessary to assure:
  - (A) The integrity of the reactor coolant pressure boundary;
  - (B) The capability to shut down the reactor and maintain it in a safe shutdown condition;
  - (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures

Definitions

- Basic Component can only come from a supplier with a Quality Assurance Program that meets 10CFR50, Appendix B.

10 CFR Part 21

- Discovery –
  - Identify the deviation or failure to comply potentially associated with a substantial safety hazard
- Evaluation –
  - Determine, if the discovery of the deviation could create a substantial safety hazard
    - A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any licensed facility or activity

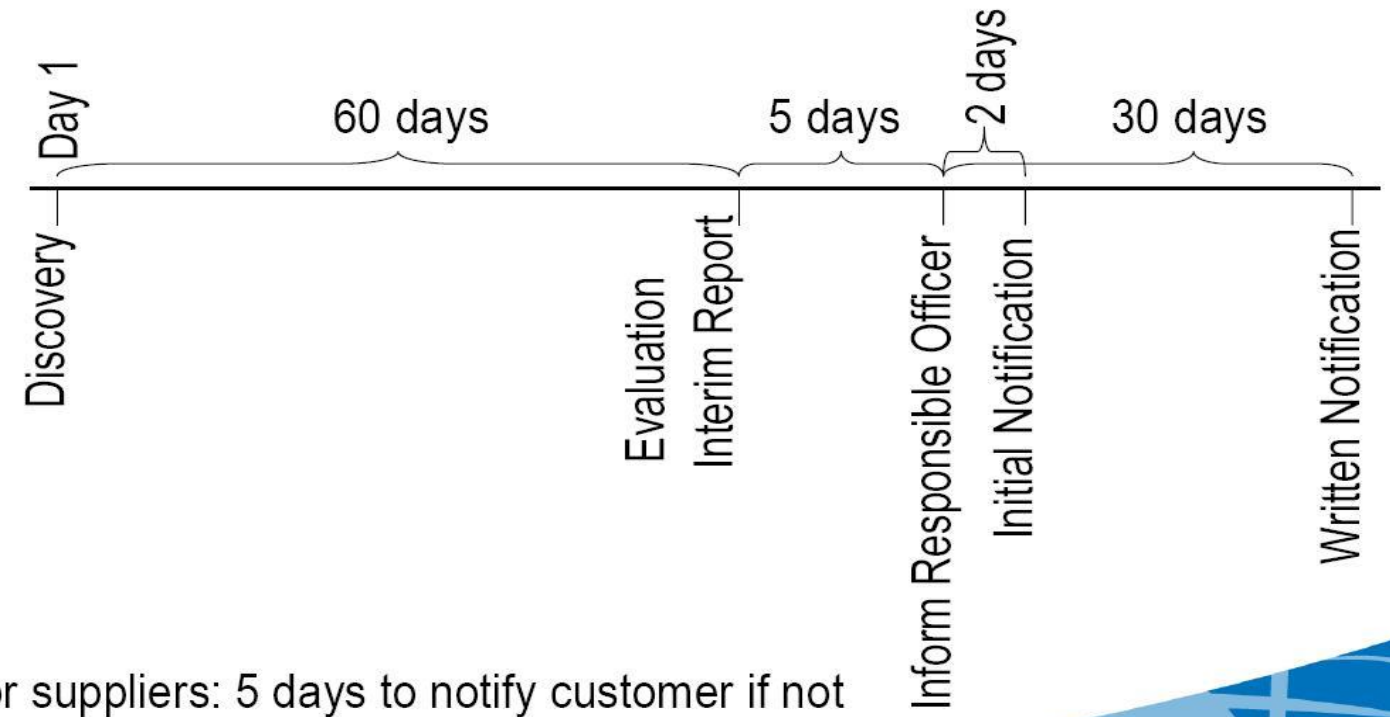
10 CFR Part 21

- Notification –
  - If the problem is reportable, going through the company's chain of command, who will notify the NRC: Follow the regulation time frames.

Timeline

10 CFR Part 21 Timeline

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment



For suppliers: 5 days to notify customer if not capable to perform evaluation

Requirement 16: Corrective Action

- Conditions adverse to quality shall be identified, controlled and corrected to prevent recurrence
  - The cause of the condition shall be determined
  - Completion of corrective action shall be verified

Requirement 17: Quality Assurance Records

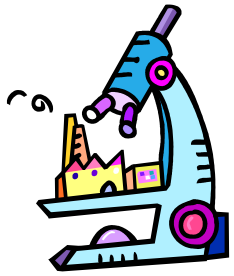
- Quality Assurance records shall furnish documentary evidence that items or activities meet specified quality requirements
  - QA records shall be identified, generated, authenticated and maintained
  - Records shall be classified as *lifetime* or *nonpermanent*
  - Records are to be legible and reproducible

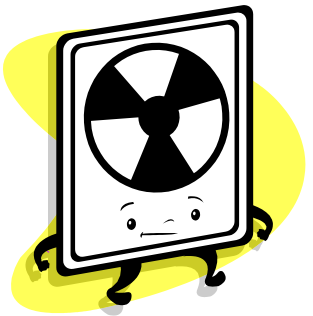
Requirement 17: Quality Assurance Records

- Quality Assurance records shall furnish documentary evidence that items or activities meet specified quality requirements
  - Records shall be stored so as to minimize the risk of loss, damage, or destruction
  - When temporary storage of records is required, the facility or container shall provide a one-hour fire rating
  - Purchasing, Receiving Inspection, Production Orders & Travelers, Inspections/Tests, Shipping

Requirement 18: Audits

- Audits shall be performed to verify compliance to QAP requirements
  - Internal audits of all requirements are performed on an annual or bi-annual frequency
  - Supplier audits are performed on a triennial frequency – with an annual desk review
  - Audits records shall contain a Plan, Checklist, Report, and completion of Corrective Action





NQA-1 Part 2, Subpart 2.7 Software Control

- Provides requirements for the acquisition, development, testing, operation, maintenance, and retirement of software
- QA maintains a Software Status Table for the four categories of software
  - Calculation/Modeling (engineering design software);
  - Process Control (software programs that control equipment);
  - Software Tools (Excel, IDL, Mathlab, etc.); and
  - System Software (operating systems, servers, etc.)

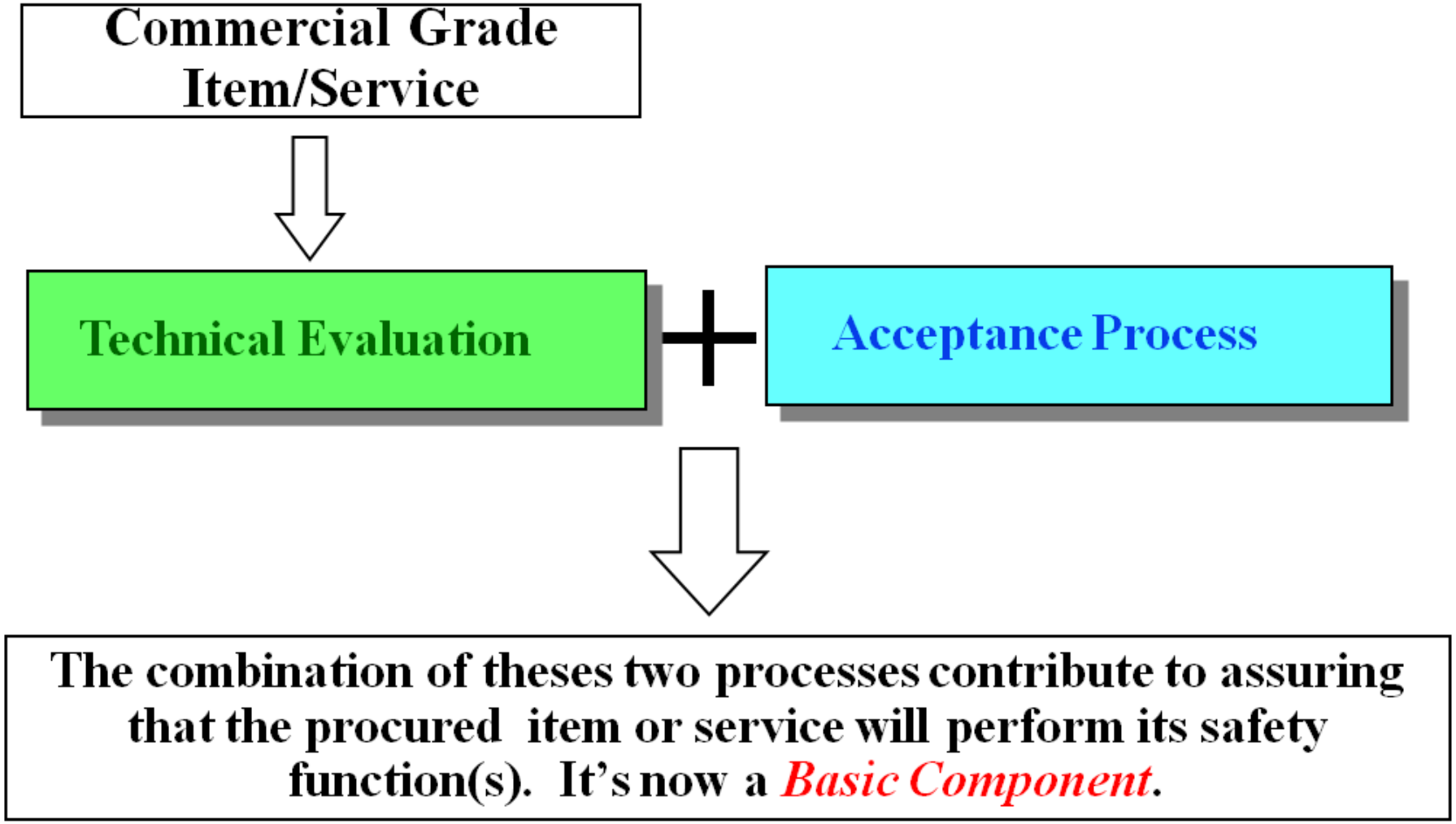
NQA-1 Part 2, Subpart 2.14
Commercial Grade Items & Services

- Quality Assurance requirements of Commercial Grade Items and Services
- Covers amplified requirements to provide reasonable assurance that a commercial grade item (CGI) or service will perform its safety function

NQA-1 Part 2, Subpart 2.14
Commercial Grade Items & Services

- What is Commercial Grade Item dedication?
  - An acceptance process undertaken to provide reasonable assurance that a Commercial Grade Item to be used as a Basic Component will perform its intended safety function.
- How is dedication performed?
  - Dedication consists of a technical evaluation of an item to identify *Critical Characteristics* followed by establishment of acceptance methods.

Safety-Related Commercial Grade Item Dedication

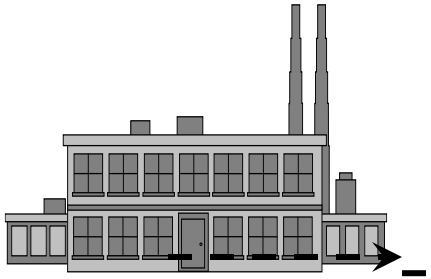


When/How Critical Characteristics Are Verified

During Manufacturing at Supplier/Sub-Supplier

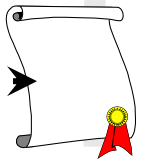
During Receiving

After Installation



In-process and final product testing

(Method 1)



Post installation testing of the item (Method 1)

Inspection of the item (Method 1)

Post installation testing of the item (Method 1)

Source Survey/Source Surveillance (Method 2 and 3)

Testing of the item (Method 1)

Conclusion

- 10 CFR 50 Appendix B is a law enforced by the NRC
- Its purpose is to focus on the safety of nuclear activities
- ASME writes NQA-1 to translate the law into practical application requirements & guidelines
- NRC reviews and sanctions some, but not all, versions of NQA-1
- Companies write procedures and work instructions on their activities at their facilities on how they meet the requirements of specific versions of NQA-1
- Companies prepare contracts to specific versions of NQA-1