

QAM 12120: Office of Quality Assurance Glossary

Revision History

| Author | Description of Change | Revision Date |
|---------------|-----------------------------------|----------------------|
| Mary Curtis | Defined new terms (QA, QC). | April 2022 |
| Mary Curtis | Initial release QAM Chapter 12120 | June 2020 |

GLOSSARY

A

AAC - Accelerator Advisory Committee^[8]

Acceptance Testing - The set of evaluation or tests to be performed to verify if predefined requirements and specifications are met which can be used to determine if the item will be accepted.^[12]

Activities - This encompasses a wide range of work performed to meet the lab's mission, including but not limited to operations work, basic and applied research, software development, procurement, design, construction, modification, and decommissioning.^[9]

AOC – Area of Concern^[10]

Application - A form of software developed or configured to perform a specific task or range of tasks.^[2]

Application Owner - The individual or group with the responsibility to ensure that the program or programs that make up the application, accomplish the specified objective or set of user requirements established for that application, including appropriate security safeguards.^[2]

Artifact - Any element created from the software development lifecycle, including but not limited to documentation, test plans, workflow diagrams, data files, and scripts.^[2]

Assessment - A review, evaluation, inspection, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. There are two main types of assessments: independent and management assessments.^[10]

Assessment Mentor - A lead assessor who has completed five or more assessments and has been recognized by the Quality Section Head as someone who will expertly advise and train assessors.^[10]

Assessor - A person with the training, experience and/or expertise to conduct an assessment.^[10] Has completed Internal Assessor training and prior assessment shadowing (observing two or more assessments) or experience or subject matter expertise.^[10]

B

Best Practice - An item type that is a positive example of a work process or innovative approach with the potential to be the basis for significant operational improvements or cost savings.^[10]

C

CAPA - Corrective and Preventive Actions^[6]

Causal Analysis - A way to uncover the underlying causes of a problem.^[15]

Causal Codes - The identified causes that lead to the incident and which are appropriately documented in accordance with the Causal Analysis Tree.^[13]

CMDB - Configuration Management Database^[11]

Collaboration Applications - Any application that has been developed by an institution in collaboration with Fermilab and utilized on-site. This type of application is split into two classifications: data collection applications and data analysis applications.^[2]

Contributing causes - The causes which did not initiate the problem, but had they not existed the problem could not have occurred or would have been less severe. They raise the probability of a problem.^[7]

Corrective Action - Action to eliminate the cause of a detected non-conformance or other undesirable situation. There can be more than one cause for non-conformance. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.^{[6] [10]}

COTS - Commercial Off the Shelf^[11]

Counterfeit item - An item that has been copied or substituted without legal right or authority to do so or one whose material, performance, or characteristics are knowingly misrepresented by the vendor, supplier, distributor, or manufacturer.^[12]

Criteria - The standards or requirements from policies or procedures that the assessment will be based on.^[10]

D

Data Driven Decision Making (DDDM) - A process that involves collecting data based on measurable goals or KPIs, analyzing patterns and facts from these insights, and utilizing them to develop strategies and activities that benefit the business in several areas.

Department of Energy (DOE) Headquarters Reviews - Reviews conducted by DOE organizations at the headquarters level (e.g., Office of Science). Methods for conducting these reviews and the response to any corrective or preventive actions that result are established by the sponsoring Office.^[10]

Direct Cause - The cause which immediately resulted in the problem, also known as the physical or proximate cause.^[7]

DOE Review - Review planned and conducted by the Fermi Site Office (FSO).^[15]

DOE Sensitive Information - Sensitive unclassified data, such as personally identifiable information (PII), official use only, and unclassified controlled nuclear information require special handling and protection to prevent misuse of the information for inappropriate purposes. (Reference <http://energy.gov/ig/downloads/audit-report-ig-0818>)^[2]

E

Effectiveness Review - A formal review of closed corrective actions of a nonconformance or management concern to determine if the actions adequately address the problem.^[10]

Effects Analysis – The study of the consequences of a failure mode being realized.^[9]

eMarketplace - The online procurement system for off-the-shelf supplies commonly requested by laboratory employees.^[12]

Enterprise Integrated Assessment Plan (E-IAP) - A subset of the annual Integrated Assessment Plan selected by the Office of Quality Assurance Head and SOG Chair after evaluating the priority and risk level of each topic.^[10]

EOP - Experiment Operations Plan^[8]

Error - Human decisions or actions that unintentionally depart from an expected behavior or some standard.^[13]

Error Precursors - Task-related conditions for a specific activity or task that provoke human error and increase the chance of a technical error or an adverse consequence; otherwise referred to as “risk factors.” Examples are time pressure, first-time activity, lack of knowledge or experience, and interruptions.^[13]

Evidence-Based Management (EBMgt) - The practice of making managerial and people related decisions with the use of critical thinking and the best available evidence.

ES&H (Environment, Safety & Health) Assessment - See *Triennial ES&H (Environment, Safety & Health) Assessment*.

Extent of Condition - Determination of the degree to which a problem or cause may exist in other portions of the system or similar systems.^[7]

F

Failure Mode - The way in which something may fail due to an error or defect.^[9]

Fermilab Quality Tool Suite (FQTS) - A system that contains three interrelated databases: iTrack, Lessons Learned and Assessment Database.^[10]

FESHCom - Fermilab ES&H Committee chaired by the Laboratory Director

FRA - Fermi Research Alliance^[8]

G

Graded Approach - The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with: the relative importance to safety, safeguards, and security; the magnitude of any hazard involved; the life-cycle stage of a facility or item; the programmatic mission of the facility.^[10]

Grading - Selecting the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the program.^[9]

H

Hazard Severity - An assessment of the potential consequences, defined by degree of injury, occupational illness, environmental impact, property damage, or project impact that is likely to occur as the result of a deficiency. This determination is subjective in nature.^[5]

Human Performance Improvement (HPI) - A set of concepts and principles associated with a performance model that illustrates the organizational context of human performance. The model contends that human performance is a system that comprises a network of elements that work together to produce repeatable outcomes. The system encompasses organizational factors, job-site conditions, individual behavior, and results.^{[1] [13]}

HPI Review - An incident investigation that utilizes HPI concepts and principles.^[13]

I

Incident - An unplanned event that interrupts the completion of an activity or causes injury and/or property/vehicle damage or a near miss. An incident is sometimes referred to as an "accident".^[13]

Independent Assessment - An assessment conducted by external or internal parties unrelated to the work or processes being evaluated.^[10]

Inspection - The evaluation or test performed on an item to verify that it meets or exceeds the specification of what was acquired or procured.^[12]

Inspection/Walkthrough - An examination of a work area for the purposes of determining compliance to a specified requirement or standard. These usually result in simple corrections or remedial actions for identified items although corrective actions may result from these activities.^[10]

Internal Audit - An independent office in Fermilab that conducts audits and provides guidance regarding internal controls.^[15]

Interviewee - A person who will be interviewed during the assessment.^[10]

ISO - International Standards Organization ^[15]

Item - A non-conformance, management concern, opportunity for improvement, recommendation, best practice, or lesson learned that is the output of an assessment and tracked in iTrack. ^{[5] [10]}

iTrack - (Issues Management Tracking System) A database used to document and facilitate the resolution of items of any nature arising from formalized activities where reports are typically generated. ^{[10] [13]}

J K L

Laboratory Level Assessment (QA) - An assessment conducted by the Quality Section against a specified procedure, requirement, or standard. ^[15]

Latent organizational weaknesses (LOW) - Hidden deficiencies in management control processes (for example, strategy, policies, work control, training, and resource allocation) or values (shared beliefs, attitudes, norms, and assumptions) that create work place conditions that can provoke errors (precursors) and degrade the integrity of controls (flawed controls). ^[13]

LDRD - Laboratory Directed Research and Development ^[8]

Lead Assessor (LA) - Completion of LA training, prior assessment experience, professional certification or training, prior qualifications (as determined by Quality Section). If professional certification or prior qualifications are not held, an alternative method to become a lead assessor is to participate in three or more assessments with a qualified lead assessor. ^[10]

Lead-in-Training - A member of the assessment team who is acting in the role of lead but has not met the requirements of a lead assessor. ^[10]

Lessons Learned (LL) - An item type that is a best practice captured and shared to promote repeat application, or an adverse work practice or experience that is captured and shared to prevent recurrence. ^[10]

Lessons Learned Report - In the LL database, the record for capturing an LL that was not discovered as part of a planned activity. ^[5]

Line of Inquiry (LOI) - An ordering of questions to gain an understanding of the process or system. ^[10]

Loss of Availability - Disruption of access to or use of information or an information system. ^[2]

Loss of Confidentiality - Unauthorized disclosure of information. ^[2]

Loss of Integrity - Unauthorized modification or destruction of information. ^[2]

M

Management Assessment - An assessment performed by an organization on its own processes and programs. (May be a Self-assessment, Triennial ES&H assessment, FESHCom Subcommittee assessment, Tripartite assessment, Management Field Observation, or ES&H Inspection and Walkthrough.) ^[10]

Management Concern - An issue management has identified that requires action to mitigate associated risk. Requires performance of a risk analysis, identification of a root cause, and identification of corrective or preventive actions. ^[10]

Management System Self-Assessment - An assessment performed by a Management System Owner of their Management System against a procedure or requirement. ^[15]

Management Walkthrough - A less formal assessment conducted by senior managers ^[15]

Mentor - A member of the assessment team who guides the Lead-in-Training. ^[10]

Mishap Probability - The probability that a hazard will result in an incident based on an assessment of such factors as location, exposure and affected population. The determination is subjective in nature. ^[5]

N

Near Miss - An unplanned event that did not result in injury, illness, or damage but had the potential to do so. Only a break in the chain of events prevented an injury, fatality or damage. Other familiar terms for these events is a "close call", or in the case of moving objects, "near collision."^[13]

Nonconformance - Non-fulfillment of a requirement. A nonconformance can be a deviation from work standards, practices, procedures, legal requirements or applicable code of federal regulations.^[6]
^[10]

Nonconforming item - Any item that does not meet specified requirements.^[4]

NSF - National Science Foundation^[8]

O

Objective - The goal of the assessment. Answers the question: why is this value added to the Laboratory?^[10]

Observer - A member of the assessment team who does not have an active role in the assessment but may provide their observations of the assessed area to the other members of the team^[10]

OFI - Opportunity for Improvement

Operational Excellence - A mindset that embraces certain principles and tools to create sustainable improvement within an organization.

OPEXShare - An online network of Lessons Learned, Best Practices and other safety and health related information for use by the U.S. Department of Energy, State and local governments, and their contractors.

Opportunity for Improvement (OFI) - An item type that is a suggestion on how to improve the identified topic.^[10]

OUO - Official Use Only

P

PAC - Physics Advisory Committee^[8]

Participant - A member of an assessment team.

PI - Principal Investigator^[8]

Plan - Description of the activities (e.g., schedule, interviewees, LOIs) of an assessment.^[10]

PDCA - Plan Do Check Act. An iterative four-step management method used in business for the control and continuous improvement of processes and products.

POC - Point of Contact ^[8]

Predictive Solutions - ES&H database used to capture observations in the field for construction safety and facility safety. ^[15]

Preventive Action - Action to eliminate the cause of a potential non-conformance or other undesirable potential situation. There can be more than one cause for a potential nonconformance. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. ^[6]

ProCard - Procurement credit cards issued to a select group of FRA employees upon the completion of training by a Procurement representative. Cardholders may use the ProCard for the acquisition of commercial goods and off-site services priced up to \$2,500 and are not available through eMarketplace as described in the ProCard Users Guide.^[12]

Procedure - Specified way to carry out an activity or process.^[6]

Q

QA Assessment - A system or program-level independent assessment conducted in various areas within the Line Management organizations and MSOs by the Quality Section. Their purpose is to evaluate process or system implementation and effectiveness and ultimately drive improvement.^[10]

Qualifications - The required training, experience, or expertise to participate on an assessment team.^[10]

Quality Assurance (QA) - All planned and systematic actions that provide confidence that quality is achieved.^[15]

Quality Assurance Manual (QAM) - A living set of procedures established to provide guidance and communicate critical quality program requirements.^[1]

Quality Control (QC) - A set of activities for ensuring the qualification of products or services. The activities focus on identifying defects and out of specification conditions in the products produced or services provided.^[15]

R

RCRA Inspections - Resource Conservation and Recovery Act.^[15]

Receipt - Delivery of an item. This does not necessarily imply that the item is acceptable for use.^[12]

Recommendation - An item type that is a suggestion or proposal from the Reviewer as to the best course of action to take on the identified topic. *This term is typically reserved for DOE or Project Reviewers.*^[10]

Record - Document stating results achieved or providing evidence of activities performed.^[6]

Remedial Action - An action taken to alleviate the symptoms of existing non-conformance or any other undesirable situation. Also, known as correction or compensatory action, remedial action is used to minimize the effects before the root cause and best solution may be identified. It is a reactive, short term action to stop immediate effects of the problem.^[6]

Requestor - FRA personnel making the request for equipment, component, or material; either acquired from a partnering/collaborating institution or via a procurement. This may also be the person responsible for performing the incoming inspections or acceptance testing.^[12]

Review - An iTrack-designated term for activities that generate items. An **assessment** is a type of review in iTrack.^[10]

Risk - Combination of the likelihood of an occurrence of a hazardous event or exposure(s) and the severity of injury or ill health that can be caused by the event or exposure(s).^[6] A fundamental consideration in determining the extent to which controls should be applied at the facility level.^[10] A fundamental consideration in determining the extent to which controls should be applied at the facility level.^[9]

Risk Assessment Code - The degree of risk associated with a deficiency that combines the elements of hazard severity and mishap probability.^[5]

Risk-Based Planning - Focuses on the strategic, regulatory, financial, and business risks to which the Laboratory has exposure. The goal is to customize a dynamic, defensible assessment plan that addresses the unique needs and risks of the work being performed. ^[10]

Root Cause - An identified reason for the presence of a defect or problem or the source of origin of an event. The most basic reason, which if eliminated, would prevent recurrence. ^[6] The source or origin of an event. There may be more than one root cause for an event. ^[5] Also known as “system cause.” ^[7]

Root Cause Analysis (RCA) - A logical thinking process using deductive and inductive searches to collect evidence to support or deny actual causes of a problem. ^[7]

S

SAC - Scientist Advisory Council ^[8]

Scope - The extent and boundaries of an assessment. ^[10]

SDSTA - South Dakota Science and Technology Authority ^[15]

Self-assessment - An evaluation of a program or process conducted by members of the organization being evaluated. ^[10]

Self-Assessment (Division/Section/Project) - An assessment conducted entirely by D/S/P personnel and reported internally to the D/S/P leadership. ^[15]

Software - All non-hardware items associated with the operation and use of a computing system. Software examples include operating systems, programming languages, spreadsheets, word processors, databases, and digital media files. ^[2]

SOG – Services Oversight Group ^[10]

SOW - Statement of Work ^[8]

Software Quality Assurance (SQA) - Processes and procedures that ensure that an application meets or exceeds established requirements. ^{[2][11]}

Subject Matter Expert (SME) - An individual with qualifications and experience in a particular field or work process; an individual who by education, training, and/or experience is a recognized expert on a particular subject, topic, or system. ^[3]

Suspect/Counterfeit Item (S/CI) - An item identified through visual inspection, testing, or other means that does not appear to conform to established Government or industry-accepted specifications or national consensus standards. Or, items whose documentation, appearance, performance, material, or other characteristics may have been knowingly misrepresented by the vendor, supplier, distributor, or manufacturer. ^[11]

Suspect Item - An item identified through visual inspection, testing, or other means that does not appear to conform to established Government or industry-accepted specifications or national consensus standards. Or, items whose documentation, appearance, performance, material, or other characteristics may have been knowingly misrepresented by the vendor, supplier, distributor, or manufacturer. ^[4]

SWOT - Strengths, Weaknesses, Opportunities, Threats. A Strategic planning technique used to help a person or organization identify strengths, weaknesses, opportunities, and threats related to business competition or project planning.

T

Third Party Audits/Assessment - Audits and/or assessments performed on the organization by agencies external to Fermilab. ^[6]

Triennial ES&H (Environment, Safety & Health) Assessment - An assessment whose purpose is to determine if the Laboratory complies with a specific DOE Order or contract requirement. Conducted on a three-year cycle. ^[10]

Tripartite Assessment - An assessment performed and planned jointly by a D/S, the ESH Section, and DOE-FSO and led by a member of the assessed organization. ^{[10] [15]}

U

UEC - Users Executive Committee ^[8]

Unexpected Outcome - An occurrence which deviates from planned requirements (activities or results) or expected outcomes which may range from a simple procedural noncompliance with minimal

risk to an accident/event having substantial risk to personnel. For ESH incidents refer to FESHM 3020.
[7] [13]



Walkthrough/Inspection (ES&H) - an examination of a work area for the purposes of determining compliance to a specified requirement or standard. [15]



REFERENCES

- [1] QAM Chapter 12002 *Fermilab Quality Assurance Program*
- [2] QAM Chapter 12003 *Fermilab Software Quality Assurance Program*
- [3] QAM Chapter 12010 *Fermilab Lessons Learned Program*
- [4] QAM Chapter 12020 *Suspect/Counterfeit Items (S/CI) Program*
- [5] QAM Chapter 12030 *Fermilab Quality Tool Suite Procedures and Risk Assignment*
- [6] QAM Chapter 12040 *Corrective and Preventative Actions*
- [7] QAM Chapter 12050 *Root Cause Analysis*
- [8] QAM Chapter 12060 *Quality Assurance Guidelines for Scientific Research*
- [9] QAM Chapter 12070 *Graded Approach Procedure*
- [10] QAM Chapter 12080 *Fermilab Assessment Program*
- [11] QAM Chapter 12090 *Software Quality Assurance Grading & Inventory Procedure*
- [12] QAM Chapter 12100 *Incoming Inspection and Acceptance*
- [13] QAM Chapter 12110 *Human Performance Improvement (HPI)*
- [14] QAM Chapter 12130 *Quality Assurance Planning Guidelines for FRA Projects*
- [15] *Fermilab Quality Tool Suite User Guide*

