Standardization Training Program

PA Management and Quality Assurance

June 2016

Introduction
Outline of Presentation

Standardization
training program
Space Project Management

Part 1 – Product Assurance Management (60 min)

- Introduction with definitions and ECSS organization
- Review of the supporting Product Assurance disciplines
- Discussion on PA Management and planning

Part 2 – Quality Assurance (80 min)

- Walk through of Quality Assurance standard (ECSS-Q-ST-20-C)

Part 3 – General Quality Management (20 min)

- General discussion on quality management, ISO 9001, and ECSS
- Comments on supply chain management and internal audits

PART 1

Product Assurance Management

Introduction

ECSS branches / disciplines

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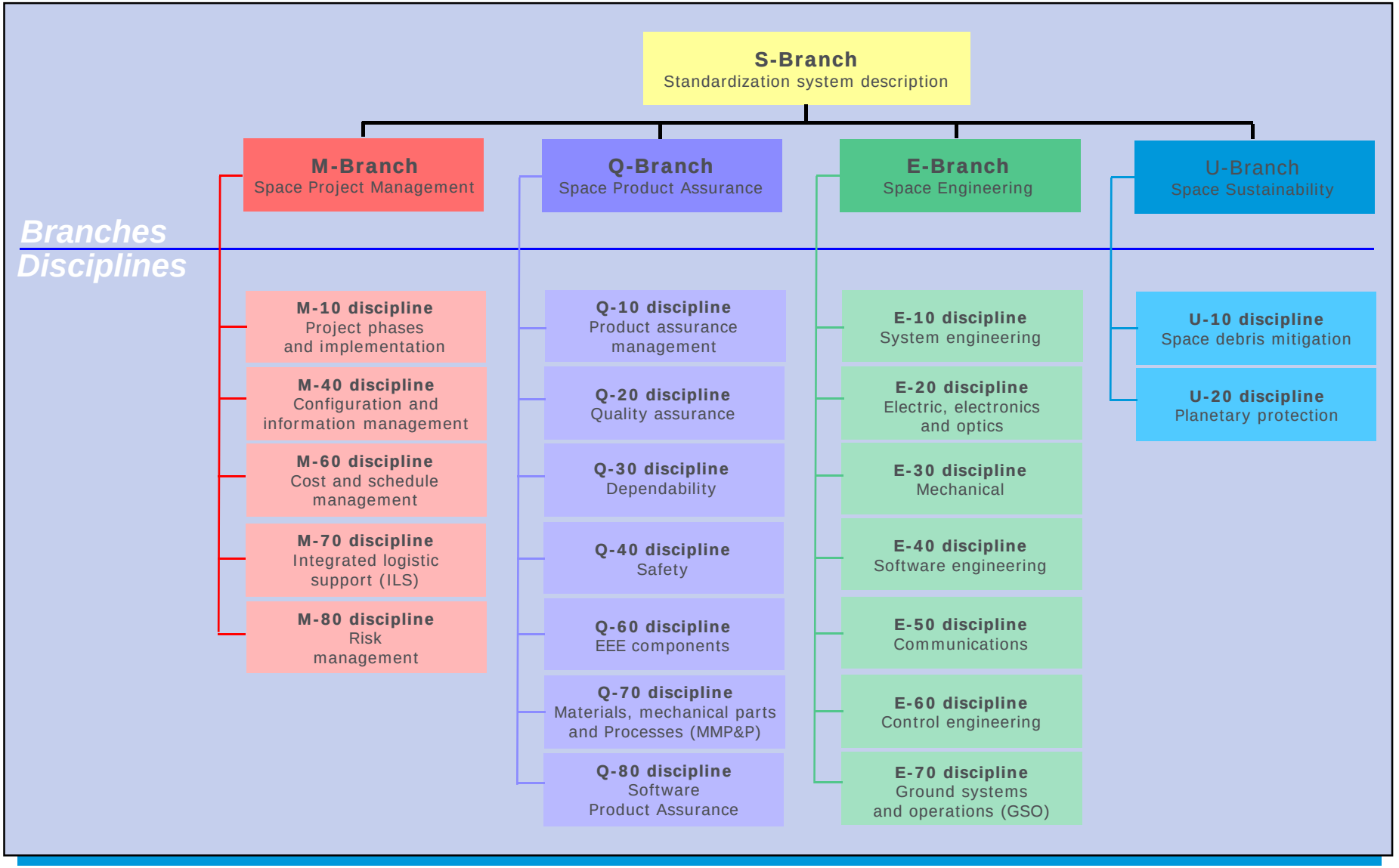

Product Assurance Standards (1/2)

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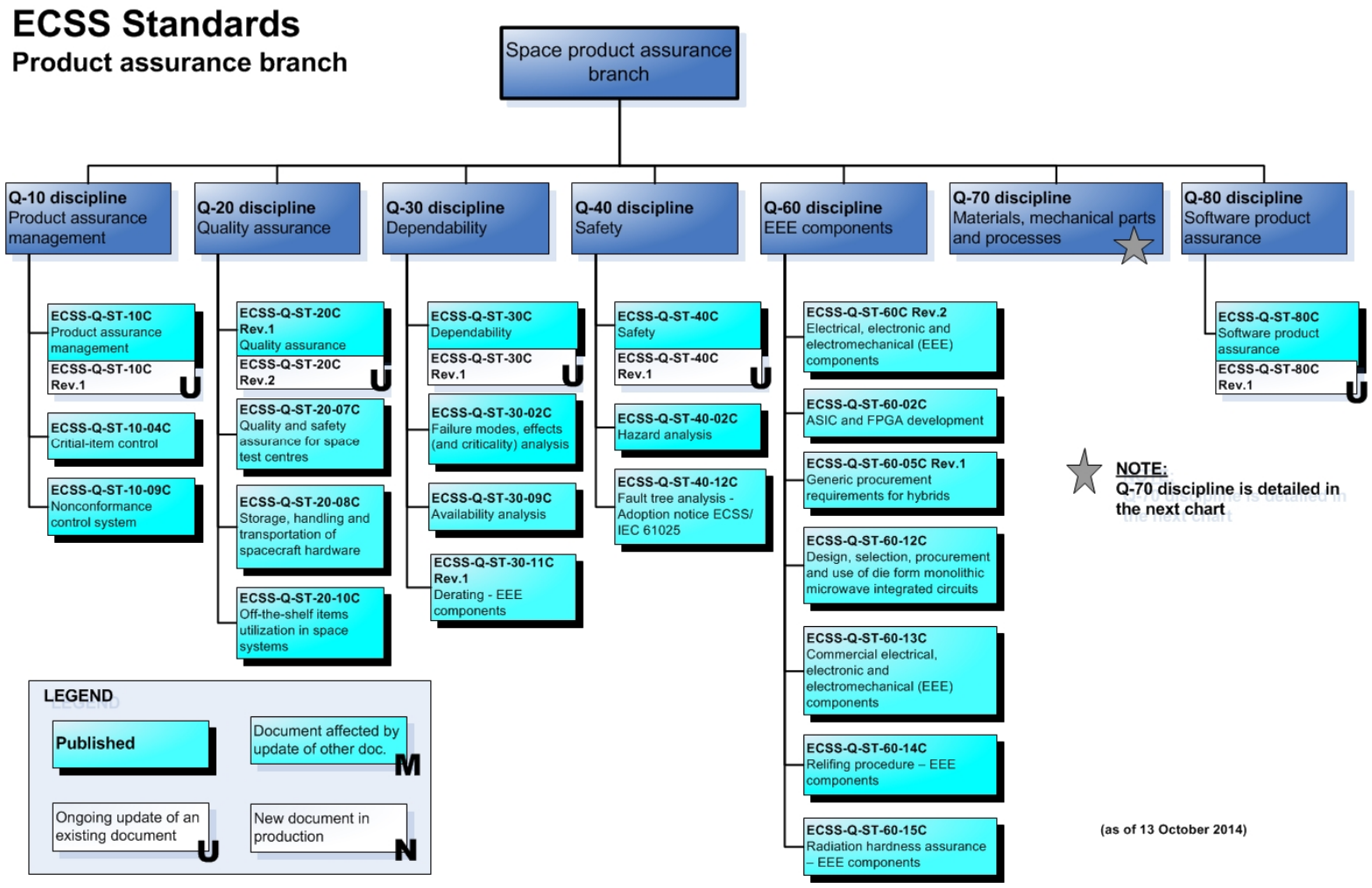

Product Assurance Standards (2 / 2)

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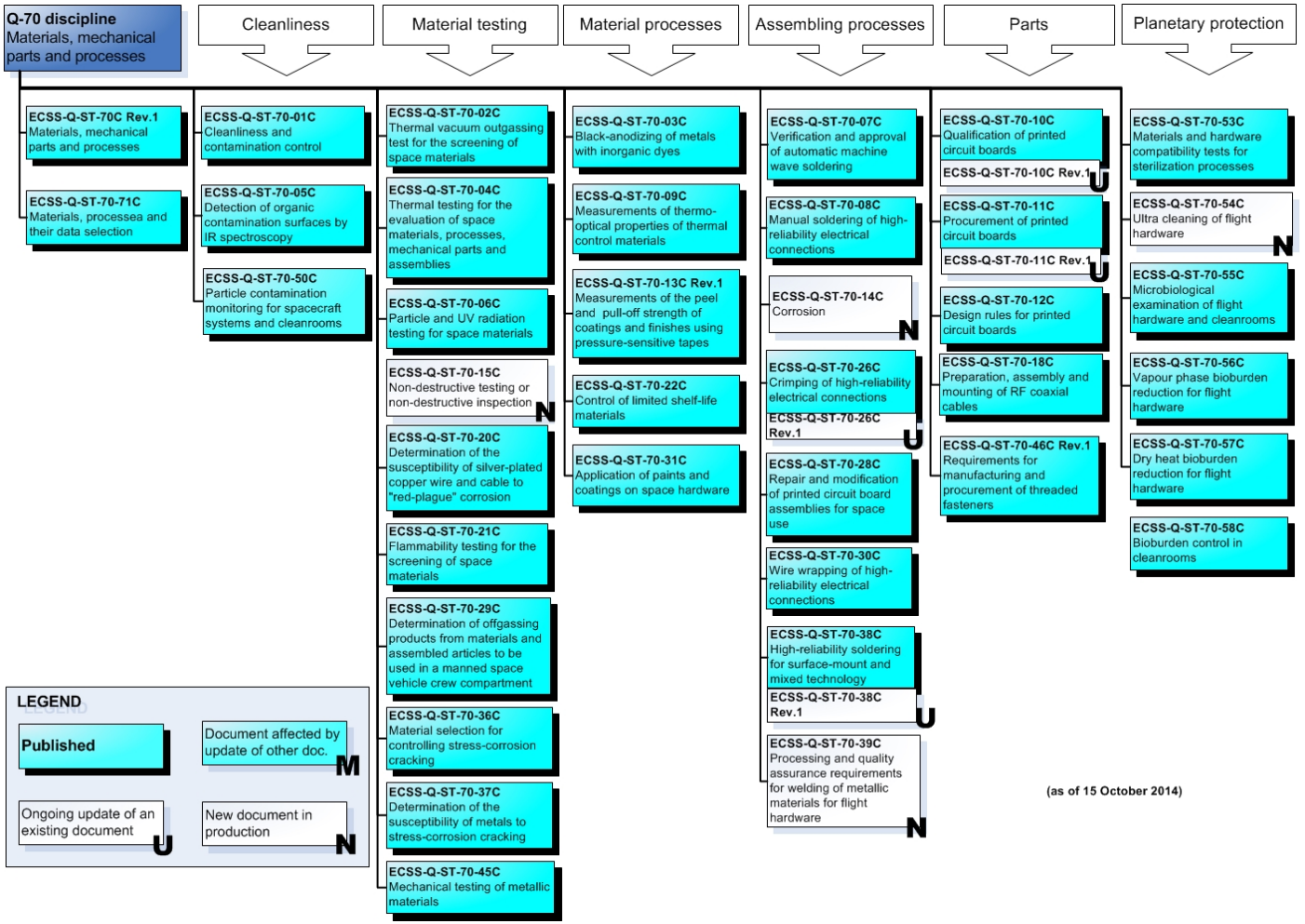

What is Product Assurance?

Discipline devoted to the study, planning and implementation of activities intended to assure that the design, controls, methods and techniques in a project result in satisfactory degree of ***quality*** *in a product.*

(cl. 2.3.158 of ECSS-S-ST-00-01C, ECSS System – Glossary of Terms)

Quality *– degree to which a set of characteristics of a product or process fulfills requirements*

(cl. 2.3.166 of ECSS-S-ST-00-01C, ECSS System – Glossary of Terms)

Product Assurance Activities

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Quality Assurance	Apply methods ensure correct development and workmanship to control errors and document quality
Dependability	Design for Reliability, Availability and Maintainability. Assess the conditions and reactions to maintain functions
Safety	Identify and mitigate risks that can lead to fatalities, injuries Environmental pollution, damage to facilities
EEE components	Select components Electrical, Electronic or Electromechanical (EEE), that meet mission requirements
Materials, mechanical parts and processes	Select Materials, Mechanical Parts and Processes which meet the requirements for environment and mission uses.
Software PA	Use specific methodology for quality and verification assessment of software with different criticalities

Before discussing PA Disciplines

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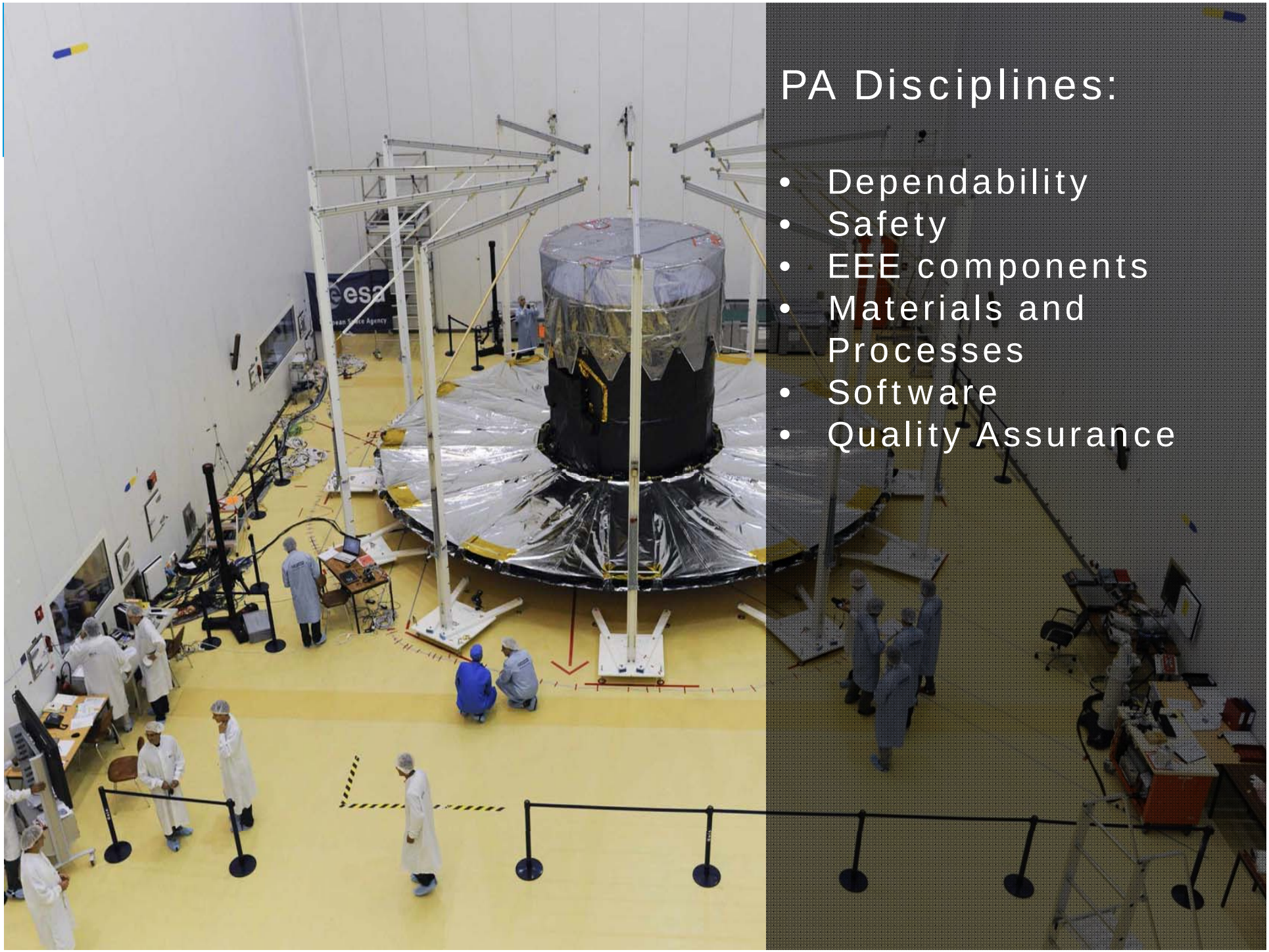
- The role of PA management is to bring together expertise and to decide on the work contents and outputs; making sure that adequate resources are available.
  - Are the quality requirements clear?
  - Is the expertise available ?
  - Are lower-level suppliers adequate for the job ?
  - Are there any issues with facilities ?
  - What level of effort will it take ?
  - Are the PA inputs and outputs in synch with project ?
  - How will risks be managed?
  - Are document contents and record keeping clear?



PA Disciplines:

- Dependability
- Safety
- EEE components
- Materials and Processes
- Software
- Quality Assurance

Establishing Dependability Requirements

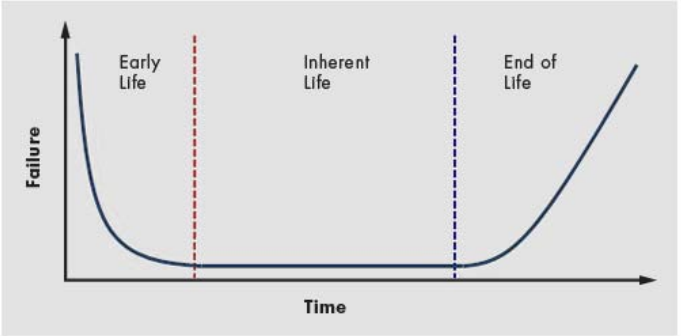
Dependability –

"the extent to which the fulfillment of a Required function can be justifiably trusted"

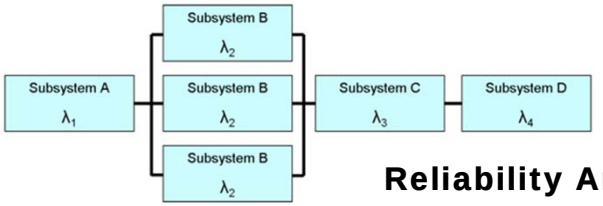
Focus on reliability, availability and maintainability. Typical tasks include

- Failure mode and effects analysis (FMEA)
- Selecting observables for monitoring
- Reliability predictions and redundancy
- Factors that reduce availability
- Assessing stress on electronics
- Failure isolation and recovery

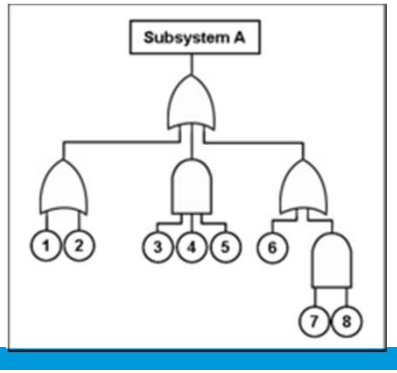
Example Outputs
- Specifications for redundant systems
- Lifetime and availability predictions



Failure rates



Reliability Analysis



Fault Trees

Monitoring Dependability Requirements

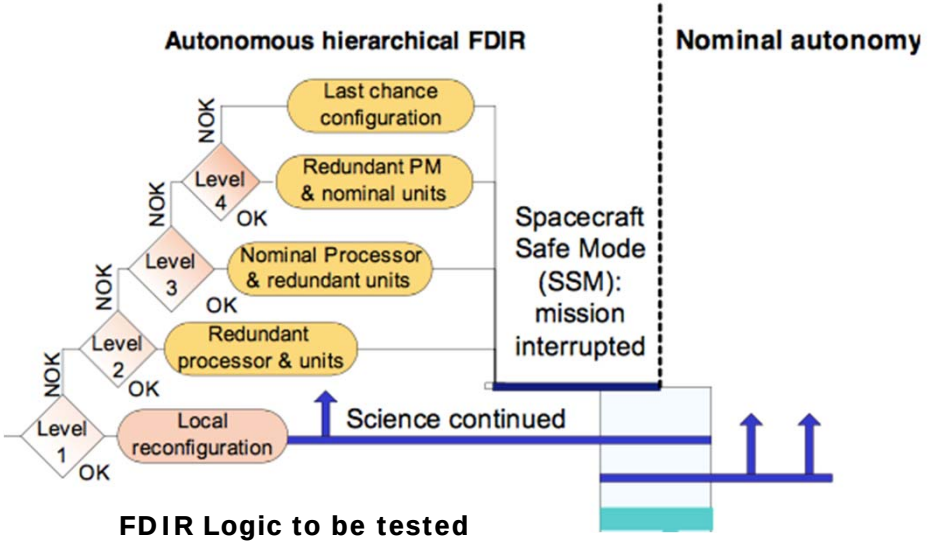
Verification of Dependability

Verification by analysis (need data)

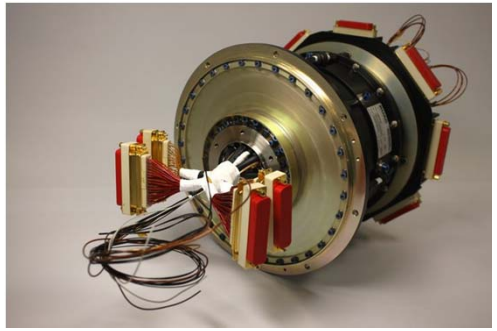
Verification of fault tolerance effectiveness by FDIR tests and simulation

Verification by testing:

- Life testing provides confidence of time-to-failure and also of the Wear out behaviour



FDIR Logic to be tested



Testing of critical mechanisms (SADM shown above)

Q-30 - Dependability

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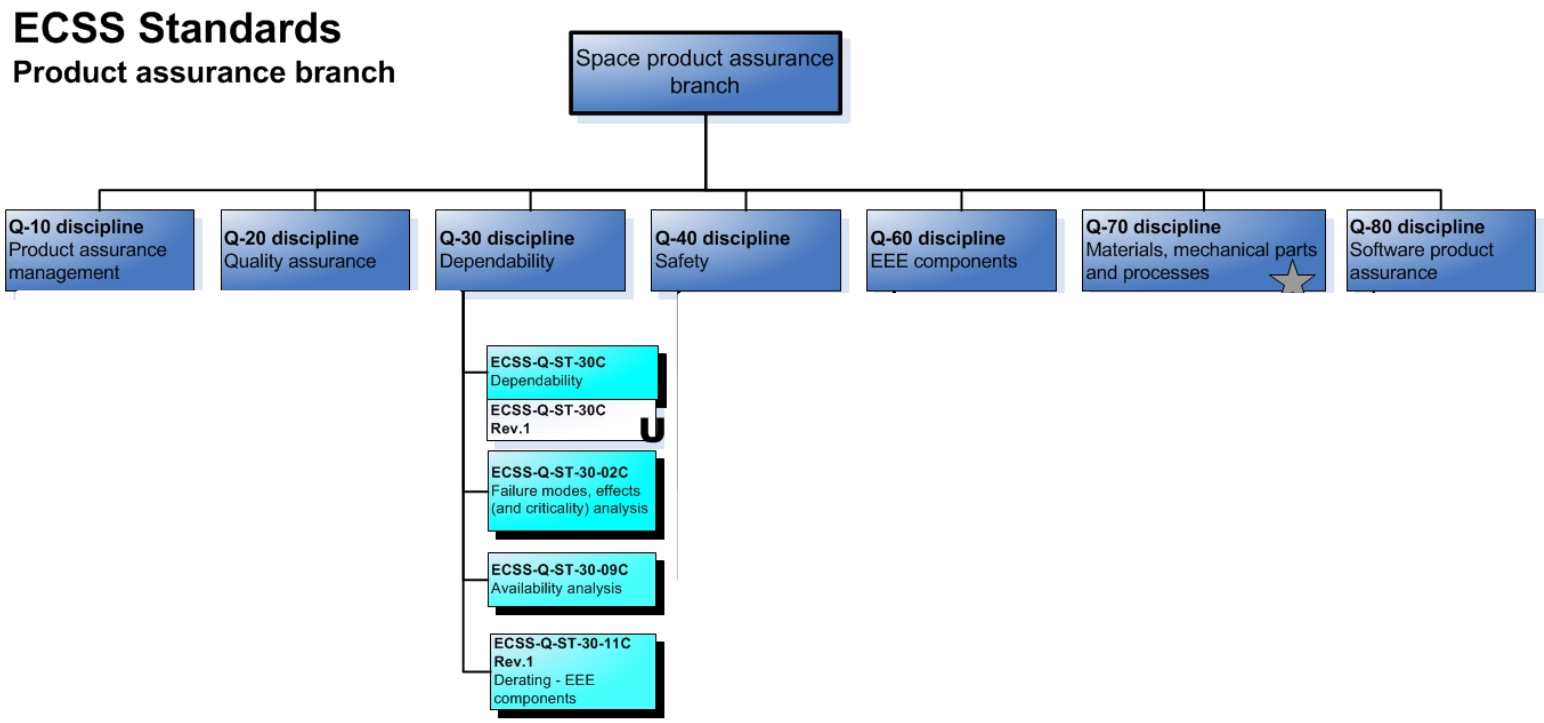

Establishing Safety Requirements

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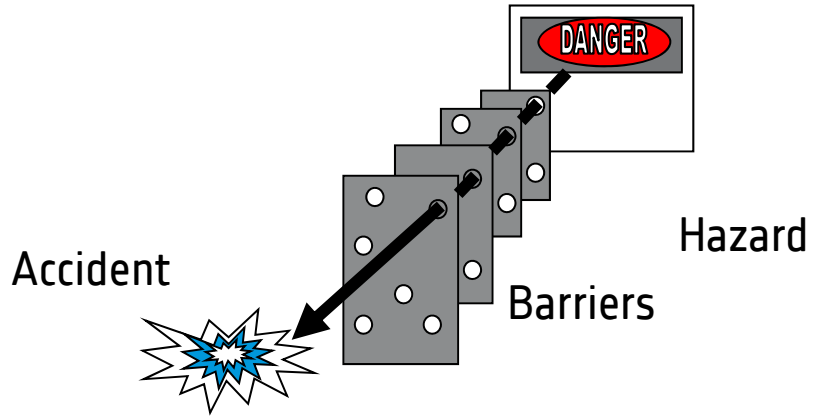
Safety requirements:

Analysis hazard conditions and design to
Determine whether risks are acceptable.
Improve design to reduce risk or information
For decisions.

Safety analysis takes many
inputs from the FMEA/FMECA analysis

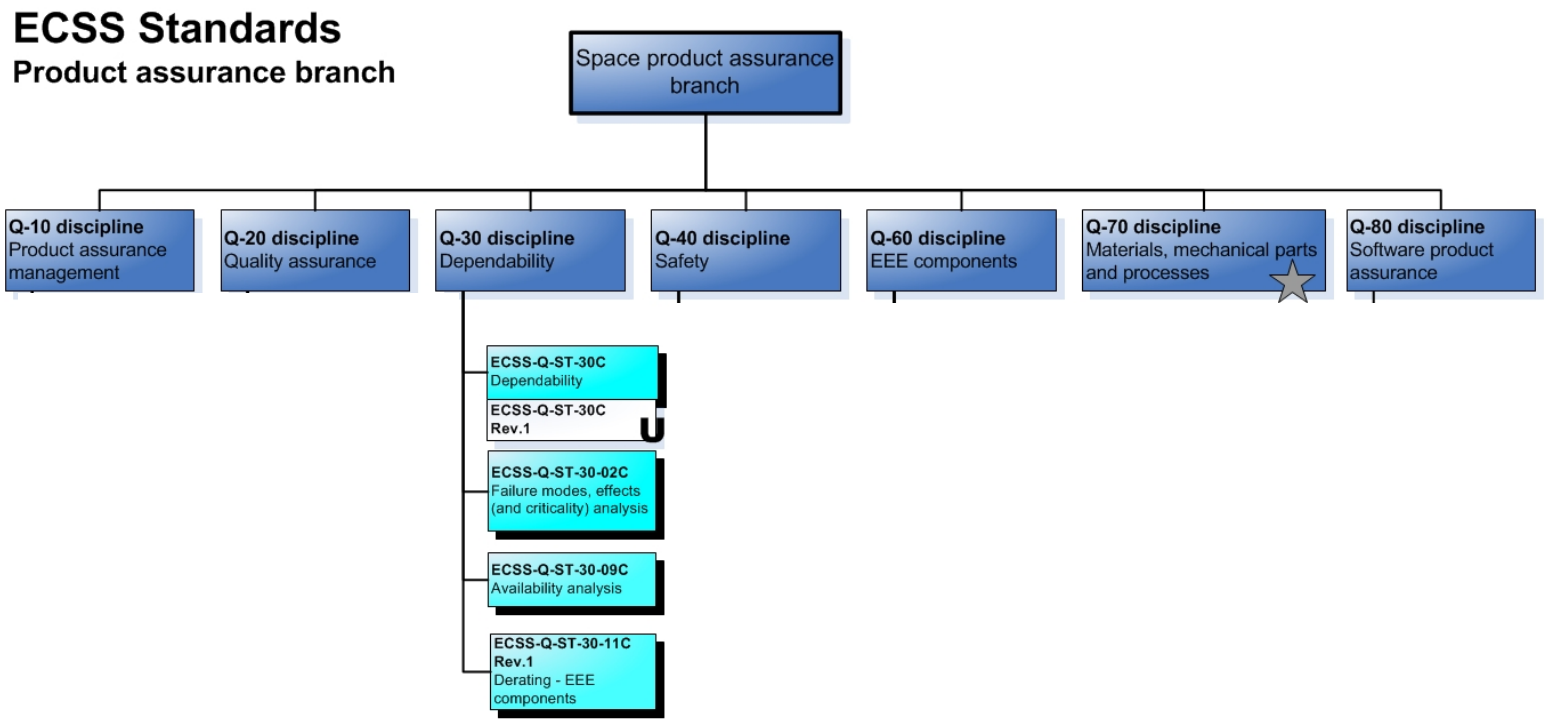
Typical Tasks and Outputs

- Identify system hazards and mitigations
- Design barriers to improve safety
- Identify constraints
- Training of personnel
- Launch safety submission



Category	Severity	Severity of safety consequence
1	Catastrophic	Loss of life, life-threatening or permanently disabling injury or occupational illness; Loss of an element of an interfacing manned flight system; Loss of launch site facilities or loss of system; Severe detrimental environmental effects.
2	Critical	Temporarily disabling, but not life-threatening injury or illness; Major damage to flight systems or loss of or major damage to ground facilities; Major damage to public or private property; Major detrimental environmental effects.
3	Marginal	Minor injury, minor disability, minor occupational illness; Minor system or environmental damage.
4	Negligible	Less than minor injury, disability, occupational illness; Less than minor system or environmental damage.

Q-40 - Safety


ECSS Standards
Product assurance branch
Space product assurance branch
Q-10 discipline
Product assurance management
Q-20 discipline
Quality assurance
Q-30 discipline
Dependability
Q-40 discipline
Safety
Q-60 discipline
EEE components
Q-70 discipline
Materials, mechanical parts and processes
Q-80 discipline
Software product assurance
ECSS-Q-ST-30C
Dependability
ECSS-Q-ST-30C
Rev.1
ECSS-Q-ST-30-02C
Failure modes, effects (and criticality) analysis
ECSS-Q-ST-30-09C
Availability analysis
ECSS-Q-ST-30-11C
Rev.1
Derating - EEE components

Establishing EEE Requirements

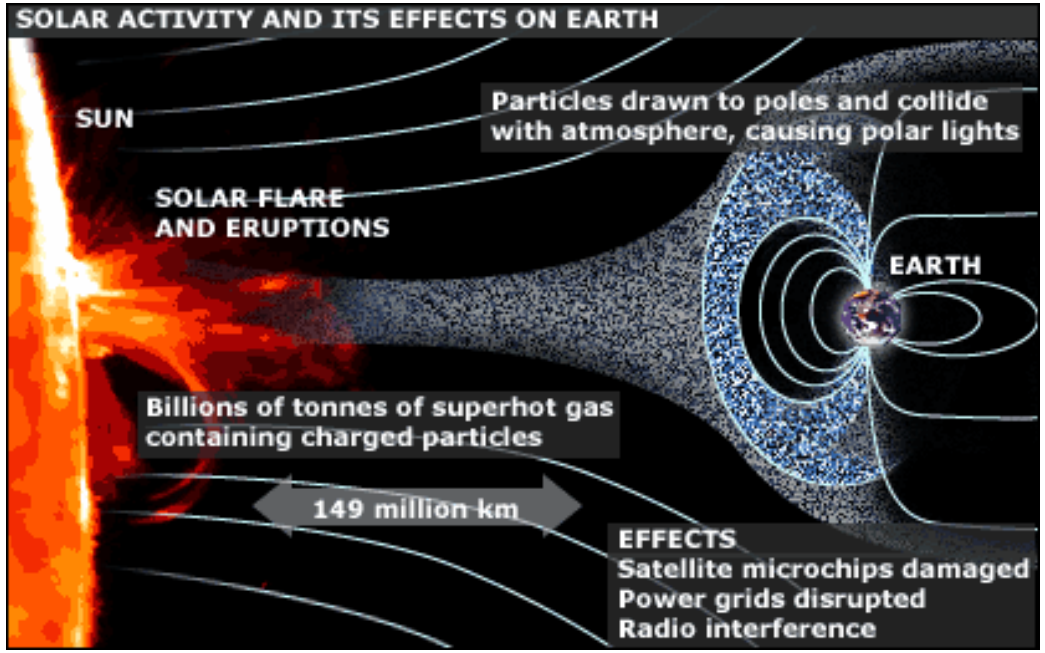
EEE components

Select components that are
are able to survive and operate in
their planned environments.

Typical Tasks and/or Outputs

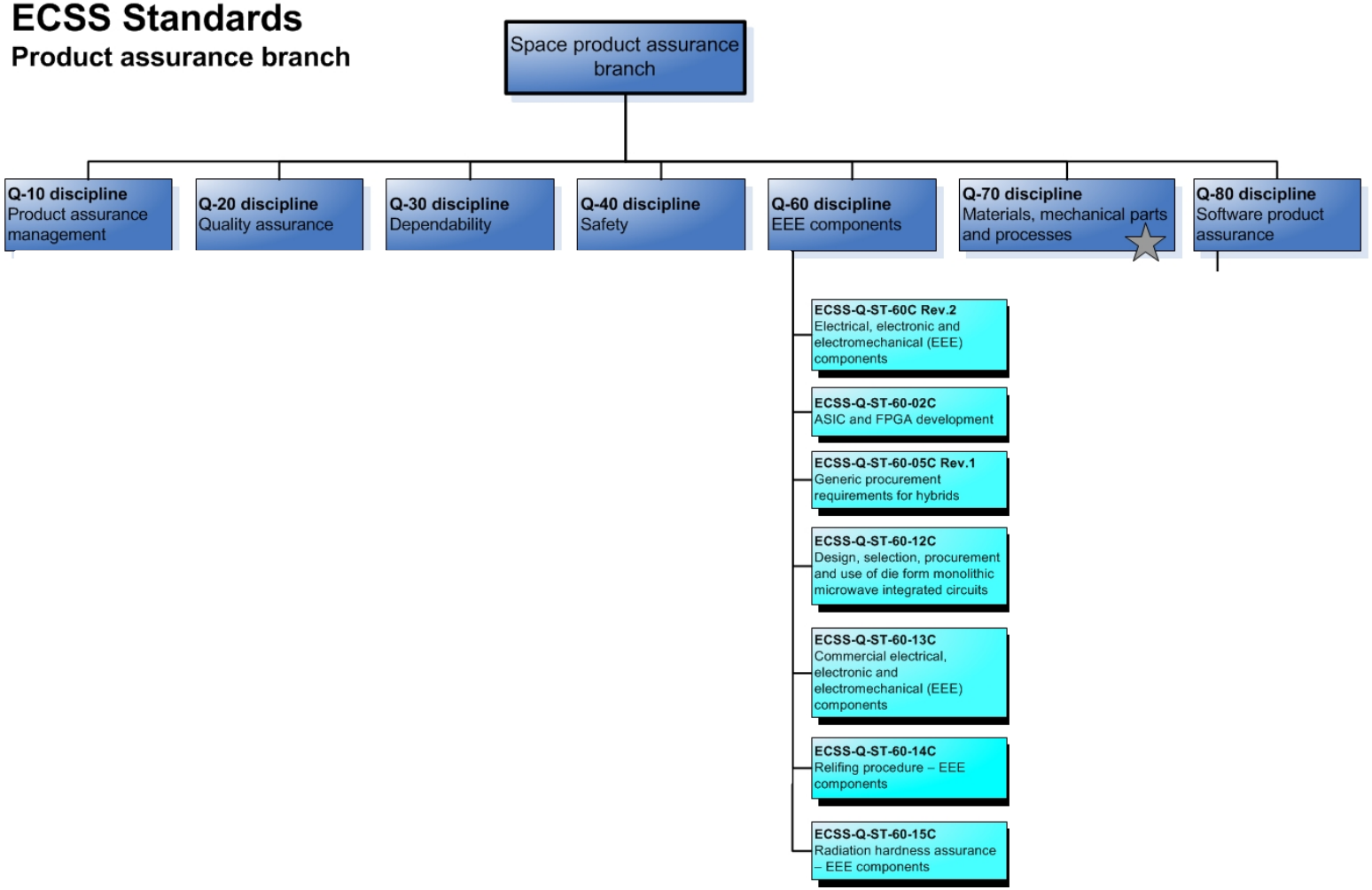
- Selection of components
- Evaluation/Qualification of parts
- Radiation effects (TID/SEE)
- Lifetime and stability
- Inspections
- Screening

This is often a complex process
with detailed justification and
traceability of parts.



Q-60 - EEE

ECSS Standards
Product assurance branch

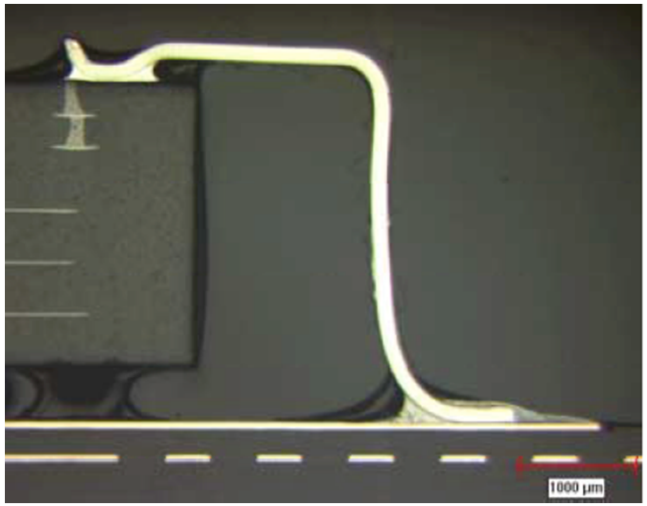


Establishing MPP Requirements

Materials, Mechanical Parts and Processes requirements

Discipline to answer questions:

- Are the materials compatible with the requirements?
- Will they contaminate or degrade?
- Are the mechanical parts well designed, manufactured and tested?
- Will processes used to manufacture and assembly withstand the environments?



Q-70 – Materials and Processes

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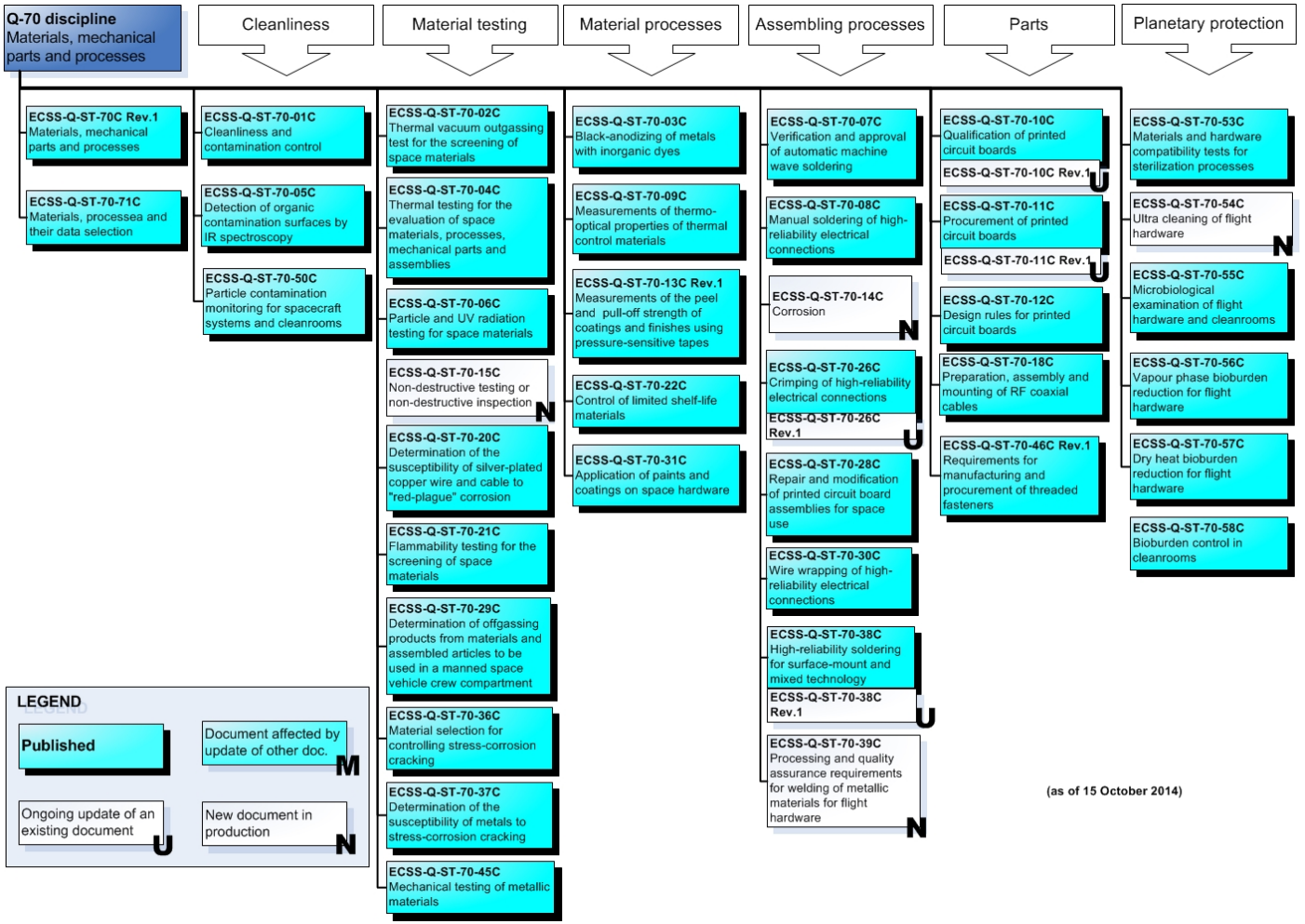

Monitoring Software Product Assurance Requirements

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Software Risks

Software is classified according to its Criticality – linked to the consequence of failures

The category then determines the degree to Which quality checks and verifications are performed.

Software assessment is the process in which software is checked and determined to be safe to use for an application.

Note: the range of input values needs to be also checked

Category	Definition
A	Software that if not executed, or if not correctly executed, or whose anomalous behaviour can cause or contribute to a system failure resulting in: → Catastrophic consequences
B	Software that if not executed, or if not correctly executed, or whose anomalous behaviour can cause or contribute to a system failure resulting in: → Critical consequences
C	Software that if not executed, or if not correctly executed, or whose anomalous behaviour can cause or contribute to a system failure resulting in: → Major consequences
D	Software that if not executed, or if not correctly executed, or whose anomalous behaviour can cause or contribute to a system failure resulting in: → Minor or Negligible consequences

Ariane 501 failure

video on Youtube

Establishing Software Product Assurance Requirements

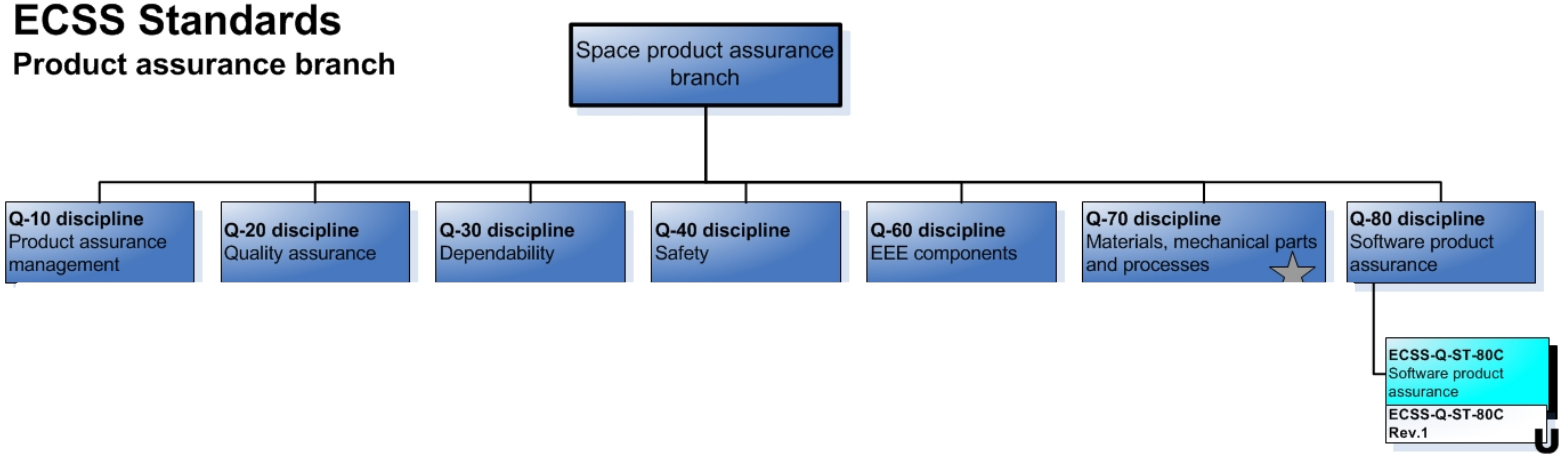
Software PA Requirements

Quality Models should be used to specify quality requirements.

Quality Models define the main goal characteristics of the software and are the basis for the measurement of the quality of the processes and products.

Q-80 – Software PA

ECSS Standards
Product assurance branch

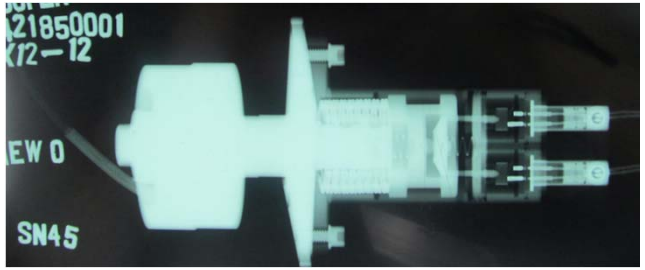


Establishing Quality Assurance Requirements

Quality Assurance Requirements

The QA activities helps prevent defects which can have major consequences.

QA methods collect quality records that are needed to contain problems when detected, including risks to parts that have been shipped to other users

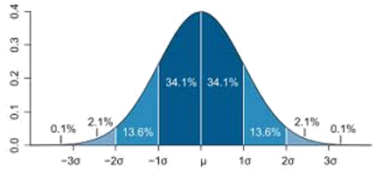


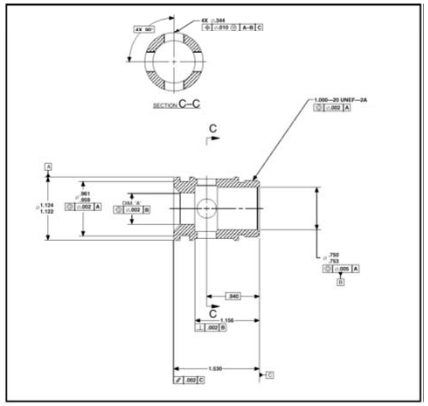
Monitoring Quality Assurance Requirements

Demonstration of Quality Assurance Requirements

Assurance that production uses
- Approved procedures, competencies
- Facilities that are appropriate
- Standards and agreed criteria
- Detailed instructions for work
- Proper metrology methods
- Quality records for traceability

Quality Control addresses
- Inspection and verification of quality
- Documentation of quality
- Resolving failures in production
- Traceability of parts and labour
- Approval and acceptance





Product Assurance Standards (1/2)

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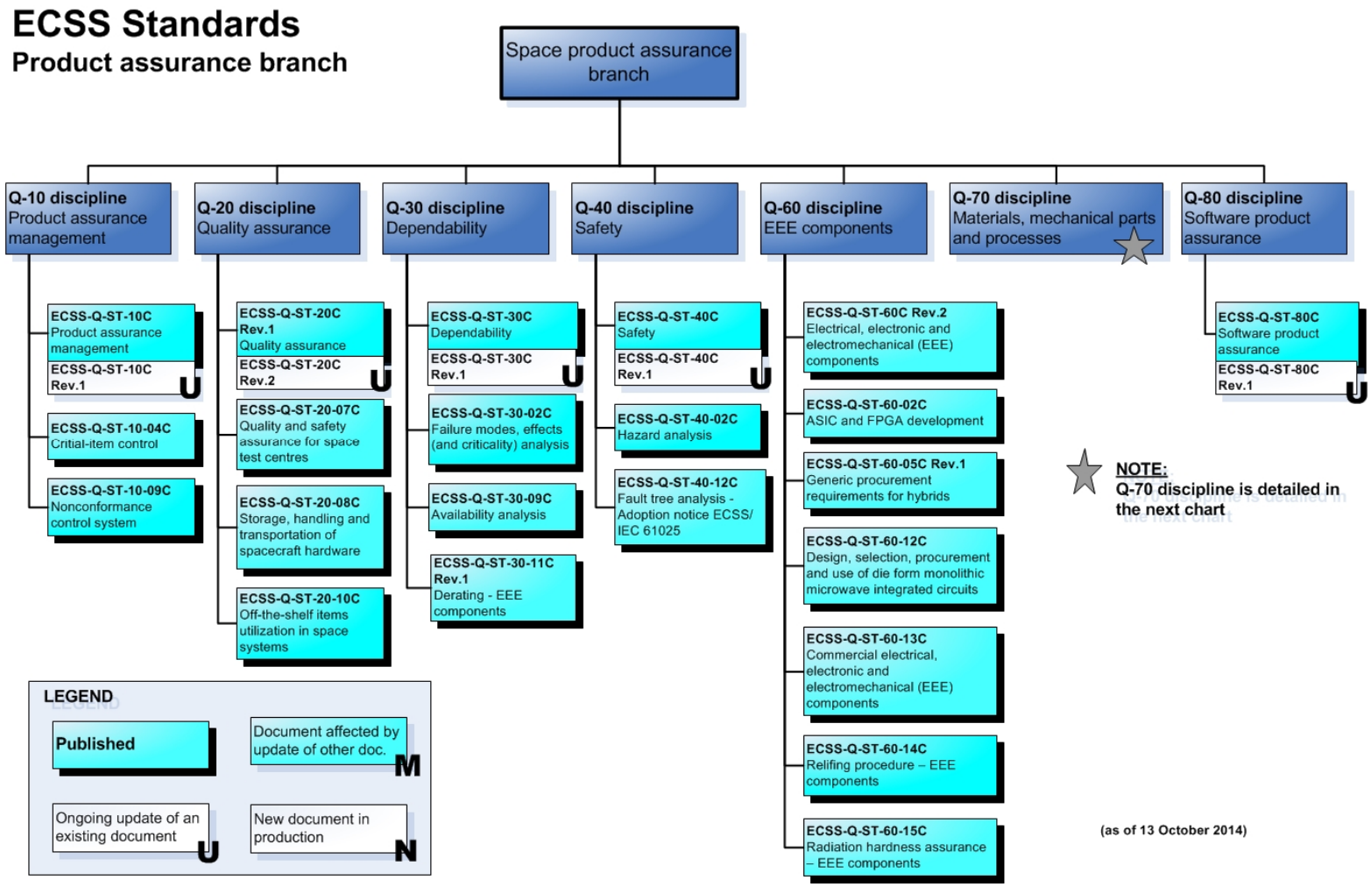

Product Assurance Standards (2/2)

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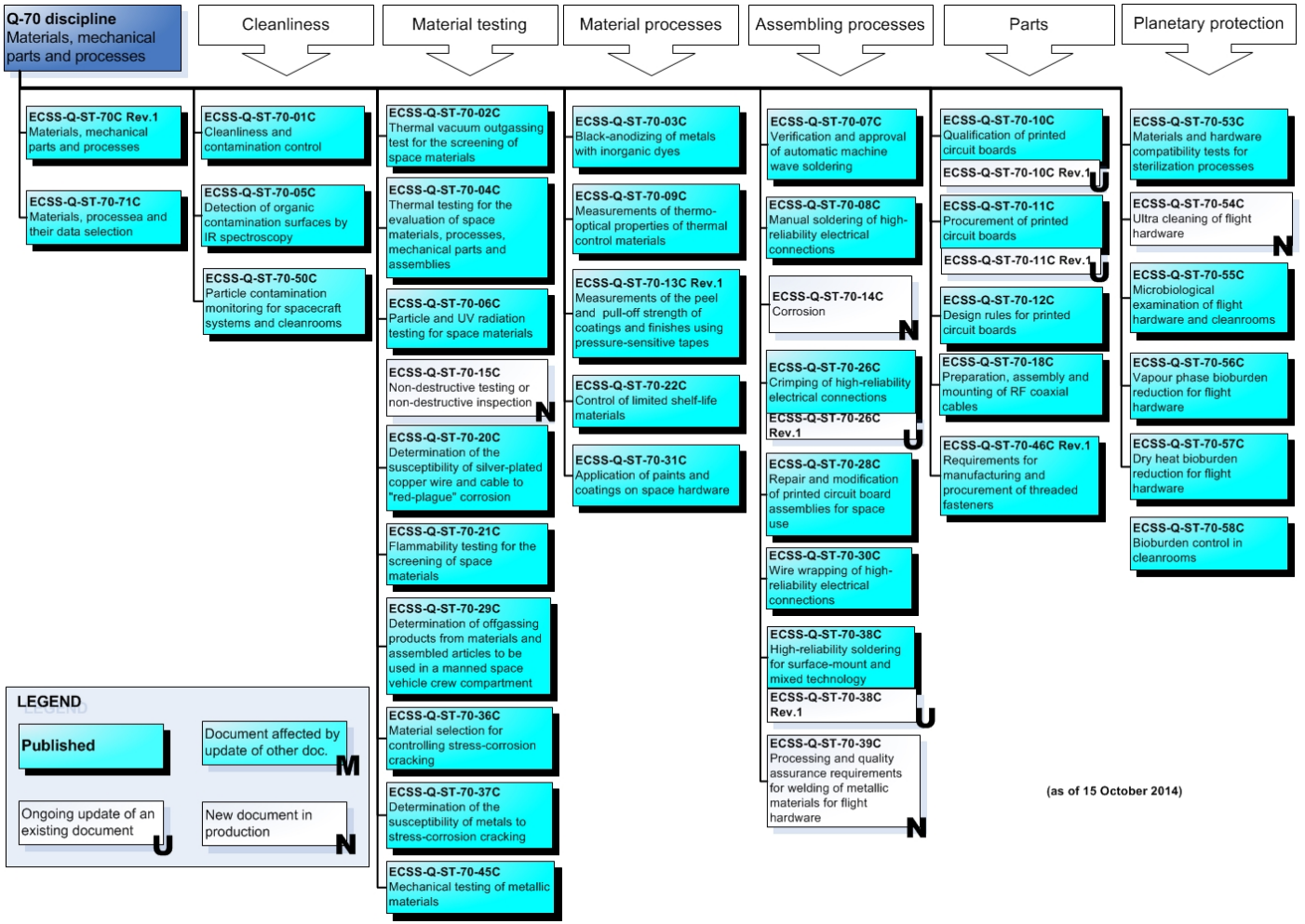

Product Assurance Management

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- PA programme planning involves :
  - Identifies the requirements (tailoring, standards, special req.)
  - Defines the PA organization, actors and processes
  - Identifies PA activities to be carried out (inputs/outputs)
  - Identifies adequate resources: expertise and facilities
  - Ensures requirements are cascaded to lower tier suppliers

- PA programme implementation addresses:
  - Managing experts in PA disciplines
  - Progress reporting of PA topics
  - Management of audits, critical items, NCRs and alerts
  - Support to risk management and configuration management
  - Lower tier supplier control
  - Demonstrates the fulfillment of requirements

PA Management

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1. Analyze the whole requirements for coverage and gaps
    a. For a large system the coverage must be everywhere
    b. Develop the work contents to estimate resources
    c. Effort will be time dependent on many disciplines
    d. Remember that there are preventive tasks such as training, audits and alert monitoring, and not just reactive tasks after problems develop
2. Use the ECSS Document Requirements Description (DRD) to ensure that work contents are covered and help guide supporting disciplines.
3. Work closely with other actors to prevent duplication or gaps, since many topics overlap. Typical cases
    a. AIT (training, record keeping, metrology)
    b. Engineering (Verification methods, dependability, qualification)
    c. Management (Risk, change control, procurement, resources)

Actors and Responsibilities

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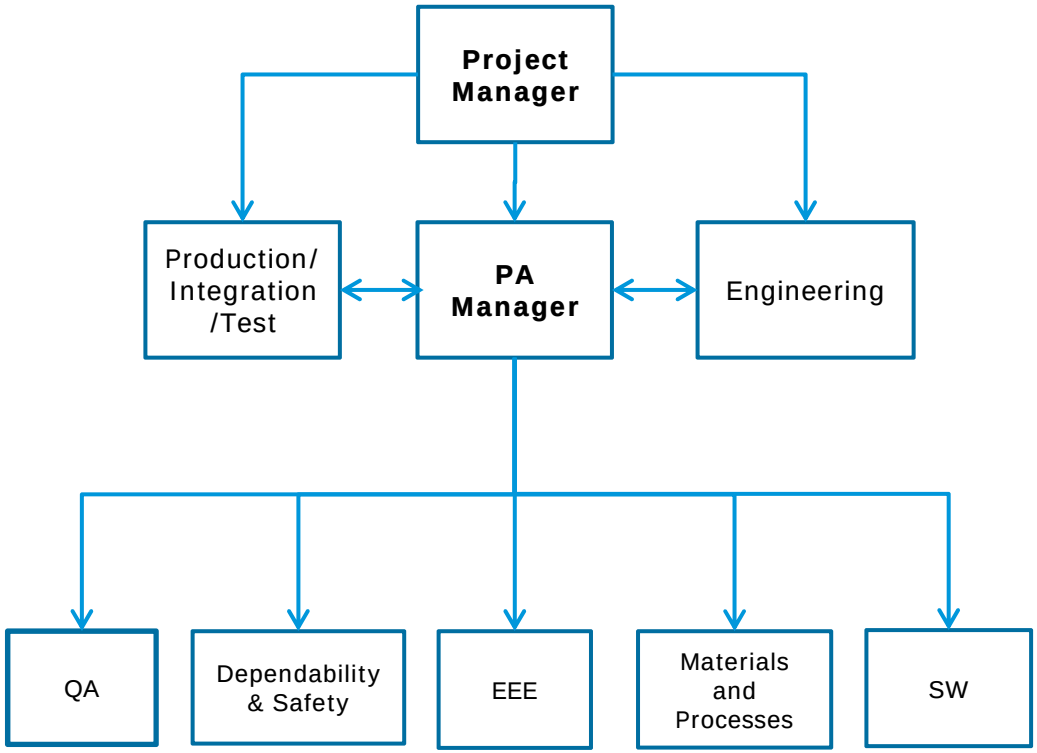
- Management Support
  - Risk assessment
  - Configuration control
  - Procurement (requirements)
- Engineering
  - Design review process
  - Verification completeness
  - Qualification and Acceptance
- Production/AIT
  - Training
  - Inspection
  - Facilities/machines/testing



Ideal organization

- PA is independent from engineering, cost control, schedule and production
- QA and other PA disciplines are managed by PA

Product Assurance Planning

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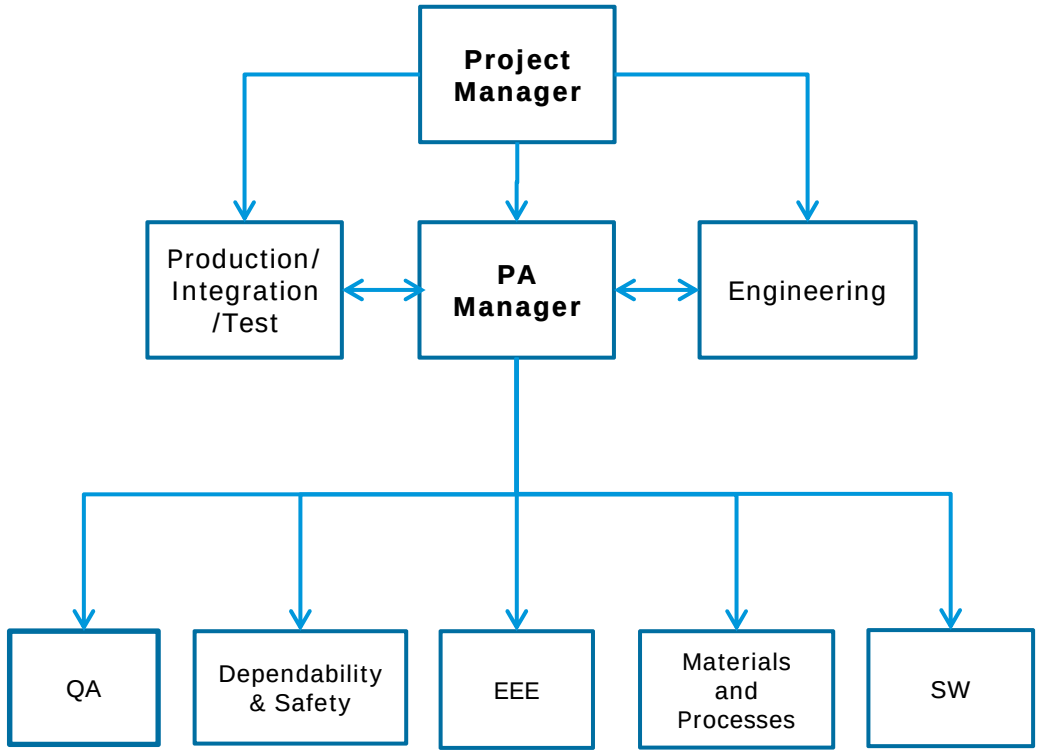
- Tailor PA Requirements
  - With Customer
  - Agree on applicable requirements based on risk and scope of project
  - Assess compliance (intent)
- **Develop PA Plan**
  - PA processes/methods
  - Needed expertise
  - Procurement and suppliers
  - Facilities and expertise
  - Quality records to be produced
  - Note ECSS DRDs to be used



- Quality requirements call up normative and informative references to be addressed in the PA or QA plans
  - ECCS with tailoring to a specific project
  - Technology specific (e.g. ESCC, ISO, MIL, IPC)
  - Agreed workmanship standards that may not be in ECSS but should be against an agreed standard (e.g. ISO, national standards)

- A clear quality plan to show how the requirements will be implemented. Topics *include*
  - Lines of responsibilities, reporting, decision processes
  - Procurement control, critical items control, quality records
  - Training of personnel, calibrated tools and machines
  - Traceability of work and parts (in both directions), storage
  - Objective criteria for fulfilling quality requirements
  - Handling of non-conforming parts (containment, traceability, corrective actions, preventive actions)
  - Overall compliance status and lists of exclusions

Quality Management Principles
PA / QA plans contents (Q20 vs. Q10)

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PA PLAN content (ECSS-Q-ST-10 Annex A):

- PA organization, responsibilities and authority, resources, PA interfaces & processes
- PA implementation procedures, including:
  - PA management
  - PA reporting
  - PA audits
  - Critical items
  - Risk mgmt. interfaces
  - Document & data control
  - Quality records
  - PA contribution to CC
  - NCRs
  - Alerts management
- QA processes & procedures
- Dependability (Q30) processes & procedures
- Safety (Q40) processes & procedures (or refer to the Safety plan)
- EEE components (Q60) processes & procedures
- MMP&P (Q70) processes & procedures
- SW PA (Q80) processes & procedures
- Specific PA process & procedures relevant to the organization, not covered above

QA PLAN content (ECSS-Q-ST-20 Annex A):

- QA processes and procedures including training and certification
- Design and verification QA activities and processes (including qualification)
- Procurement QA activities and processes
- Manufacturing, assembly and integration (MAI) QA activities, including:
  - MAI Planning, processes & workmanship
  - MMP&P and equipment control
  - CCCP (Cleanliness & cont. control plan)
  - Inspection
  - Records
  - ESD protection programme
- Testing QA activities and processes
- Acceptance & delivery QA activities (including among others EIDP & Delivery Review Board)
- QA specific activities, including:
  - Critical items
  - NCRs
  - Alert management
  - Authority media
  - Traceability
  - Metrology and calibration
  - Handling and storage
  - Statistical quality control

Coverage

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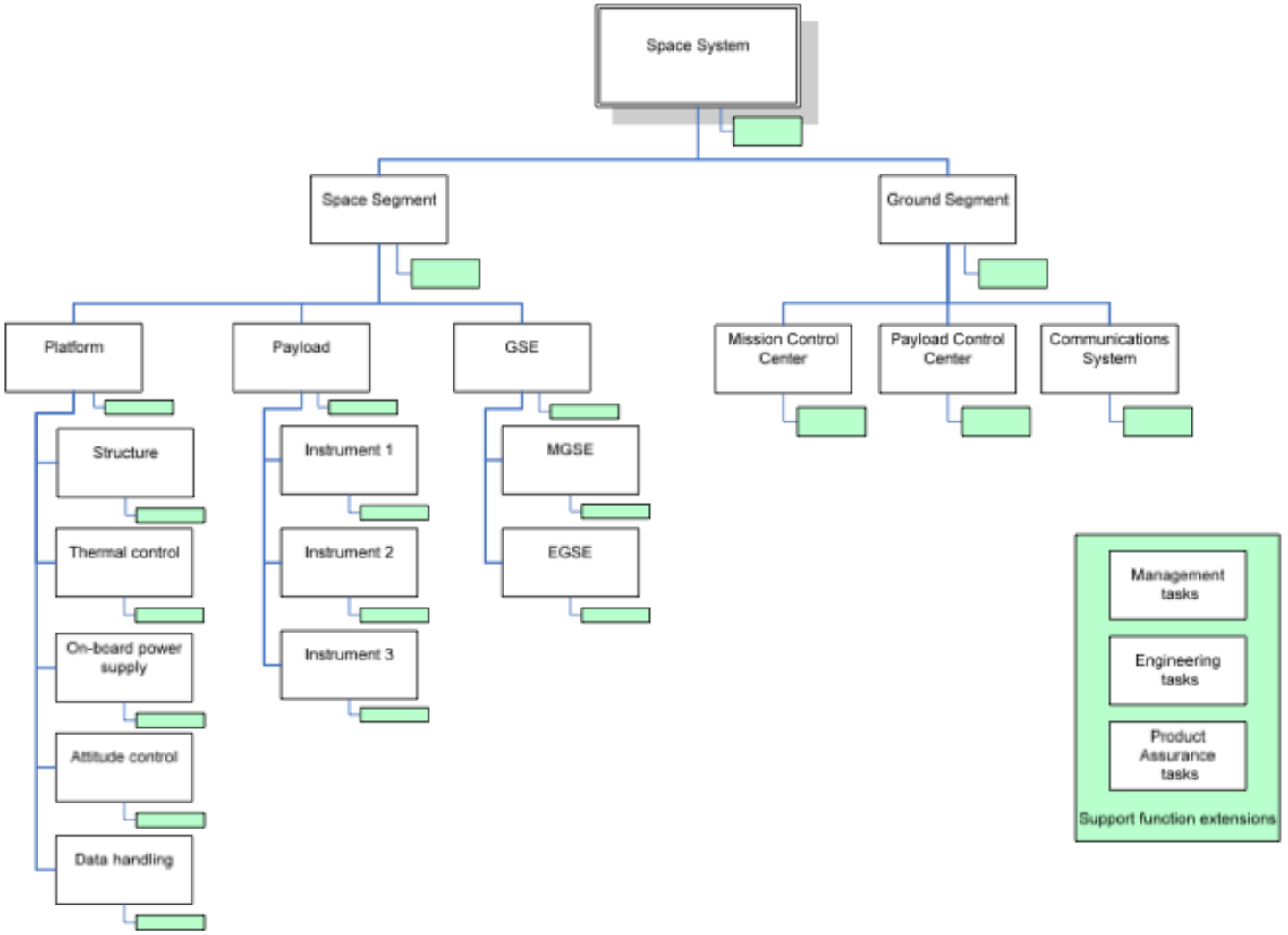

Problems to avoid (examples)

- Do not underestimate the time and resources to comply with documentation requirements.
- Many problems can be avoided by emphasis on training and use of developmental models.
- Be wary of unproven technology – add resources to monitor risk
- Monitor implementation and look out for bottle necks such as long delays in approving changes, backlog of unresolved anomalies, delays due to long lead items (consider spares as preventive action)
- Weak procurement practice can lead to non-compliances that are difficult to redress without cost and time.
- Noncompliance with respect to internal procedures (poor record keeping)
- Weak suppliers can cause great problems; carefully evaluate suppliers and examine their supply chains. New facilities, training programmes and active quality management are important considerations. Consider audits and active reporting and inspections for continuous monitoring.

PART 2

Quality Assurance

Definitions

- **Quality Assurance** - provides confidence that the product requirements will be met.
- **Quality Control** - part of quality management focused on fulfilling quality requirements. Focus on demonstration.
- **Quality Records** – data that demonstrates compliance to requirements. Cannot be altered once recorded.

QA General Requirements

- Critical Items
- Non Conformance Reporting
- Alert management
- Acceptance Authority Media (formerly stamp control)
- Traceability
- Metrology
- Handling & Storage
- Data analysis

QA General Principles
Critical Item Control (Q-20 5.2.1 +Q-ST-10-04)

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- Critical items are potential threats to the performance, quality, dependability or safety of a system. These items require special attention.

- Annex C of ECSS-Q-ST-10-04 provide for a checklist; examples include:
  - Single point failures with major loss of function
  - Unqualified technology or units whose performance cannot be tested
  - Items with life-limited parts, contamination sensitive parts etc.

- The method of assessing and tracking critical items, in a critical items list (CIL) is fully described in a dedicated standard ECSS-Q-ST-10-04.

QA General Principles
Critical Item Control (Q-20 5.2.1 +Q-ST-10-04)

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- The items shall be kept in the CIL which lists the mitigation actions and criticality of the item. Refer to ECSS-Q-ST-10-04 § 5.1 for the prescribed process

- The identification of critical items is done by the supplier as soon as a preliminary design emerges, first issue of CIL at PDR.

- Part of the mitigation actions could be to create special handling and monitoring procedures for the procurement or AIT use; these should trigger a check by the PA/QA that the actions are completed before their intended use. The tracking of project risks will be done by PA, the QA tasks are more to track progress on critical items.

- The CIL shall be reviewed during the design reviews and all listed critical items shall be closed by the acceptance review.

QA General Principles
Non-Conformance (Q-20 5.2.2 +Q-ST-10-09)

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- Manufacturing, integration or test personnel are trained to react to results that indicate a failure or anomaly.

- In case of mishap or serious anomaly, actions are time critical
  - Ensuring the immediate safety of personnel and equipment
  - Preserving information needed to investigate the cause of the problem
  - Stop, if necessary, the activities to contain the problem and protect item
  - Alert QA personnel, if not present

- The QA manager or engineer must collect the information and document in a non-conformance report (NCR)

QA General Principles
Non-Conformance (Q-20 5.2.2 +Q-ST-10-09)

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- The process of issuing, processing and dispositioning an NCR is fully covered in a dedicated standard **ECSS-Q-ST-10-09.** Annex A of this documents provides the normative requirements for the NCR contents.
- The decision to investigate, contain and/or correct the problem is taken by an NCR Review Board (NRB). Possible dispositions (decisions) are
  - Use-as-is: allows the use of the item despite the report noncompliance
  - Rework: action to bring item into compliance without changing parts
  - Repair: action to bring item into compliance with changing of parts
  - Scrap: reject item and remove it from active inventory
  - Return to sender: refuse to accept item and return for corrective actions or replacement.

QA General Principles
Non-Conformance (Q-20 5.2.2 +Q-ST-10-09)

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- The NRB shall be convened necessary actors and design authority. This may include manufacturing, AIT and invited experts.
- Internal NRB is quickly held to
  - decide on immediate actions (safety, segregation, work-flow)
  - NCR classification (major/minor)
  - Collection of additional data
  - Root-cause analysis
  - Preventive actions

- If NCR is major then a customer NRB shall be convened
  - Within a prescribed time (5 working days)
  - Reporting to be in-line with project agreed media and format

QA General Principles
Non-Conformance (Q-20 5.2.2 +Q-ST-10-09

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- Many NCRs require multiple NRBs to progress in the investigations, assessment of corrective actions and conclusive evidence that all preventive actions have been implemented.
- NCRs are collected with all supporting documentation in well maintained databases (NCTS for example).
- Typical problems in dealing with NCRs
  - Poor description or incomplete data collection that hinder investigations
  - Root-cause analysis not conclusive or cannot be proven
  - Mistaking an intermediate cause for the root-cause
  - Poor maintenance of NCR information and poor follow-up of actions
  - Disagreement on whether use-as-is is acceptable

- PA requirements must be very clear on NCR processing. A status list is part of the quality records (see Annex B ECSS-Q-ST-10-09)

QA General Principles
Alert Management (Q20 5.2.3 + Q10 § 5.2.9)

Standardization training program
Space Project Management

- Alerts are formal notification from a supplier or agency of a problem that can affect more than one user. Some sources
  - GIDEP (US **G**overnment **I**ndustry **D**ata **E**xchange **P**rogram)
  - NASA Parts advisory
  - ESA Alerts
  - NASDA Alerts
  - CNES Alerts

- Industry also issue alerts, sometimes under different names
  - Letter or notice
  - Warning Notice (e.g. Airbus Defence and Space)

- Refer to **ECSS-Q-ST-10**, § 5.2.9 for a more detailed description of the processing of alerts

QA General Principles
Alert Management (Q20 5.2.3 + Q10 § 5.2.9)

Standardization
training program
Space Project Management

- Alerts need to be assessed to determine whether a particular risk exists in the project (i.e. if item is within perimeter of the alert)
- If product is affected then alerts usually provide recommendations that depend on the state of development.
- Alerts can have major cost and schedule impacts. An example is to replace a EEE component after a unit has been completed.
- Contractors are to maintain a listing of all alerts and the responses – this is reviewed periodically and is recommended to be part of the project progress reporting.

QA General Principles
Acceptance Authority (Q20C 5.2.4)

- Acceptance Authority (formerly stamp control) is used to trace completion of operations and QA approval or inspections.
  - Source or incoming inspection
  - Process inspection, tests and final inspections, e.g. KIP/MIP
  - Storage and shipment preparations

- The PA Plan should indicate the media that is used, electronic, stamp, signatures to document that work is traceable to the approved operators/inspectors

- This traceability also improves integrity and commitments to quality since the responsibility is documented and link to individuals.

QA General Principles
Traceability (Q20C § 5.2.5)

Standardization
training program
Space Project Management

- Traceability covers many type of activities
  - Requirements/verification traceability
  - Materials and parts traceability (procurement)
  - Machine/operator/metrology traceability

- Focusing on the production aspects
  - Decision early in the design to determine what mechanical parts, assemblies or units to serialize
  - Proper storage management, handling during AIT (bag/tag control)
  - EEE and certain materials traced through date-codes or lot identification
  - Shop travellers to contain information on machines, operators
  - Quality records must be able to provide ***traceability in both directions*** – the source of a material/part and where it is eventually used/installed.

QA General Principles
Traceability (Q20C § 5.2.5)

Standardization training program
Space Project Management

- Traceability is vital information
  - Assessing the impact of an alert
  - Investigating a non-compliance
  - Data collection for routine monitoring of quality (correlation)
  - Containment and segregation of unsuitable materials or parts

- Traceability documentation is found throughout
  - As-built configuration list (ABCL) → in EIDP
  - As-built declared component lists (DCL)
  - Shop travellers or as-run procedures
  - Inventory lists

- Verification of proper traceability should be included as part of
  - Audits/MIPs
  - Review of AIT procedures
  - Review of EIDP

QA General Principles
Traceability (Q20C § 5.2.5)

Standardization training program
Space Project Management

- Traceability is vital information
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- Verification of proper traceability should be included as part of
  - Audits/MIPs
  - Review of AIT procedures
  - Review of EIDP

QA General Principles
Metrology (Q20 5.2.6)

- The emphasis in the ECSS-ST-Q-20C is the completeness of the calibration of any items used for metrology.
  - Calibration is up-to-date and traceable to calibration standards
  - Traceability of machine/operator and training
  - Validation, especially for use of software
  - ensure that the means are adequate for the purpose of measurements (accuracy, resolution and precision)

QA General Principles
Handling and Storage (Q20 5.2.7)

Standardization
training program
Space Project Management

- Despite the obvious need for safe handling, accidents do occur during handling and transportation. The QA approach is to assess the risks, ensure personnel are trained and procedures are complete

- Some of the handling risks to guard against
  - Unwanted contact, scratches to sensitive surfaces – consider handling devices, tooling protections, tethers, covers, captive screws
  - Cleanliness – training of personnel, facilities, monitoring
  - Access constraints – to be tackled during design phase
  - ESD – personnel training, grounding
  - GSE design – ensure complete validation before acceptance
  - Untested procedures – to be tackled during development using BB, EQM

- Some of the storage & transportation risks to guard against
  - Container not properly labelled, no packing procedure
  - Stores management (no mix-up with other projects or segregated items)
  - Defect in container or improper packing
  - Contamination from improper packing or exposure to unfiltered air
  - Temperature and humidity *controls* not adequate
  - Lack of environmental *monitoring* (temperature, shock, humidity)
  - Poor physical security
  - Unlabelled parts, especially if loose
  - Poor de-storage or unpacking procedure
  - Condensation
  - Lack of pre-shipment/pre-storage inspection

QA General Principles
Statistical Data Analysis (Q20 5.2.8)

- Effective quality management requires objective data to be collected and analysed to support decisions, for example:
  - Inspection, sampling, screening of parts → accept/reject parts
  - Material properties → accept into production chain
  - Process repeatability and accuracy → are processes stable
  - Performance (accuracy, resolution, and repeatability)→ accept/reject
  - Failures → correlation, reasons, containment, correct and improve
- For companies producing many parts, statistical quality checks by sampling is permitted (e.g. EEE components)
  - Requirements in § 5.2.8 of Q-20
  - Lot definition, lot sampling approach and allowable failures to be justified
  - Statistical methods must be approved by customer
- Remember that the *assurance* provides confidence, but data is demonstrates quality.

QA General Principles
Statistical Data Analysis (not in ECSS)

- The “Basic Seven” is a group of often used data analysis methods, many are used to determine the frequency of values and estimate random contributors.
  - **Ishikawa diagram** : more of a *qualitative tool* in collecting potential causes to an effect.
  - **Check sheet** – used to collect data to look for patterns.
  - **Control Charts** – used to look at process variations (mean, max values,
  - **Histogram** – very useful to establish distribution of events/results
  - **Pareto Analysis** – very useful to rank the sources or error contributors; the logic being that fixing the largest contributors is the most effective means to improve quality.
  - **Scatter Diagrams** – essential for establishing patterns and correlations
  - **Stratification Analysis** – a control method to separate data that is collected from different sources, since the collection process itself may create patterns that are not in the actual variations that are being measured. (added tags for machines, operators, etc.)

- Other test data should also be used when possible to spot drifts from expected values
  - **Trend data**: observable values that should have long-term repeatability; useful at equipment level.

- There is no standard approach – the contractor shall justify the proposed data collection and analysis in the PAP or QAP; the customer shall approve it.

QA During Product Development

1. Overview
2. Design
3. Procurement
4. Manufacturing
5. Assembly and Integration
6. Testing
7. Acceptance
8. GSE

Quality Management Principles
Quality activities and contributors

Standardization
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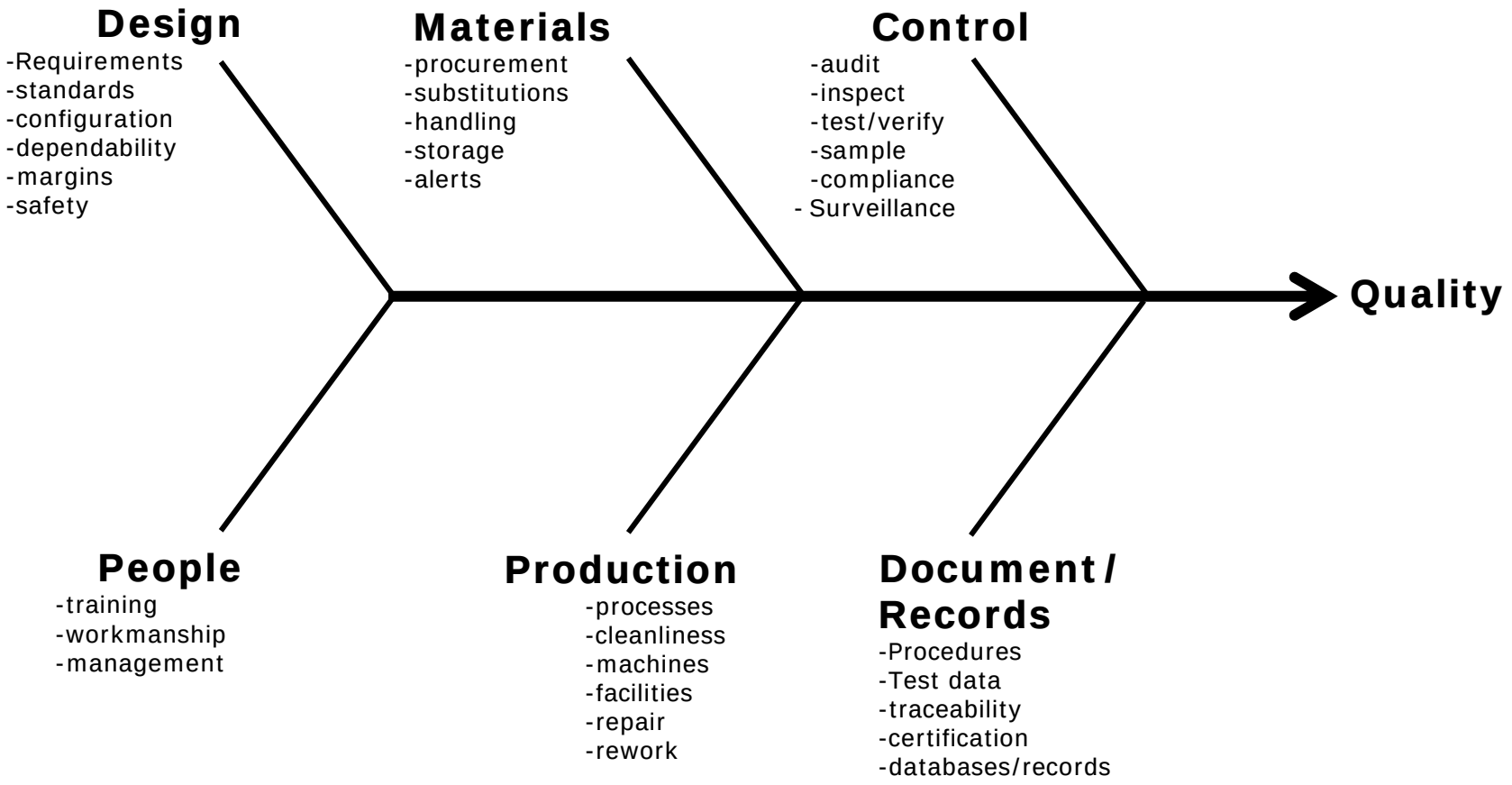
Space Project Management



QA during Product Development

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Space Project Management

- This next section examines the *Quality Assurance* activities in relation to the development of the product

  - **In general**...

  - *Quality Assurance* during Phases B/C are oriented towards procurement support. Making sure requirements and business agreements provide comprehensive quality policy and actions. This includes tasks such as reviewing the PA/QA plans, flow-down of quality requirements and supply chain quality.

  - *Quality Control* effort is more prevalent in Phase C/D activities such as manufacturing, integration and test phase, where there are more quality control functions (inspections, data, non-conformance handling, verification, critical item close-out).

QA During Product Development

1. Overview
2. Design
3. Procurement
4. MAIT
5. Acceptance
6. GSE

- Requirements
- Design rules
- Configuration
- Verification
- Qualification
- Design Reviews

QA during Product Development
Design - Requirements (Q20#4.3)

Standardization
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Space Project Management

- The start of a new project generally requires tailoring the PA requirements to the agreed project risk
  - ECSS Tailoring → generate requirements
  - Gaps in ECSS → make other standards applicable or create specifications

- There is no set rule, but within the PA domain, Quality Assurance is not an area with too much relaxations. Tradeoffs are more frequently made in the other PA disciplines , examples:
  - EEE → quality class of components, LAT criteria, test methods
  - M&P → fewer restrictions (out-gassing)
  - RAMS → relaxation of reliability
  - SW → degree of verification/criticality designation

QA during Product Development
Design – design rules (Q20 4.3 & 5.3.1)

Standardization
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Space Project Management

- Basic design rules (excerpt from § 5.3.1)
  - **Produceability** – avoid design features that are too difficult to manufacture, pose integration/disassembly or interface problems.
  - **Tolerance control** – stack-up method to be clear.
  - **Repeatability** – design should allow for tolerances to make other identical units similar in performance
  - **Inspectability** – parts or assemblies should be accessible. Not always possible; when future access is to be lost, MIP/KIP should be planned.
  - **Testability** – test points to be included to allow for fault identification
  - **Operability** – limit the constraints to hinder operations during ground testing, or provide as part of the design the necessary GSE or test mode to avoid this limitation.

- There is an obvious need to limit critical technologies. If these must be used to achieve function or performance, then inspection, testability and operability are to be emphasised.

- **A few words about configuration control …**
  - Design change and the process of approving, recording and reporting the changes is crucial to maintain order. Configuration management is the discipline that performs this function.
  - Configuration Management is technically part of the project management standard ECSS-M-ST-40 and is no longer called up in the latest release of the Q-20, Issue C.
  - *Product assurance supports* configuration control; *QA will be more of a stakeholder and user*

- **Change control**
  - Some ways that a design requirements can change by
    - Updating of specifications
    - Deviations (RFD)
    - ICD changes
  - Changes are tracked by documentation number and issues, all changes require a formal approval process. ESA needs to approve certain categories of changes.
  - Changing one requirement can affect many others – needs attention.
  - The design status at any instance can be summarized by a list of document numbers and issues (set of requirements, ICD, approved deviations etc.)
  - Baselines are established, refer to **ECSS-M-ST-40** for details. The purpose for QA is to have a design status to compare with the build status

QA during Product Development
Design - Verification (Q20 4.3 & 5.3.2)

Standardization
training program
Space Project Management

- Design verification aspects need to be considered early as this may drive other requirements, GSE design and risk.
- Q20 § 4.3 lists many design requirements related to verification – these are addressed with engineering and AIT since specific knowledge of test methods may be required. From a QA perspective, the following are highlighted
  - Verification coverage: best is by test or inspection, but having too many requirements verified by analysis is not advisable (risk)
  - Verification sequence: “test as you fly and fly as you test” approach is advisable. Not always possible, but should remain an objective.
  - Verification risks: late disassembly, cases where no test is possible need to be carefully studied for risk.
- QA can question the logic and propose changes to improve the design to allow better verification, more data or additional facilities.

QA during Product Development
Design - Qualification (Q20 4.3 & 5.3.2.4)

Standardization
training program
Space Project Management

- Qualification shows that a design demonstrates margins with respect to the acceptance limits.
- The basic approaches:
  - **Prototype** qualification – prototype is often engineering qualification model (EQM). This model is represent in form, fit and function to the full design, but quality levels of components may be reduced.
  - **Protoflight** – the qualification is demonstrated on the actual flight hardware, fully representative. Levels are the same as prototype, with reduced durations or cycles equal to acceptance.
  - **Similarity** – the flight hardware will be *identical* in design that has been qualified. Note that the original qualification must have been done to environments and conditions that cover the application/mission for which qualification by similarity is claimed.

- Sometimes the “similarity option” is a little complicated
  - Similarity is not total since some conditions may differ from the original application. In such cases a “delta-qualification” is necessary. This subjects the flight article or an equivalent to a sub-set of test conditions to demonstrate that all requirements have been qualified to the intended applications and conditions. This is often adopted for OTS items.
  - Sometimes processes used in the manufacturing of the original qualification model have changed (new materials, new technology). This requires a tailored approach – qualification at materials and process level and some delta-qualification. No rule exists, and this is a shared decision with engineering and management.

- Examples of potential complications
  - Often more than one model is used to cover the complete design. There may be a life-test model that covers a portion of the design, but is adapted for cost schedule to be a separate model to test lifetime of mechanisms, for example.
  - The qualification can be spread throughout various levels of integration complexity. For example, some structural components may require testing as part of a higher-level assembly in order to properly test loads.
  - Most challenging are qualification of requirements where testing of a complete structure or interfaces is constrained. This requires a significant engineering to estimate margins. For example, separate thermal vacuum tests for payload module and service module – large spacecraft may not fit into thermal vacuum chambers, or the modules are not ready at the same time.

- **Qualification Plan and the QSL** …

  - **Qualification Plan** - the qualification logic must be contained in a detailed plan.
    - Provide the logic and sequence
    - Traceability to the margins or factors to be demonstrated
    - Explain the model approach
    - Test conditions, accuracy, standards applied
    - Justify any qualification by similarity
    - Identify any requirements that cannot be qualified by test

  - **Qualification Status List** (QSL) - tracks the qualification; especially useful to summarise the conditions for all elements on a spacecraft. The QSL should contain a summary with enough detail (sadly the quality of this document on some programmes is poor). Refer to Annex B of ECSS-Q-ST-10. Document to be available at PDR

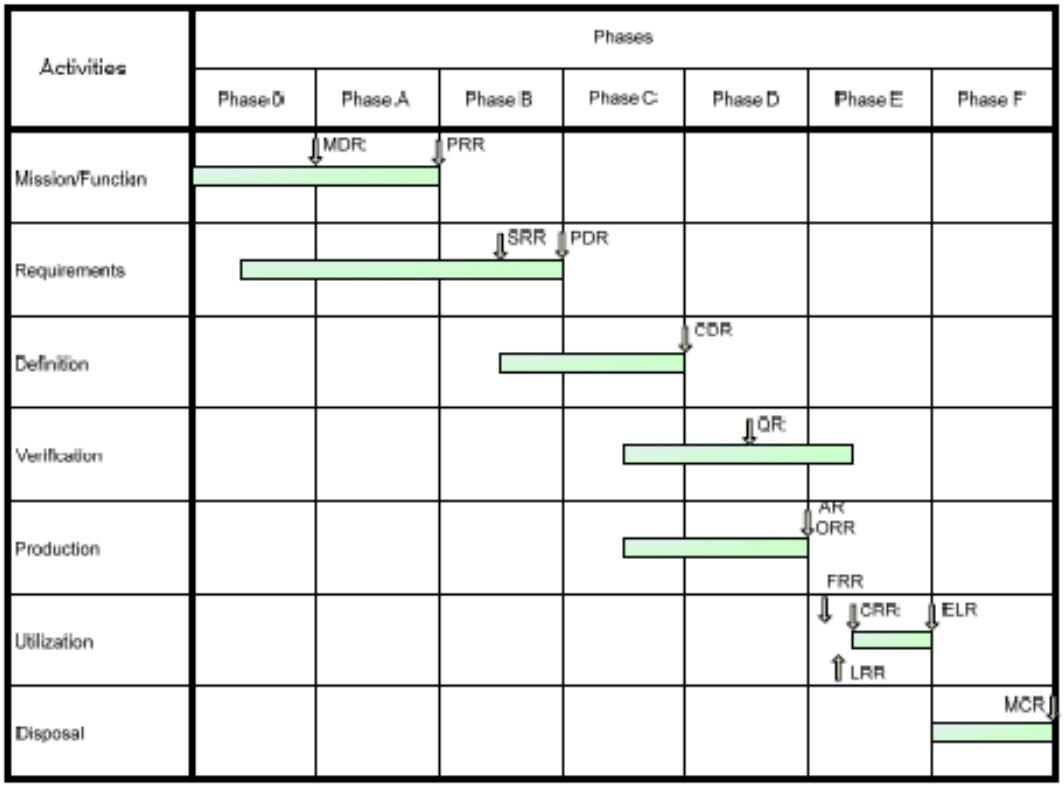
- **Qualification Review**
- Normally, the qualification is completed before the manufacturing and integration of the flight model(s). A formal review is held to confirm that the qualification of the design is complete. Among the points that are checked

  - Qualification tests results can be traced back to requirements
  - All RFDs affecting qualification were properly accepted
  - Test results are unambiguous and no NCRs are open comprising the result
  - No design changes have been introduced that were not tested/assessed
  - The models used for the tests were representative for the requirements for which qualification is claimed
  - Qualification by similarity is in-line with mission conditions
  - Qualification reports are approved and QSL is up-to-date

QA during Product Development
Design - Reviews (Q20 4.3 & 5.3.2.3)

Standardization training program
Space Project Management

- QA supports the project to ensure the review process is held in accordance to **ECSS-M-ST-10-01C**.
- The Q20 makes a very brief statement of the contents
  - Quality requirements and design approach are documented
  - Methods and data for development phase provided
  - Highlight Risk control (CIL, risk mitigation)
- Much more detail in the ECSS-M-ST-10-01C.



QA During Product Development

1. Overview
2. Design
3. Procurement
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- Objectives
- Audits
- Supply Chain
- Source Selection
- Off-the-Shelf
- GSE
- EEE

QA during Product Development
Procurement - Q20 4.4 & 5.4

Standardization training program
Space Project Management

- The QA role in procurement support is important. The objectives include:
  - Checking that the requirements and business agreements are complete with respect to QA
  - Evaluating potential suppliers: audits/proposal
  - Examining carefully the supply chain to spot risks
  - Supporting any negotiations to improve QA points
  - Ensuring clarity on qualification and acceptance
  - Ensuring clarity of documentation requirements with project milestones
- The next few slides looks at some of these points in more detail

QA during Product Development
Procurement -Audits (Q20#4.4 + Q10 5.2.3)

Standardization training program
Space Project Management

- QA can be called upon to evaluate potential sources; the usual approach is analyse the QMS to conduct a compliance audit
  - How does the company comply to its own QMS?
  - Are there any significant gaps between the QMS and PAP?
  - Does the company have the resources to achieve full compliance to PAP?
- If a process is of concern, then an audit oriented towards processes could be useful.
  - Identify weakness in the supply chain (procurement, traceability)
  - Internal handling and management of materials and processes
  - Are the machines and training adequate for quality assurance?
- If an off-the-shelf item is envisaged, then a product audit may be the most appropriate choice
  - What type of anomalies have occurred?
  - Controlling of design changes?

QA during Product Development
Procurement – Supply Chain (Q20 4.4)

Standardization training program
Space Project Management

- Analysis of the supply chain is a Prime contractor's responsibility, but merits highlighting the main objectives
  - Flow-down of all PA requirements and compliance status (SoC)*
  - Audit status
  - What surveillance is put in place (reporting, data) *
  - What critical items or processes are involved *
  - Change of facilities *
  - Recurrent problems*
  - Export sensitive items identified and licenses up-to-date
  - Scope/duration of business agreements
  - Spares/attrition
  - Post-delivery support *
  - Health of supplier's business

- * items that are most germane to QA

QA during Product Development
Procurement – Source Selection Q20 4.4

Standardization training program
Space Project Management

- With the first set of requirements established, the QA task is consider the likely points in evaluating proposals.
  - **Design** → consistent with basic design rules? If not, is it justified?
  - **Maintenance** →Spares, attrition parts and support
  - **Traceability** → assess what parts need to be serialized
  - **Verification** → are some critical requirements unverifiable due to constraints (environment), test limitations (metrology)
  - **Standards** → coverage to be assessed with other PA disciplines to determine if additional test and analysis methods are needed.
  - **Build and Quality records** → set of procedures, travellers, data collection for quality monitoring, log books… satisfies quality req?
  - **Supply chain** → ensure that contractor is required to follow-up and report on quality throughout the supply chain (flow-down, audits, alerts management, inspections, data deliverables)
  - **Documents** → refer to Q20 § 5.4.2

QA during Product Development
Procurement of OTS items (Q-ST-20-10)

Standardization training program
Space Project Management

- Equipment can sometimes be found from a supplier that meets the requirements and can be procured as an “off-the-shelf” (OTS) item.
- Refer to ECSS-Q-ST-20-10C on the evaluation process for OTS items
- Projects typically convene an “equipment qualification status review” to formally approve the item as acceptable to the design
  - Design assurance and engineering is involved
  - Delta qualifications may be necessary
  - OTS plan and dossier to be created (see annexes for DRD)
- This process is sometimes complicated when dealing with export controlled items
  - Business agreement and ITAR Technical Assistance Agreement (TAA) to include the points listed in the OTS dossier.

QA during Product Development
Procurement of GSE items (Q20 4.8 & 5.8)

Standardization
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Space Project Management

- For QA, emphasis is often placed on the quality control aspects, i.e. testing and inspection.
- A few points to consider…
  - GSE is procured before flight equipment, so risk of changes can affect design. Verification also requires some flight hardware simulators.
  - Procurement should cover design assurance analysis, such as RAMS and safety to cover fault propagation risks, Safety engineering.
  - Specification of materials should take into account environments since they too may be used during environmental test, e.g. EGSE harness outgassing.
  - Emphasize good maintainability in the design
  - Software quality assurance and testing
  - Calibration requirements (before and after shipping as well)
  - Cleanliness risks, clean room requirements
- More later in the presentation…

QA during Product Development
EEE Procurement (Q60 discipline)

- **A few words about EEE procurement…**
  - Procurement of EEE components is a major and complex procurement process and controlled by the Q-60 line of standards and handbooks.
  - The procurement is normally lead by an EEE expert with no direct QA involvement. The PA manager is involved and participates in the special parts control board (PCB), which manages the quality requirements for all EEE.
  - QA will be involved with the incoming inspection of purchased parts and ensure that as-built data is correctly recorded in manufacturing records.
  - Management of the quality records associated with the parts can vary; what is important is to verify the collection of the data and ensure that decisions are based from this data. Quality records include PADs, lot traceability, DCL (note that PADs collect the specifications and test data – note that EEE parts that are already qualified may not require PADs)

QA During Product Development

1. Overview
2. Design
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- Manufacturing
- Assembly
- Integration
- Test

QA during Product Development
Manufacturing – Q20 4.5 & 5.5

Standardization
training program
Space Project Management

- This next section will address the quality assurance activities during the manufacture, assembly and integration
  - Assessing design readiness
  - Materials and processes
  - Facilities and machines
  - Procedures/travellers and flowcharts
  - Personnel, training
  - MRR
  - Follow-up

Design readiness for manufacturing

- QA to check
  - Ensure that design documents are approved and configured.
  - No RFDs open, design review actions closed
  - No Parts Control Board open action that affect final design
  - ICDs checked
  - Qualification status, do any open items affect the design readiness
  - All relevant alerts that have been assessed
  - Manufacturing drawings have been reconciled with latest design *

Facilities and Machines readiness

- QA to check
  - Facilities report nominal conditions
  - Machines are not affected by NCRs, within calibration
  - Software configuration of machines noted and traceable
  - Test run to be done?
  - Process recording of parameters operational
  - Witness samples available
-

Materials and Processes and Mechanical parts

- QA to check
  - No changes from declared materials and processes
  - Processes are qualified and PID is unchanged
  - Special or critical processes identified (Q20 § 5.5.3.2)
  - All material sample tests or characterisations are completed
  - No open MPCB actions affects manufacturing activities
  - Traceability of materials is clear and documented
  - Serialisation of mechanical parts (if needed) confirmed
  - Kitting of mechanical parts checked and CoC available
  - Statistical process controls to be confirmed (Q20 § 5.5.3.3)

Procedures / travellers and flowcharts

- QA to check
  - Top-level MAIT flowcharts up-to-date and configured
  - Procedures and travellers approved and configured
  - Process and parts traceability activities are clearly defined
  - Hazards or precautions are clear (e.g. ESD)
  - Cleaning processes in line with declared materials and processes
  - Workmanship standard clear (e.g. visual aids), see Q20 § 5.5.4
  - Metrology requirements clear (e.g. pass/fail criteria)
  - Documentation activities clear (e.g. photos, data files)
  - QA inspection, self-inspection steps, QA witness
  - Location of MIP in manufacturing sequence, criteria in Q20 § 5.5.8 (f)

Personnel, training

- QA to check
  - Operators have the necessary training to perform their jobs
  - Stamp control in place to trace operators
  - Operators trained for precautions and safety
-

Manufacturing Readiness Review (MRR)

- Review held to grant authority to proceed with manufacturing
  - Manufacturing representative (required – covers facility too)
  - Management representative (usually present)
  - Engineering (design authority required)
  - PA or QA
- PA/QA very much an active participant
  - Report on readiness (see previous slides)
  - Formal meeting with minutes
- Customer participation based on project decision

Manufacturing Follow-up

- During and following the manufacturing, an assessment is needed to conclude if the manufactured item conforms to the specifications. A few methods can be used.
  - Physical Metrology to ensure dimensional properties
  - Non Destructive Inspection (NDI) of finished parts (e.g. x-ray)
  - Destructive analysis on in-process samples or witnesses (e.g. microsectioning, chemical analysis)
  - Inspection results for workmanship (see Q20 § 5.5.3.2)
  - Cleanliness measurements
  - First article testing or full production lot test, as agreed by project

- QA to check with manufacturing for completeness of the collected data and documentation. **Certify conformity.**

QA during Product Development
Assembly and Integration – Q20 4.5 & 5.5.9

Standardization
training program
Space Project Management

- This next phase of development is assembly and integration. The quality assurance approach follows a similar logic as before.
  - Assessing design readiness
  - Materials and processes
  - Facilities and machines
  - Procedures/travellers and logbooks
  - Personnel, training
  - Integration Readiness
  - Follow-up

Design readiness for Assembly and Integration

- Assembly and Integration design readiness follows same basic logic as before, but with focus on design for assembly and integration
- QA to check
  - Ensure that design documents are approved and configured.
  - No RFDs open, design review actions closed
  - No open NCR/RFW from manufacturing affects design/interfaces
  - ICDs checked (special attention to tolerances and alignment)
  - Harness routing is clear in design and drawings
  - GSE interfaces are checked
  - GSEs for handling and protection are approved and ready for use
  - Assembly drawings and set are complete and up-to-date

Facilities and Machines readiness

- QA to check
  - Facilities report nominal conditions
  - Machines are not affected by NCRs, within calibration
  - Software configuration of machines noted and traceable (e.g. special metrology equipment)
-

Materials and Processes and Mechanical parts

- QA to check
  - No changes from declared materials and processes
  - Processes are qualified (fewer processes expected since activity is more assembly and integration, notable exception is use of adhesives)
  - Special or critical processes identified (Q20 § 5.5.3.2)
  - All material sample tests or characterisations are completed
  - No open MPCB actions affecting activities
  - Traceability of materials is clear and documented
  - Serialisation of mechanical parts (if needed) confirmed
  - Fracture control actions for fasteners completed (if applicable)
  - Kitting of mechanical parts checked and CoC available
  - Life-limited items are checked to confirm validity (e.g. tapes)
  - Logbook available (e.g. mating/cycles)
  - **Non-flight items to be properly marked and logged (e.g. savers)**

Procedures / travellers and flowcharts

- QA to check
  - Top-level MAIT flowcharts up-to-date and configured
  - Procedures and travellers approved and configured
  - Process and parts traceability activities are clearly defined
  - Hazards or precautions are clear (e.g. ESD, cleanliness)
  - Cleaning processes in line with declared materials and processes
  - Workmanship standard clear (e.g. visual aids), see Q20 § 5.5.4
  - Metrology requirements clear (e.g. pass/fail criteria)
  - Documentation activities clear (e.g. photos, data files)
  - Temporary installations, open work items to be clearly noted
  - QA inspection, self-inspection steps, QA witness
  - Location of MIP in sequence, criteria in Q20 § 5.5.8 (f)

QA during Product Development
Assembly and Integration – Q20 4.5 & 5.5

Personnel, training

- QA to check
  - Operators have the necessary training to perform their jobs
  - Stamp control in place to trace operators
  - Operators trained for precautions and safety
  - Operators trained for GSE
-

Integration Readiness Review (IRR)

- Review held to grant authority to proceed with manufacturing
  - AIT representative
  - Management representative (usually present)
  - Engineering (design authority required)
  - PA or QA
- PA/QA very much an active participant
  - Report on readiness (see previous slides)
  - Formal meeting with minutes
- Customer participation (can be an observer)

Integration Follow-up

- The main proof of success will, of course, be test results. Other supporting data before testing *(depends on requirements)*
  - Physical Metrology to ensure dimensional properties
  - Non Destructive Inspection (NDI) of assembly (e.g. x-ray)
  - Destructive analysis on in-process samples or witnesses (e.g. adhesive curing and bonding strength from witness samples)
  - Inspection results for workmanship (see Q20 § 5.5.3.2)
  - Cleanliness measurements (processing of stage samples for PFO and molecular, if applicable)
- QA to check with AIT for completeness of the collected data and documentation.
  - Special attention to all non-flight items that are installed. For the next phase these need to be assessed for compatibility with environments

QA during Product Development
Test– Q20 4.6 & 5.6

Standardization
training program
Space Project Management

- This next phase of development is Testing. The quality assurance approach follows a similar logic as before.
  - Assessing design readiness for planned tests
  - Materials and processes
  - Facilities and machines
  - Procedures/travellers and logbooks
  - Personnel, training
  - Test Readiness Review
  - Post Test Review
  - Test Review Board

QA during Product Development
Test – Q20 4.6 & 5.6

Design readiness for Testing

- Testing design readiness follows same basic logic as before, but with focus on design for assembly and integration
- QA to check
  - Ensure that design documents are approved and configured.
  - **Difference between design status for test and status for flight**
  - No RFDs open, design review actions closed, qualification status updated
  - **No open NCR/RFW from previous phases**
  - ICDs checked (special attention to tolerances and alignment)
  - **GSEs are approved, interfaces checked and ready for use**
  - TMTC database ready for use
  - Design constraints clear (temperature, operations, etc.)
  - **Test specification is approved and configured**
  - **Test and Instrumentation plan is ready**

Test Centre or Facility

- QA to check
  - If a test will be conducted in an external facilities, greater emphasis by test team and QA to ensure preparations are complete.
    - Is there a QMS and is it compliant to ECSS-Q-ST- 20-07?
    - Review of *any* facility problems that could affect test specimen
    - Readiness of test equipment and calibration
    - Personnel certification for use of test equipment
    - Dry-run procedures (to be agreed)
    - Interface to test specimen
    - Review of test procedures and levels to apply
    - Safety
    - Configuration control of test centre's equipment/SW/procedures
    - Archiving of data
    - Cleanliness

Test Equipment

- QA to check
  - Calibration and functioning confirmed prior to interface to test specimen
  - Control software tested, configured and tamper-proof
  - Can meet test specifications
  - Safety mechanisms (abort, current limitation)
  - Cleanliness status
  - Contamination risks (chambers, pumps)

Materials and Processes and Mechanical parts

- QA to check
  - No process are expected during testing
  - Special attention to outgassing of materials from temporary installation, test aids, instrumentation harness, test connectors etc.
  - **Non-flight items to be properly marked and logged (e.g. savers)**

Procedures and log books

- QA to check
  - Procedures approved and configured
    - Responsibilities are clear (go/no-go decisions, test director)
    - Rules for test deviation or stopping test
    - Step-by-step detail
    - Pass/fail criteria clear, inspection points
    - Hazards or precautions are clear (e.g. ESD, cleanliness)
    - Instructions for documentation clear (photos, data recording)
  - Test monitoring methods and intermediate assessment when necessary (engineering and PA review); e.g. phase reviews
  - Log-book(s) available (see Q20 Annex C for DRD)
    - The start of logging may be dependent on project requirements
  - Test scripts to have been tested (Automatic Test Procedure)

Personnel, training

- QA to check
  - Operators have the necessary training
  - Stamp control in place to trace operators
  - Operators trained for precautions and safety
  - Operators trained for GSE
  - Test rules to allow stopping of test if necessary – operators should be briefed.
-

Test Readiness Review (TRR) Agenda (example)

- Typical Agenda for TRR
  1. Test specimen description
     a) Build standard for test vs. build standard for flight
     b) As-built configuration data
     c) Reconciling as-designed vs. as-built
  2. Status NCRs, RFDs, RFWs (to ensure that no open NCR, deviation or waiver affect or block the test)
  3. Procedure status
  4. Software status and configuration (EGSE, ATP etc.)
  5. Safety (Hazardous operations and training status)
  6. Facility Readiness
     a) Cleanliness/constraints/AOB
  7. Test organization
     1. test team organization & responsibilities
     2. test rules
     3. key-events/milestones
  8. Agreement to proceed with test

Post Test Review

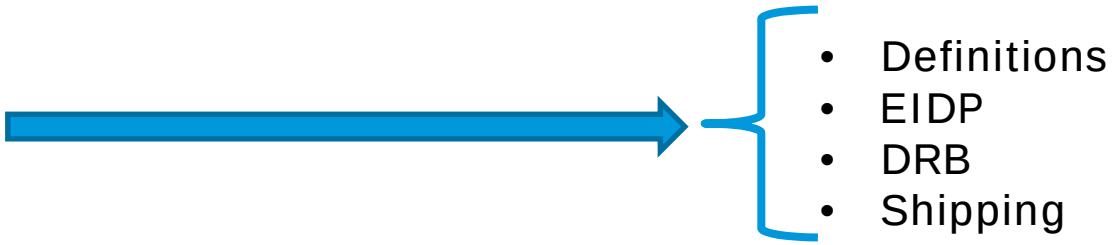
- Following test, a review shall be held to conclude that test is completed and set-up can be broken
  - All steps completed and no retest required (e.g. NCR investigation)
  - Data collected, all test deviations properly noted
  - Any NCRs that occurred do not prevent the end of testing
  - Preliminary assessment of data completed
  - Agreement to release test article

Test Review Board

- After a more thorough review of the data, this convenes
  - Presentation of more definitive assessment of test results
  - Update of NCRs raised in testing
  - Release of test report and verification status from test

QA During Product Development

1. Overview
2. Design
3. Procurement
4. MAIT
5. Acceptance
6. GSE



QA during Product Development
Acceptance –Q20 4.7 & 5.7

Acceptance

- *"Acceptance is the act by which the customer agrees that the product is designed and produced according to its specifications and the agreed deviations and waivers, and it is free of defects when delivered by the supplier."*
- The acceptance process also includes the preparation of the end-item data package (some called acceptance data package) which is the agreed set of documents in the business agreement that provide evidence of quality.
- The delivery of the product is agreed at a Delivery Review Board.
- This section describes the procedure to conclude on acceptance and delivery of items to the customer.

End-Item Data Package

- The contents of the EIDP are to be stipulated in the PA Requirements, early on, and should follow the DRD in Annex B of the Q20. Note that tailoring is possible.
- At acceptance it is necessary that all NCRs, RFDs and RFW are closed. Exceptions can be made for supplemental documentation, but there must not be any question open on the quality of the product.
- The EIDP is normally delivered 3-4 weeks ahead of the Delivery Review Board (Q20 term for Acceptance Review Board).
- Customer QA should review all quality records for completion, the customer reviews verification control documents to conclude that all requirements have been properly verified as planned.
- In addition to quality records, documents also include design data, operation manuals, verification evidence, GSE information, export license, list of all delivered items. The supplier must also certify that the product is in full compliance (see Q20 Annex D for CoC DRD)

Delivery Review Board

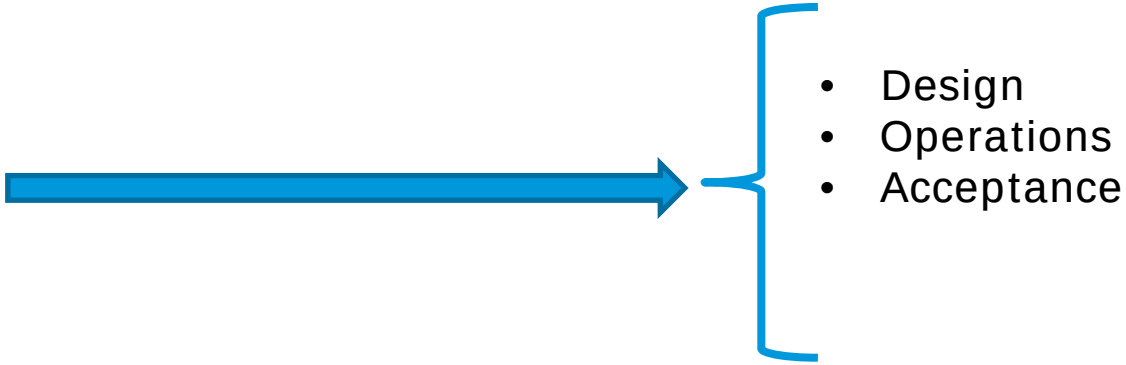
- The composition and conduct of the DRB is described in § 5.7.3
- The DRB is the venue to make agreements with the supplier to provide additional information or agreements to update documents based on the review of the EIDP.
- The DRB must conclude on the acceptance for delivery.
- Deliverable items should be made available for inspection by customer.
- Certification shall be presented on conformity, cleanliness (if applicable) and any safety declarations.

Shipping

- Out-going inspection to be completed by supplier.
- Status of shipping container and procedure to be presented to ensure safe transportation. Packing to mitigate risk of environment (cleanliness, humidity, shock)
- Export license shall also be available to allow for shipment to all future locations that the customer has declared to use the product.
- Insurance shall be confirmed
- Transport traceability to be provided

QA During Product Development

1. Overview
2. Design
3. Procurement
4. MAIT
5. Acceptance
6. GSE



QA during Product Development
GSE Design (Q20 4.8 & 5.8)

Standardization training program
Space Project Management

- GSE covers any equipment that is used support test operations. Some additional points for QA
- The design must be safe:
  - Check that dependability analysis has fully assessed design risk of fault propagations from GSE failure to a flight interface.
  - Check that GSE design has identified risk of operator error in operation that can lead to a stress on flight hardware – these should be noted in the GSE User's Manual.
  - GSE must comply with European Directives for Safety and Environment
  - Handling devices and jigs to have proof load or safety factors
  - As GSE is often moved, safety is important in designing for personal safety in transportation (e.g. tipping hazards, toxic materials)
  - The GSE should have, when feasible, self-test or monitoring of its health to alert operator. This is to be considered on a case-by-case basis, to balance cost and risk with need

QA during Product Development
GSE Design (Q20 4.8 & 5.8.1 & 5.8.2)

Standardization
training program
Space Project Management

- The design must be maintainable
  - As reliability requirements are less stringent and transportation frequent, the mean-time to failure could affect availability
  - Use of standard parts is recommended; Spare philosophy to be considered to reduce schedule risk.
  - The diagnostics capability to address software corrections/improvements is recommended.
  - Network security and virus protection to be considered
  - Data should not be lost in a crash and archival
  - Mechanical GSE should be designed for ease of inspection
  - Maintenance activities to be planned (TBC with project)

- The design must be configured
  - This includes source software, development kit, firmware, database, operating systems

QA during Product Development
GSE Operations

Standardization
training program
Space Project Management

- GSE must be commissioned before use
  - Details to be worked out at project level, but from a QA perspective, proof of proper operation is necessary before any connection to flight hardware

- User's Manual and supporting documents to be approved by customer
  - Details to be agreed by project, but this is a fairly simple requirement to fulfil.

- Software should log all operations as needed for test records.
  - Details to be agreed by project, but this is a fairly simple requirement to fulfil.

QA during Product Development
GSE Acceptance (Q20 4.8 & 5.8.5)

Standardization
training program
Space Project Management

- GSE acceptance to be done via formal process
  - EIDP to be delivered to customer for review
  - DRB to conclude on the acceptance based on a previous acceptance plan, inspection and test reports and verification data.
  - Acceptance requires all certification for conformity and safety
  - Calibration data

- Shipping to be done in a manner to protect hardware
  - Being non-flight, complacency can creep in
  - Keep the GSE clean
  - Calibration data

PART 3

General Quality Management

What is a quality management system (QMS)?

QMS – Management system to direct and control an organization with regard to quality.

Management system – system to establish policy and objectives and to achieve those objectives

(ISO 9000:2005)

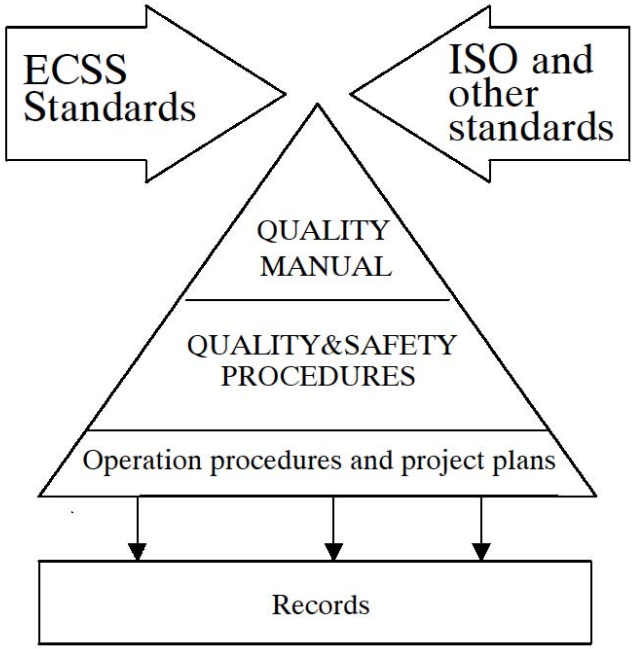
Product quality depends on many variables. The raw materials, processes, organization, resources and procedures that manufacturers and suppliers use to control these variables to produce a product of consistent quality which meets defined specifications is usually called a ***QUALITY SYSTEM.***

- General Quality Management
  - The QMS contains the company's Quality Manual and a set of procedures to ensure consistent control of activities, rectification of problems and improvement.
  - A QMS on its own is not a sufficient guarantee that a project's quality is assured or controlled to the extent required by ESA.
- The PA and QA plans are prepared in response to the ESA project's Quality Requirements (PARD).
  - Intended compliance to be known at proposal stage and any non-compliance to requirements to be approved by customer.
- The ECSS requires dedicated plans to show how quality requirements will be fulfilled. Outlines for these plans are given in DRDs below:
  - PA Plan (as described in ECSS-ST-Q-10C, Annex A)
  - QA Plan (as described in ECSS-ST-Q-20C, Annex A)

Quality Management Principles
Composite quality approach

Standardization training program
Space Project Management

- The composite of a company's quality manual, supporting procedures and use of the relevant standards can be used to cover a product's quality requirements.
- Special attention to be paid to "applicable" standards – those which are contractual requirements; as opposed to informative documents.
-



A PA Plan can refer to existing company procedures and processes.

Other standards may cover the same topics as the ECSS – it is up to the customer to assess this; substitution shall be justified before acceptance.

Audits are helpful to gain confidence and address improvements

- A QMS can be certified by some industry respected quality authority, e.g. ISO, or recognized engineering/process authority e.g. IEC. Examples of certifications found in large companies
  - ISO 9001 – standard and most widely used certificate for QMS
  - AS 9100/EN 9100 – Quality management Standard for aerospace
  - ISO 17025– Quality management for test facilities (test specific)
  - ISO 14001 – demonstrates environmental compliance

- QSM Certification is not generally a requirement for ESA, though it may be needed for subcontracting to other ESA contractors.
  - Certification may be necessary to demonstrate compliance to certain ESA ISO requirements (e.g. soldering, testing)

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  - ISO 17025– Quality management for test facilities (test specific)
  - ISO 14001 – demonstrates environmental compliance

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Recognition of Quality Management

1. The usual business model is to have a quality management system certified as being compliant with the de facto international standard, of ISO 9001
    a. This is a so-called third-party recognition system
    b. Companies must pass audits to become certified

2. Specific business sectors may have other ISO standards to meet additional certification; for example in the Aerospace market the AS 9100 covers the ISO 9001 with additional areas specific to the industry segment, e.g. configuration control.

3. Not all requirements for quality for space are covered in ISO, so Space business customers also audit suppliers for compliance with customer imposed requirements (more on this later).

ISO 9001 in a nutshell

- ISO 9001 is implemented in about 175 countries and there are about 1.1M ISO 9001 Certificates worldwide
- ISO 9001 contains quality management system requirements, not product requirements.
- ISO 9001 is a generic Standard, it means it can be applied to any organization (large, small, public, private, ...) and in any sector.

The ISO 9000 family

1. ISO 9000:2005, Quality Management Systems – Fundamentals and vocabulary
2. ISO 9001:2008, Quality Management Systems – Requirements
3. ISO 9004:2009, Managing for the sustained success of an organization — A quality management approach

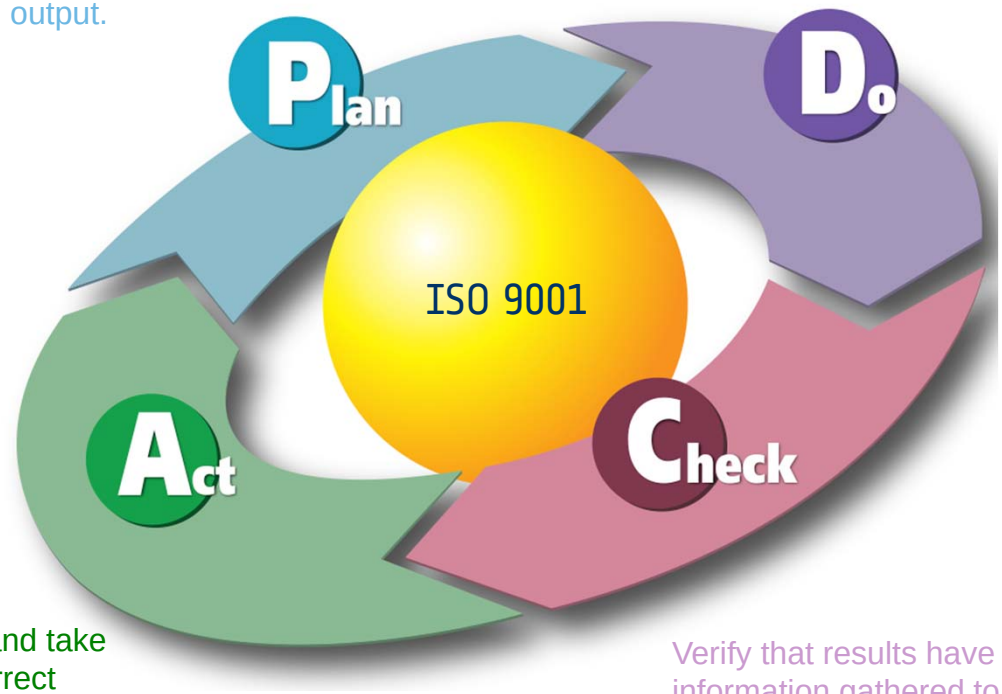
Only ISO 9001 is auditable!

Note: Other Standards, such as “ISO 19011:2011 Guidelines for auditing management systems”, may be used for specific parts of the QMS.

Plan / Do / Check / Act

Define the objectives and processes necessary to deliver results according to expected output.

Implement the planned approach with necessary resources, operating processes and take measurements as planned.



Analyse differences and take action to improve, correct deficiencies.

Verify that results have been achieved. Analyse the information gathered to determine whether the plan has achieved what it set out to do.

What ISO 9001 *is* and *is not*

- It provides the requirements for what an organization must do to manage processes affecting quality of its products and services.
- It is a management process standard, not a product standard.
- However, processes affect final products or services...

ISO 9001 is about company management processes, not products requirements

ISO 9001
Quality Management Principles

Standardization
training program
Space Project Management

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. Improvement
6. Evidence based decision making
7. Relationship management

The new ISO 9001:2015

1. Emphasizes a holistic approach to management systems management. Organizational context must be understood.
2. Replaces preventive actions by risk management: assessment and control.
3. Increases flexibility on the creation and use of documentation. “Documents” and “records” replaced by “documented information”.
4. Strengthens the control of externally provided products and services (purchasing/outsource).

ISO 9001:2015 – Contents

- Section 0: General
- Section 1: Scope
- Section 2: Normative references
- Section 3: Terms and definitions (specific to ISO 9001)
- Section 4: Context of the Organization
- Section 5: Leadership
- Section 6: Planning
- Section 7: Support
- Section 8: Operation
- Section 9: Performance Evaluation
- Section 10: Improvement

EN/AS/JIS Q 9100 in a nutshell

- 9100 is a management system standard tailored to the aerospace industry.
- It embeds the requirements of ISO 9001 and includes delta requirements important to the aerospace business:
  - Configuration control
  - Product safety
  - Risk management
  - Stronger supplier chain focus
- Unlike ISO 9001, certification process has to comply with specific requirements regarding auditor qualifications and assessment process.

ISO 14000 in a nutshell

- ISO 14000 is an environmental management systems series of standards, similar to ISO 9000 series.
- Process oriented approach similar to ISO 9001. Replace “customer satisfaction” with “minimum environmental impact”.
- ISO 14001:2004 does not set up requirements for environmental performance, but provides requirements for establishing an effective environmental management system.
- Simplifies the compatibility of two goals, quality and environmental impact (“integrated management systems”)

ISO/IEC 17025 in a nutshell

- ISO/IEC 17025 can only be applied by testing and calibration laboratories. It was born from ISO Guide 25.
- ISO/IEC 17025 is harmonized with ISO 9001 for the management requirements, and contains technical requirements addressing specific requirements for testing/calibration labs.
- Accreditation to 17025 ensures conformity with an internationally recognized standard and mutual acceptance of test results and measurements between countries.
- Conformity to 17025 demonstrates the competence of the lab to produce technically valid data and results.

Internal audits

- Sometimes the problems are in the internal organization
  - New staff
  - Complacency
  - New procedures/equipment with training
  - Multiple projects in same area

- Internal audits can spot these problems and help avoid problems
  - Periodic audit with rotating focus
  - Work place and storage place monitoring
  - Frequent inventory control

Supply Chains

- Complex products have long supply chains and special attention must be paid to the proper flowdown of requirements and agreements to changes.
- New companies should be audited for evaluation. Audits may also be triggered by
- Right to design information must be carefully negotiated; especially important for critical technology. Careful attention to export control items to prevent lack of visibility.
- Reporting must be made to end customer, so that information is not lost for proper risk assessment or design problems.
- Procurement specifications and business agreements are important to maintain clarity of requirements.

CONCLUSION

Learning Objectives

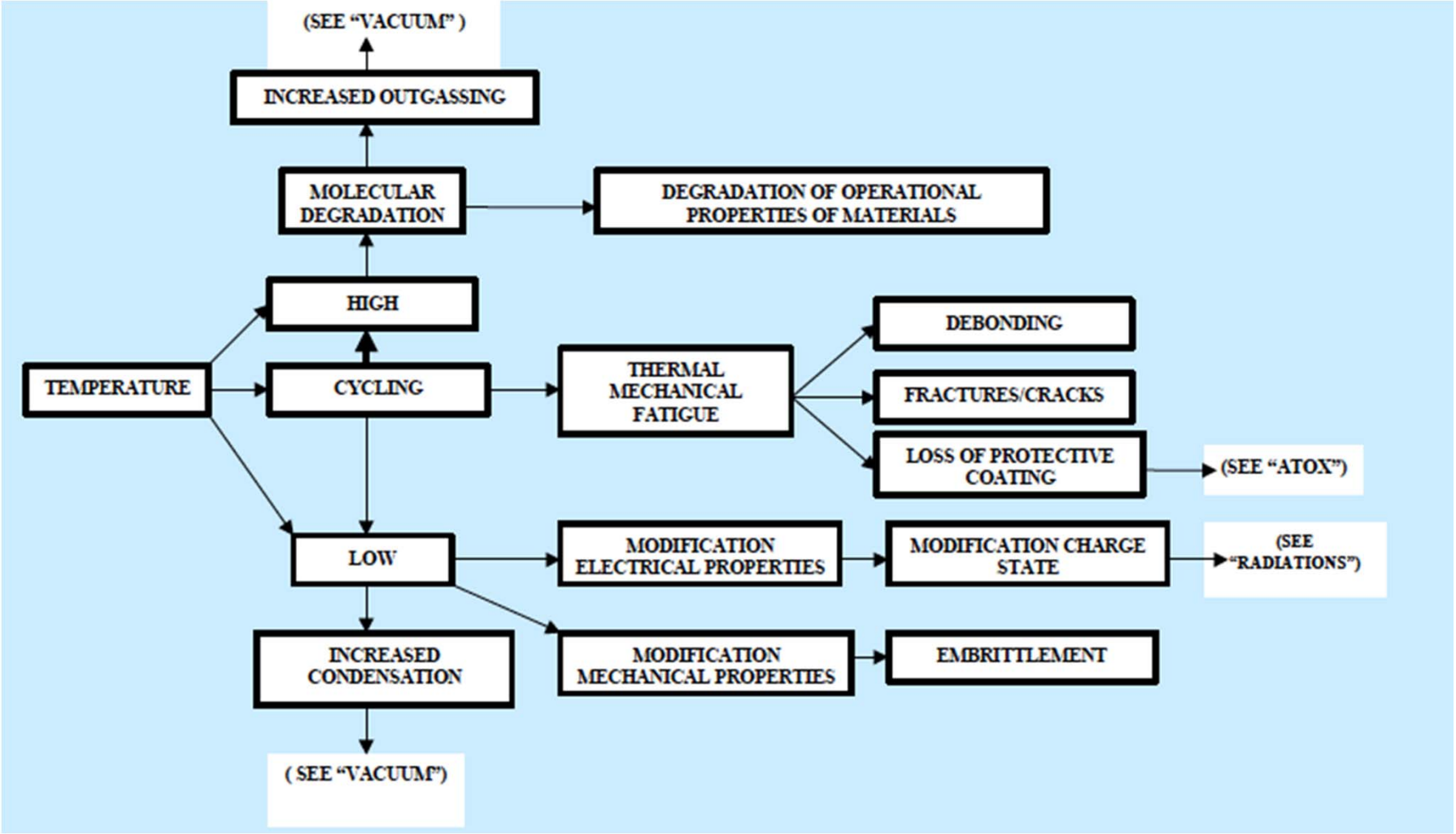
Standardization
training program
Space Project Management

- Understanding of Product Assurance and supporting disciplines
- How to use the ECSS Q branch documents to plan and implement a Product Assurance programme
- Understanding of the Quality Assurance requirements in the ECSS and the basic principles
- Notional understanding of terminology associated with general quality management and its use with ESA projects

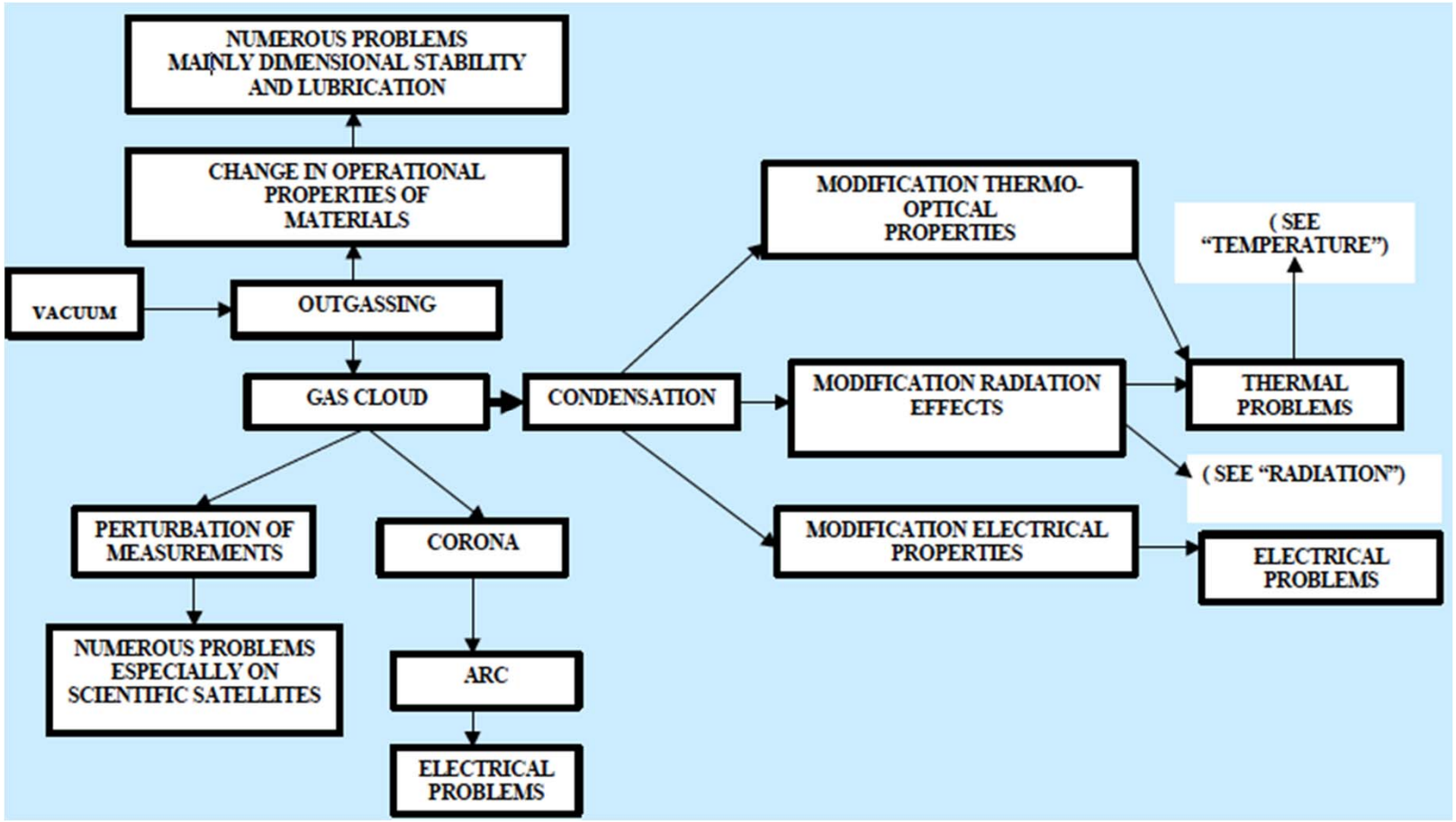

esa
Thank you for your attention
esa
European Space Agency

Backup

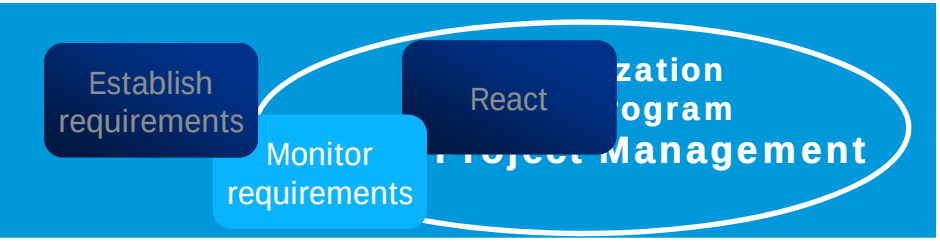
Environmental Effects



Environmental Effects



Verification of Requirements



Demonstration of Materials, Mechanical Parts and Processes requirements:

Verification through inspection test and analysis (examples).

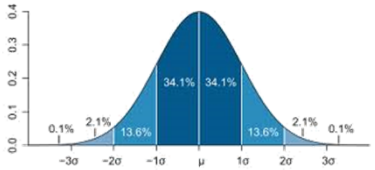
- Cleanliness & contamination
- NDI inspection
- Destructive test

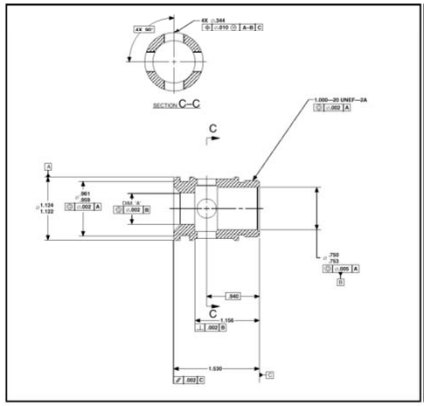
Monitoring Quality Assurance Requirements

Demonstration of Quality Assurance Requirements

Assurance that production uses
- Approved procedures, competencies
- Facilities are appropriate
- Standards and agreed criteria
- Detailed instructions for work
- Proper metrology methods
- Quality records for traceability

Quality Control addresses
- Inspection and verification of quality
- Documentation of quality
- Resolving failures in production
- Traceability of parts and labour
- Approval and acceptance





Monitoring Quality Assurance Requirements

Examples where Quality Control failed

- NOAA N Prime satellite falls off AIT cart during routine handling due to lack of procedural discipline.

- Hubble optics manufactured perfectly to wrong shape due to poor quality assurance and trivial maintenance of test equipment

Costly mistakes due to trivial reasons