DEFENCE SIG
Chartered Quality Institute

Defence

BODY OF QUALITY KNOWLEDGE

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Gerry was formerly Head of Communications and Skills at the UK Ministry of Defence, and as well as representing the Ministry of Defence, served as Chair of the DIG Steering Committee. Gerry has now retired from all of these roles and we wish him a long and happy retirement.

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Introduction

Paul Barlow

The Defence Body of Quality Knowledge (DBoQK) has been written as a guidance document for the UK Defence Sector inclusive of the Defence Industry and the MOD. It is intended to provide a detailed breakdown of the knowledge required by any person working for or on behalf of Defence Sector bodies or organisations.

It has been written to complement the Chartered Quality Institute Body of Quality Knowledge (BoQK) and is aimed mainly at those that have little or no experience of UK Defence contracting whilst also providing a reference for the more experienced Quality Professional within the Defence Sector. It is also intended as a guide for Certification Body auditors when assessing Defence Contractors wishing to attain ISO 9001 certification under the MOD Sector Scheme.

The DBoQK aims to avoid duplication the CQI BoQK by only highlighting information and practices that are specific to the UK Defence Sector. It will, for example provide detailed guidance and information on standards and requirements that apply to Defence contracts and will also explain some of the practices and processes that are used and required by the MOD. Within the CQI Competency Framework this work fits in the Context section.

It is envisaged that the topics and information in the DBoQK will evolve over time and will be regularly reviewed and updated by the CQI Defence SIG Steering Committee given this first version will not address everything in the sector.

Note | This work was undertaken before the release of ISO 9001:2015 and has not been written to address the changes it introduces. The DIG Steering Committee will commence a review of the Defence Body of Quality Knowledge during 2016 to begin addressing these new requirements.

Contents

History & Future of Quality in Defence

Gerry Fice

Scope and Approach

The aim of this chapter is to outline how Quality has developed, how it has influenced the UK Defence Sector, how it has since transformed to reach where it is today and to indicate known changes on how it is being transformed for the future.

Standards – a Historical Perspective

Inspection against standards has been around since the Pharaoh Imhotep provided his workers with wooden gauges to ensure the stones for his pyramid were uniform.

On and off throughout history craftsman's Guilds have imposed standards and restrictions on local trade to protect their industries from charlatans and to ensure their monopoly. These restrictions governed the training of apprentices, standards of goods, weights and measures and access to the trade.

In 1300, Edward I of England introduced the first mark of Quality on gold and silver, the King's Mark. This was later institutionalised so that the Hall of the Guilds could test precious metals for quality and purity and apply their own Hallmark as well as adopting responsibility for quality control of their members, setting and maintaining certain standards for Guild membership.

13th Century. War with France broke out and King John of England appointed William Wrotham to report about quality control in the construction and repair of his warships. Centuries later Samuel Pepys, the Secretary to the British Admiralty appointed multiple overseers to undertake this role.

18th and 19th Centuries. The Industrial revolution saw massive developments in industry and the rise of scientific management leading to a system where large groups of people performing a specialized type of work were grouped together under the supervision of a foreman who was appointed to control the quality of work manufactured.

Late 18th century. The realisation that fault-free goods were more valuable than those with defects. French General Jean-Baptiste Vaquette de Gribeauval promoted standardised weapons in what became known as the Système Gribeauval after it was issued as a royal order in 1765. (Its focus at the time was artillery more than muskets or handguns.)

One of the accomplishments of the system was that solid cast cannons were bored to precise tolerances, which allowed the walls to be thinner than cannons poured with hollow cores.

However, because cores were often off center, the wall thickness determined the size of the bore. Standardized boring allowed cannon to be shorter without sacrificing accuracy and range because of the tighter fit of the shells. It also allowed

standardization of the shells.

Before the 18th century, devices such as guns were made one at a time by gunsmiths, and each gun was unique. If one single component of a weapon needed a replacement, the entire weapon either had to be sent to an expert gunsmith for custom repairs, or discarded and replaced by another weapon. During the 18th and early 19th centuries, the idea of replacing these methods with a system of interchangeable manufacture was gradually developed. The development took decades and involved many people.

World War I Production

Variability in production and inspection methods in the munitions industry during the 1st World War led to the creation of an army of Government Inspectors. During this time, manufacturing processes had typically became more complex with larger numbers of workers being supervised.

This period saw the widespread introduction of mass production and piece work, which created problems as workmen could now earn more money by the production of extra products, which in turn occasionally led to poor quality workmanship being passed on to the assembly lines.

To counter bad workmanship, full-time inspectors were introduced to identify, quarantine and ideally correct product quality failures.

World War I to World War II

1920s and 1930s. Quality control by inspection led to the growth of quality inspection functions, separately organised from production and large enough to be headed by superintendents.

Some initial work on Statistical Quality Control (SQC) was also undertaken in the 1920's. These included the concept that not every single item produced could be inspected and allowed the manufacturer to sample and test a certain proportion of items to achieve a level of confidence in the whole batch being produced.

The systematic approach to Quality started in industrial manufacturing during the 1930's in America where attention was focussed on the cost of scrap and rework.

World War II

With the impact of mass production required it became necessary to introduce an improved form of Quality Control now known as SQC.
One of the major problems during World War II was the number of bombs going off in factories. The Ministry of Defence therefore placed inspectors in those factories producing munitions and at the same requiring the suppliers to document their procedures making the product, ensuring that their workforce adhered to those procedures and having their complete process inspected by the MOD Inspector.

This was successful in that bombs stopped exploding in factories and the term Quality became associated with Conformance and Quality Assurance with the Assurance of Conformance

Post World War II

W. Edwards Deming & Joseph M Juran promote the concepts of Quality to the Japanese during the rebuilding of their manufacturing base.

The UK Defence Industry continued to utilise the MOD Inspector in its supply chain, both looking at and, in some cases, accepting the products being made

and in 2nd Party Assessments of potential Suppliers and adding the to the Defence Contractors List.

1951. J M Juran documented the principles of QM in his Quality Control Handbook.

1959. The first Quality Management Standard, Mil Std-Q-9858 was issued by the US Department of Defense.

Late 1960's and 1970's. Revisions of defence standards i.e. AQAP 1, Def Stan 05-90 series.

1979. A British Standard BS5750 in three parts matching Def Stan 05-90 series issued although the MOD continued to use the Def Stan 05-90 for a short while after.

1982. The recognition by the UK Government that the efficiency and international competitiveness of British Industry need to be improved and that enhanced recognition for Standards and QA was necessary. The MOD for its part began to devolve its 2nd Party Assessment of Suppliers to 3rd Parties starting with Stockists by BSI QA and laboratories and test houses to the National Testing Laboratory Accreditation Service.

Sept 1991. MOD accepts 3rd Party Assessments of its suppliers to the ISO Standards. This replaced the 2nd Party Assessments to Allied Quality Assurance Publications (AQAP) 1, 4 or 9 with AQAP 13 being invoked when software was involved undertaken by the MOD.
The role of the MOD Inspector also changed to reflect these new arrangements with many of the mandatory "inspection" duties carried out by them being made the responsibility of the Supplier and change from inspection of products to a more systems approach based around the Suppliers Management System based on risk.

2000. ISO9001:2000 based on 8 principles of Quality Management introduced. This has been updated twice, the current version being ISO9001:2008 which is used Defence wide to demonstrate acceptable Quality Management throughout.

Today and the Future.

As seen above, Quality has had a long and illustrious history from Pharoah Imhotep times going through many phases of control, inspection, assurance and now quality management as detailed in the ISO9000 family.

This focus on Quality Management is demonstrated by the MOD's policy of "Appropriate Certification" in preferring to do business with Suppliers that have a certificated Business Management System.

However, they do not place contracts to the ISO Standards because they do not address all of the MOD'S requirements for Acquisition; Defence Standards and AQAPs are used to apply these requirements on Suppliers. The AQAP 2000 series embody the requirements of the ISO 9000 standard and the requirement for a certified Management System but also embeds additional requirements which are not included in the ISO standard.

Today there is also much more contact and joint working between the MOD and Industry. This is carried out under the direction of the Defence Industries Quality Forum (DIQF) who set out their joint objectives within their Business Plan; further details can be found on the CQI DIG website.

International Organisations, Legal and Regulatory Requirements

Andy Lennon

Scope and Approach

1. International Organisations
2. Legal and Regulatory Requirements
3. Acquisition Operating Framework

The aim of this section is to outline some of the International Organisations the Defence regulations for the UK: how that translates into legal requirements for the UK Defence Industry; then to outline how the regulatory expectations are explained in codes of practice; safety, security and transport guidance , indicating international aspects where appropriate.

International Organisations

Many UK MoD Defence Contracts are now placed with overseas suppliers; similarly many overseas Government's contracts are placed with UK suppliers.

North Atlantic Treaty Organisation (NATO)

Government Quality Assurance (GQA) is provided by NATO nations, on request from another NATO nation. Requests for GQA must be in accordance with Standardisation Agreement (STANAG) 4107, using the Allies Quality Assurance Publication (AQAP) 2070 GQA procedure and associated templates and guidance. STANAG 4107 invokes the principle of reciprocity to allow nations to provide GQA to other NATO nations without charge provided the resources required to complete the GQA request are not excessive.

The NATO Standardisation Agency (NSA) is an independent NATO Agency that reports to the Committee for Standardization (CS) for general oversight and direction. The NSA reports directly to the Military Committee Joint Service Board (MCJSB) The Agency's mission is to foster NATO standardization with the goal of enhancing the combined operational effectiveness of Alliance military forces. As a key part of the NATO Standardization Organization (NSO), the NSA takes an active interest in all standardization related activities in NATO.

Standardization is defined within NATO as the process of developing concepts, doctrines, procedures and designs to achieve and maintain the most effective levels of "compatibility, inter-changeability and commonality" in the operational, procedural, materiel, technical and administrative fields. The primary products of this process and NATO's tools for the enhancement of interoperability are Standardization Agreements (STANAGs) between member nations.

The NSA, as the focal point for NATO standardization efforts, accomplishes its mission through the promotion of co-ordination among all NATO Committees/Working Groups dealing with standardization. Furthermore, it provides support to some 46 operationally oriented working groups that have been established by the Service Boards (Joint, Army, Naval and Air) pursuant to authority delegated by the Military Committee.

A small staff co-ordinates Agency activities and supports the Director of the NSA. The NSA is functionally organized into five branches (Policy and Co-ordination, Joint, Army, Naval, and Air) and an administrative support element. The Chief Joint Branch chairs the Military Committee Joint Service Board (MCJSB), which is supported by the Joint Service Branch. The NSA single service branches support the Army, Naval and Air Boards by providing the Chairman and four supporting Staff Officers. Under the sponsorship of each Board, specialist Working Groups of experts from nations and commands develop doctrine and procedures which are ultimately published as STANAGs and Allied Publications. NSA Staff Officers serve as the Secretaries to these Working Groups.

Organisation Conjointe de Coopération en matière d'Armement (OCCAR)

OCCAR is the multinational organisation for Joint Armament Co-operation established to enable European countries to collaborate on defence equipment procurement in order to compete in the global market and deliver projects more efficiently and economically.

At this moment six nations are member Nations of OCCAR: Belgium, France, Germany, The United Kingdom, Italy and Spain.

OCCAR mission is to facilitate and manage collaborative European Armament Programmes and Technology Demonstrator Programmes through their life cycle to the satisfaction of their customers.

Through Life Management (TLM) means managing a programme throughout its whole life cycle, in a use-centric way. TLM is achieved by applying and integrating best practice management techniques in a coherent manner across all system aspects in order to deliver, sustain and dispose the required cost-effective defence system.

International Traffic in Arms Regulations (ITAR)

If you are a UK company which exports controlled military goods to the United States you will need to comply with US controls, specifically the International Traffic in Arms Regulations (ITAR). ITAR is the set of US government regulations that control the import and export of defence related items and services as listed on the United States Munitions List (USML).

The requirement to comply with ITAR is in addition and separate to any responsibilities for applying for a UK export licence resulting from UK export control legislation as administered by the Export Control Organisation, part of the Department for Business, Innovation and Skills (BIS).
Under the US-UK Defence Trade Cooperation Treaty the UK's ECO (Export Control Organisation) has issued a specific Open General Export Licence. As with all other OGELs issued by the ECO you need to meet all the specified terms and conditions if you are considering exporting under authority of the licence.
In 2011 the US Department of State issued a rule change to ITAR (section 126.18) which provides an exemption for UK end user and consignee companies only. This removes the need to obtain prior approval from the US Department of State for transfers of unclassified defence articles (including unclassified technical data) to dual and third country national employees of foreign business entities, foreign government entities or international organisations that are approved end users or consignees for such defence articles.
If you are an approved UK end user or consignee company then you should be aware of the regulations and the exemption, which is subject to satisfying certain screening and record keeping requirements.
The US government has agreed that the UK pre existing Baseline Personnel Security Standard (BPSS) meets the screening requirements of ITAR rule 126.18(c)(2). However, if you choose not to use the BPSS you must ensure you are able to meet the screening requirements through suitable, alternative means.

Legal and Regulatory Requirements

Nuclear Safety

The International Atomic Energy Agency (IAEA) safety standards are recommended to be adhered to by States and National Authorities.

The UK MoD has exemptions from the requirements of the law/regulations in some nuclear-relevant areas but where exemption applies MoD Safety policy also applies.

MoD safety policy is promulgated in JSP 815 (Defence Environment and Safety Management) Essentially this states that wherever MoD has exemptions from statutory requirements, the MoD will so far as is reasonably practicable apply measures at least as good as those required by law.

In recognition of the difficult legal position resulting from exemptions and MoD policy, an agreement has been reached between the Health and Safety Executive, who regulate the HS&W Act and the MoD. It is called the MoD-HSE General agreement and is recorded in JSP 815. A specific feature is that the MoD cannot be prosecuted but it can be censured for breaches.

Nuclear Submarine Site Licensing

The primary legislation related to the handling of fissile material is the Nuclear Installations Act (Section 1) which involves a licensing regime. This act is regulated by the Nuclear Directorate of the HSE and usually referred to as the Nuclear Installations Inspectorate (NII) who thus function as the civil Regulator.

The NIA does not apply to dockyard and shipbuilder activities except when the reactor is complete in a submarine. So reactor testing and

submarine movements/dockings will not normally be licensable activities even when controlled by the commercial site operator.
Obviously, however such activities, which do carry a nuclear risk, must still be controlled somehow. The solution is to regard such exempt activities as "Authorised (by MoD)" activities even if conducted by a commercial operator on a commercial site. The result is that such activities will be regulated by the MoD Authorisation process

Authorisation Conditions (ACs)

Since the process of authorisation is based on that for civil Licensing we need the Defence Sector needs a Regulation process to mirror the role of the HSE/NII in the civil sector. MoDs equivalent is called the Defence Nuclear Safety Regulator (DNSR)

DNSR has published a set of 36 Authorisation conditions that mirror as closely as possible the Licence conditions published by the HSE/NII but have a broader scope than the NII licence conditions, to cater for additional needs owing to the mobile nature of the naval reactor plant.

Site Safety Justification (SSJ)

JSP 518 (regulation of the naval nuclear propulsion programme) requires that sites which support nuclear submarines should produce a Site Safety Justification (SSJ) to demonstrate that an adequate level of safety has been achieved for the site and its various support facility activities. The SSJ is generally considered to be comprised of 3 main parts.

a. The Site Safety Case
b. Facility Safety Case
c. The Management arrangements for safety

Independent Nuclear Safety Assessment (INSA)

INSA services in support of the nuclear plant on submarines is provided to the Naval Reactor Plant authorisee (HNP) by Serco Submarine Reactor Department (SRD)

The NPIPT-SRD INSA process is, of course monitored by DNSR as the overall MoD regulator.

Berth Assessment

Berths include dry-docks, ship-lifts, tidal berths and mooring buoys. Berth clearance relates to the process of minimising the consequences of a nuclear accident and so is an element of nuclear safety and safety case.
Generally each berth requires an assessment to be made by its sponsor. This assessment is subsequently agreed by DNSR.

Berth Categories

Two main categories of berth have been defined. These are known as Licensed/Authorised Site Berths (used to be called X berths) and Operational Berths (Used to be called Z Berths). Operational Berths are all berths (in UK, UK dependent territories and foreign berths) outside of Licensed or Authorised Sites.

Explosives Regulations

There are no specific international regulations or codes of practice that relate directly to the safe storage of ammunition and explosives, this is a national responsibility. However, international alliances do have consolidated literature that covers this technical area.

An excellent example is the NATO Allied Ammunition Storage and Transportation Publications 2. (AASTP 2) - Safety Principles for the Storage and Transport of Military Ammunition and Explosives.

Defence suppliers contracted, to manufacture or store explosives, by the MoD must apply to the HSE for a licence under the Manufacture and Storage of Explosives Regulations 2005 (MSER) Such Licences are termed Explosive site licences and, unless they are fixed rule licences are subject to Local authority assent. Further guidance on how to apply is provided within Joint Service Publication (JSP 482) Classification for Transport: 'Classification' identifies the hazards posed by explosive substances and articles as packaged for transport. The Competent Authority of a Contracting Party to ADR must assign the classification of explosive materials before they can be transported. This involves assessing an explosive to determine whether it is assigned to – or excluded from – Class 1 of the UN classification scheme for the transportation of dangerous goods. An explosive assigned to Class 1 is given an appropriate UN Serial Number, hazard code and compatibility group, depending on its composition, type, and hazard. A Competent Authority is a body designated or recognised to carry out duties under transport of dangerous goods regulations. In Great Britain: HSE is the Competent Authority for the classification of non-military explosives Military explosives, ie explosives under the control of and/or in connection with the execution of contracts for the Secretary of State for Defence are classified by the Explosives Storage and Transport Committee (ESTC) of the Ministry of Defence Once the Competent Authority has agreed the classification, it issues a Competent Authority Document (CAD).

Environmental

MOD recognises the importance of protecting the environment and being able to demonstrate good environmental management performance. The strategic policy is set out in Joint Service Publication (JSP) 815 and the policy sets out the framework for the MOD EMS as the ISO 14001 Standard for environmental management.

While with each Defence Supplieris expected to adopt the key principles of ISO 14001 Standard, some flexibility is acceptable. The work required must be proportional to the potential environmental impacts and the organisation's other priorities.

MOD takes a systematic approach to incorporating environmental considerations into every business decision including all aspects of policy making, procurement and change management. It provides a framework for continual improvement in performance and represents a long-term commitment to environmentally responsible management.

Acquisition Operating Framework (AOF)

Managing Quality

The AOF is a source of policy and good practice on Managing Quality for all members of the UK Ministry of Defence and their industry partners concerned with Defence Acquisition.
It is intended to improve the consistency of the MoD's application of policy and best practice and play an important role in delivering better solutions for defence in the future.

Responsibilities

Although MoD delivery team leaders are responsible for the quality of the product they acquire, Suppliers are totally responsible for the Quality of the product they deliver, and Suppliers are required to maintain adequate control of their supply chains. This responsibility extends to all levels of subcontractor, including those overseas.

Appropriate Certification

Where contracts are placed for products / services that are not simple, commercial-off-the-shelf or of low-value, and conformance to requirements cannot readily be checked after receipt, the MoD delivery team leader shall ensure that such contracts are only placed with contractors holding an appropriate quality system certification.

Order of Preference

Appropriate certifications are outlined in order of preference.

First Preference

Third Party Certifications such as:

- BS EN ISO 9001:2008 issued by a UKAS recognised 3rd party certification body
- BS EN ISO 17025 (previously EN45001) accreditations issued by UKAS
- BS EN ISO 14001 Environmental Management Systems issued by a UKAS recognised 3rd party certification body.

Provided that the scope of the certification covers the work to be done, UKAS accredited sector scheme appropriate to the contract, for example:

- AS 9100 (Quality Management System - Aerospace Requirements)
- AS 9110 (Quality Maintenance Systems - Aerospace Requirements for Maintenance organisations)
- TickIT (Software)
- NF EN 46001 Medical Devices (Quality Systems Medical Devices)
- ISO/TS 16949:2002 (Quality Management Systems applicable to the Automotive Industry)

Provided that the scope of the certification covers the work to be done, MOD approved sector scheme appropriate to the contract, for example:

- Design Approved Organisation Scheme (DAOS) – Aerospace
- Maintenance Approved Organisation Scheme (MAOS) – MOD owned aircraft

Second Preference

Second Party Certification by a NATO government organisation to an appropriate:

- AQAP
- ISO 9001:2008

Third preference

Delivery team leader approved alternative arrangements, agreed by the Defence Quality Assurance Authority (DQAA).

Management Systems, Standards and Assessment

Chris Hughes

Overview

Management systems have been a key part of the UK Defence industry throughout it's history[1]. The Ministry of Defence (MoD) has been instrumental in the development of standards since quality problems were found with munitions in World War 2[2].

There is a long history of continual improvement which started with BS9000 and the US based MIL-Q-9858, led to BS5179, then BS5750 which was submitted to ISO in 1979 as a proposal for a global standard on Quality Assurance. Work by an ISO Technical Committee began on this standard in 1981 and it was published in 1987 as the ISO 9000 series of standards. The standard has undergone a further 3 iterations published in 1994, 2000 and the latest in 2008.

The purpose of these standards is to ensure that organisations meet the needs of their customers and other stakeholders whilst meeting statutory and regulatory requirements related to the product.

Management Systems Standards for Quality in the Defence Industry

The Defence industry is quite unique in some ways

- cutting edge, ground-breaking technology
- coupled with the best in breed of technologies pulled from other industries,
- assets in low volume compared to the automotive or consumer sectors but that are in service for a generation

In other ways the Defence Industry desires to be like other industries

- Low cost (although this is better realised as value for money given the constraints above)
- Short time to market (difficult due to assets generally being designed from scratch)

In summary the spectrum of standards is a patchwork quilt of defence requirements with the best in breed from other industries pulled through. There are 2 benchmark standards in the industry right now in the form of ISO 9000 (globally recognised quality standards) and AS9100 (originally ISO 9000 with extra requirements for the aerospace industry, now evolving into THE standard for aerospace, defence and space industries). AQAP 2000 series was developed by NATO to standardise Quality Management System requirements, add additional requirements needed for the Defence Industry and the requirements for government to government quality assurance activities across NATO countries. It should be noted that there is no accreditation in place in the UK to grant certification to AQAP Series of Standards.

Health and safety of workers and the health and safety impact of products on

[1] Wikipedia http://en.wikipedia.org/wiki/Quality_management

[2] Systems Thinking Website http://www.systemsthinking.co.uk/home.asp

users is fundamental to the Defence industry so OHSAS 18001 is a popular management system certification. Similarly the impact of the industry, and the impact of the product in the environment drives a lot of businesses to certify to ISO 14001.

Other Standards

There are a number of other standards relevant to working in the Defence Industry which provide extra requirements depending on the process being employed to manufacture a product or product being integrated.

A number of these standards were initiated by the MoD through the Defence Standardisation service (http://www.dstan.mod.uk) and cover specific products and processes. It's a very extensive list.

Anything falling into the Process section can be considered to be a "Special Process" as referred to in ISO 9001 vocabulary.

Approach to 1st Party Auditing

By virtue of being certified to ISO 9001:2008 there is a requirement for businesses to audit adherence to planned arrangements and to determine how effective they are. There is no requirement for businesses to perform self assessment or have independent assessments undertaken such as those seen in the nuclear industry.

Approach to 2nd Party Auditing

There are two kinds of 2nd Party Audit:

1. Between the acquirer (UK MoD) and a Prime Contractor which is more often than not performed for the UK MoD by the Defence Quality Assurance Field Force (DQAFF)
2. Between customers and suppliers in the supply chain from Prime Contractor downover.

Given the nature and complexity of assets suppliers in the chain will design and integrate their products, but not necessarily make everything themselves. This often means a lot of the risk to quality and schedule (costs are often fixed) are located two, three or four tiers down from the prime contractors. It is therefore not unusual to see a customer in the supply chain spend a lot of time and effort at their suppliers ensuring quality is correct and risk to schedule is minimised.

Key to minimising this effort is in the selection of a robust and competent supplier, preferably one who understands the needs and differences that are demanded by the Defence Industry.

There are some specific technologies whereby the UK MoD will work directly with the primes and their supply chain to ensure requirements are met. For example proofing of ordnance where the Defence Ordnance Safety Group (DOSG) will ensure that Ordnance and associated Munitions are fir for purpose and safe to handle. There are other examples of this…

Approach to 3rd Party Certification

Defence Prime Contractors are required, through invocation in contracts with the MoD, to have and maintain certification to ISO 9001:2008 as a minimum for the duration of the contract. Some Prime Contractors have opted to be certified to the more onerous AS9100 standard.

Further down the supply chain there is a mix of certifications between ISO 9001:2008 and AS9100 (currently at Revision C although some certifications to Revision B are still in place). The Prime Contractors prefer to deal with suppliers

who are certified to ISO 9001:2008 but do not necessarily mandate the requirement to their supply chains.

There is special arrangement in place under a pilot programme between UK MoD and UKAS whereby companies who operate in the Defence Sector and have signed up to pilot scheme have extra assessor mandays by the Certifying Bodies and allow members of the Defence Quality Assurance Field Force (DQAFF) to attend planning, opening and closing meetings to raise their concerns.

Management System Roles

Quality professional's involvement with the management system in the Defence Supply Chain will be one or a combination of the following, depending on the organisation and local needs:

- Owner of all or part of the management system and therefore responsible for ensuring that the management system is defined, controlled, in a fit state, available to the organisation and continually improved. This involves liaison with senior and middle management who are the authors and approvers of the content.
- Working to the management system as a person with some kind of quality responsibility; customer / stakeholder / regulator facing, project facing, function facing, or supply chain facing.
- Working to your own company management system supplying products or services while interpreting the requirements of the supply contract and associated specifications.
- Overseeing or auditing arrangements and monitoring compliance with, and/or effectiveness of, the management system.

Knowledge Management

Chris Hughes

Knowledge management (KM) as a buzzword is a relative newcomer to the defence industry. However, management of knowledge has been undertaken for a number of years across many industries probably better known as "on the job training". If you have a number of special, maybe unique, processes how can you sustain the outcome if you do not manage the knowledge? Defence companies must manage knowledge to be effective.

Knowledge management is finally recognising the importance of this "between people's ears" or "tribal" knowledge of the specifics of "how do I do…?"

In Defence, and moreover in the Quality arena of Defence, KM is a key factor to continued success for two primary reasons:

Long design and manufacture phases can mean a turnover in staff put companies behind schedule while the learning is relearnt. Couple this with the generally long service life of the assets (30 years and more in some cases) a way to hand over the learning from designing, manufacturing and operating the asset in service is critical for UK MoD and it's supply chain.

KM has its own "language" and is growing as a specialism and area of expertise. Knowledge is categorised as:

- Explicit, written knowledge
- Implicit, not written, but obvious to the knowledge worker
- Tacit, used by the knowledge worker but more derived from experience and hard to capture

A simple summary of KM is:

The right people + the right information = knowledge management in control

There is no consistency, within nuclear sector companies, as to the function that has primary responsibility for KM but the quality function with it's links to process will always play an active role as there is an active role as there is interaction with the quality management system, the records (process and training/competence).

Regulatory Requirements

ISO 9001:2008 does not specifically reference knowledge management but it is intimated under Section 6.2.2 b) Human Resources – Competence, training and awareness which states:

"The organization shall, where applicable, provide training or take other actions to achieve the necessary competence."

It's hard to train someone in knowledge so transfer of knowledge through knowledge management techniques may be appropriate.

Risks

There is a perception amongst a number of leaders in the industry that age demographics of the quality professionals will soon become a problem. Years of tacit knowledge to be transferred or retained poses a considerable challenge.

Procurement and Supply Chain Assurance

Gary Illingworth

Overview

Very few defence organisations have the capability and infrastructure to undertake all the work and processes that are required in support of their product development and manufacturing within their own organisation. From concept design through to disposal the use of specialist support can vary from Design and manufacturing support through to the undertaking of special processes, inspection and test, record storage and third party auditing

The development of a supporting Supply Chain is essential to most organisations within the Defence Industry and lays claim to a significant part of an organisations budget.

Regulatory Guidance

Standards

AS9100C – Quality Management System - Requirements for the Aviation, Space and Defence Organisation (all requirements detailed below)

ISO 9001-2008 – Quality Management Systems Requirements (does not include requirements detailed below in "bold")

Para 7.4.1 – Purchasing Process

This standard sets out the requirements for Purchasing thus:

The organisation shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and purchased product shall be dependent upon the effect of the purchased product on the subsequent realisation of the final product.

The Organisation shall be responsible for the conformity of all products purchased from suppliers, including sources defined by the customer.

The organisation shall evaluate and select suppliers based on their ability to supply product in accordance with the organisations requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained

Note: One factor that can be used during supplier selection and evaluation is supplier quality data from objective and reliable sources, as evaluated by the organisation (e.g., information from accredited quality management system or process certification bodies, organisation approvals from government authorities). Use of such data would be only one component of an organisation's supplier control process and the organisation remains responsible for verifying that purchased product meets specified purchase requirements.

The organisation shall

a) Maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of approval (e.g., product type, process family)

b) Periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls to be implemented
c) Define the necessary actions to take when dealing with suppliers that do not meet requirements
d) Ensure that where required that both the organisation and all suppliers use customer approved special process sources
e) Define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the suppliers approval status
f) Determine and manage the risk when selecting and using suppliers

Specific Aspects

As the Defence Industry are embedded within and reliant upon a robust Supply Chain in order to provide support to all aspects of the Product lifecycle, from Design Concept through to Product Disposal (which could span some 40 years) a industry specific Supply Chain Development Lifecycle has been developed, which will be tailored to suit individual organisations specific business requirements, but are generically outlined below and are in line with the International Aerospace Quality Group (IAQG) Supplier Quality Management Basics:

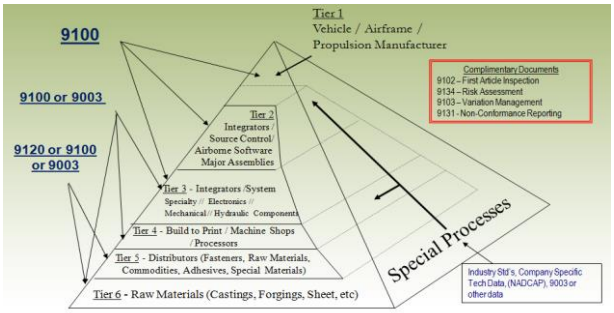
Quality Requirements Flow Down

The first step in any product cycle for managing the quality performance of a supplier is to establish a process for identifying, documenting and flowing down quality requirements and expectations. Appropriate quality requirements must be flowed down to the lowest level of the supply chain in order to ensure all requirements are met for the product's end user, the customer.

Appropriate requirements are determined based on product category and design, customer requirements, statutory and regulatory compliance.

This is usually done through the use of quality notes detailed in the purchasing contract.

The Procurement and Quality Professionals in an organisation work together to establish the quality requirements expected of the supplier and then must ensure that the requirements along with other contractual expectations are clearly understood and complied to.
For the aviation, space and defence industry, IAQG has established and advocates the use of a set of Industry Quality Management Standards represented in the figure below.



Supplier Selection

A trend of standardisation within the aviation, space and defence industries has created generic methods of assessing suppliers. It is becoming more and more prevalent, and supported by the SC21 initiative, that customers are becoming reliant on Suppliers having the appropriate Quality Management Systems Certifications from an accredited third parties such as 9100, 9110, or 9120 (all of which are based upon the ISO requirements) especially if these are contractually mandated

The data generated from these assessments provide customers with the assurance that a Certified Supplier has an acceptable Quality Management System in place. These certifications will not mean that the customer does not undertake his own "product specific" reviews with the supplier in order to gain confidence that contractual specific requirements shall be met.

Supplier Pre-Production Planning Advanced Product Quality Planning (APQP)

The APQP process is intended to produce Control Plans that support the manufacturing of "defect free" product and facilitate in the compliance to the established targets for the product life cycle.

The APQP process contains a number of tools and techniques and will be undertaken, as appropriate, by multi functional teams including Quality Assurance

Work Instructions (Manufacturing Planning)

Work Instructions shall flow the engineering requirements into the manufacturing process and define the methods used to meet these requirements. The organization should develop a documented system for the creation, review, approval and maintenance of work instructions. Work instructions provide a comprehensive, step-by-step sequence of activities required to produce product.

Competency Development

The Aerospace Industry is reliant upon a complex supply chain and a wide range of sophisticated equipment, processes, skills and competent people. Consequently, it is important that the planning process includes a review of the supplier's program for managing and maintaining the skills, knowledge, personal attributes and experience of its employees.

Preventive Action from Lessons Learned

Organisations should have defined processes for knowledge management including lessons learned for use in future product development and production. Lessons learned should be assembled by subject matter experts from applicable disciplines. Pertinent information should be incorporated into the Manufacturing Planning and/or Advanced Product Quality Planning.

Production Readiness Pre-Production Runs

Prior to a production run, a trial part/assembly (prototype) should be manufactured to validate that the design and the manufacturing methods are appropriate to create a product compliant to the manufacturing plan.

All the elements of the manufacturing method (NC program, fixture, tooling, etc.) are verified and feedback is provided to the relevant functions for appropriate action prior to starting the production process.

On Site Product Validation Audit

Product validation audits should be performed on products/processes representative to the scope of initial approval (similar parts or processes) to assess the supplier's capability to produce conforming product or service. These audits should be conducted by the Buyer's personnel who are cognizant of the specific product or service being assessed

First Article Inspection (FAI)

A FAI is "a complete, independent, and documented physical and functional inspection process to verify that prescribed production methods have produced an acceptable item as specified by engineering drawings, planning, purchase order, engineering specifications, and/or other applicable design documents"

The purpose of an FAI is to provide objective evidence that all engineering design and specification requirements, including process and manufacturing validation, are correctly understood, accounted for and recorded.

Process Capability Validation

Supplier should develop a methodology to establish process capability through the use of a structured approach. The goal is to reduce process variability and dependency on inspection. As a feedback mechanism, statistical techniques can be used to make adjustments to the process.

Continuous Improvement (CI) Loop

Process Capability is studied through the use of process monitoring tools such as statistics. The process should remain in control. Processes not in control should be cause to initiate corrective actions. In order for a process to be in control, all assignable causes must be eliminated and re-evaluated.

Purchase Product Verification

There are several methods for verifying the conformance of purchased products.

Receiving Inspection

This is the process for inspection and acceptance of purchased product by the customer at the customer site to ensure compliance with all requirements of applicable drawings, specifications, Purchase Orders (PO) and approved Quality standards, as well as to ensure identification and traceability.

Source Inspection

Source Inspection is an examination of purchased product performed by the Customer/Buyer at the Supplier's or Supplier's sub-tier facility to verify product integrity and conformance to specified requirements, through product inspection, test, and/or documentation review.

Source Delegation

Source delegation is a process where external Suppliers or other Party Inspectors may be delegated the authority to act on behalf of the Buyer to inspect and accept product. The Buyer and the customer need to create criteria in a documented process under which, product acceptance can be delegated. A Buyer can delegate the source inspection authority to suppliers meeting the acceptance and performance criteria established by the Buyer

Supplier Performance Monitoring Program Reviews

Program review meetings should be conducted between buyer and supplier during the initial phases of the supplier or program development, and continued as required during the supplier maturing process. Best practice should be to conduct these meetings face- to-face.

Supplier Performance Metrics

The following metrics, but not limited to, should be used to monitor supplier performance and jointly reviewed by customers and suppliers:

- On-Time Delivery (OTD): The measurement baseline is the customer PO delivery terms and should be calculated monthly
- On-Quality Delivery (OQD): The OQD calculations should include receiving inspection rejections, in-process/assembly rejections, concessions, disclosures,

escapes, supplier corrective action requests (SCAR) etc.

Supplier Performance Improvement

The following activities should be initiated to improve supplier performance (eliminate non-conformances, reduce lead times, reduce costs, improve OTD, etc.):

- Root Cause Analysis and Corrective Action
- Lean events
- Six Sigma methodologies
- 9100, 9110, 9120 QMS certification.
- Special process certification
- Improvement plans (quality, delivery, design, etc.).
- Supplier mentoring

Supplier Continual Improvement

The use of a continual improvement philosophy and tools are fast becoming a buyer requirement. Leadership should drive the culture of engagement and empowerment leading to an environment of continual improvement. The goal is to improve process performance (quality, delivery, and cost) and eliminate waste in all areas of business and is a never ending process.

Supplier Surveillance

Supplier Surveillance covers the activities associated with the monitoring of a Supplier's performance through a risk based, assessment model. The frequency and level of audit depends on a number of factors including but not limited to audit results, escaping defects, supplier performance metrics and rejection rate.

To promote conformance throughout the supply chain, it is important that the Supplier has a robust sub-tier supplier control program. The Buyers' surveillance audit should include an assessment of this program with emphasis on the Buyer's specific requirements as defined in the flow down documents.

The following activities shall be considered as part of the supplier surveillance plan:

Product Audits

A Product Audit will provide a test of the Supplier's Quality Management System (QMS) for its compliance to the contracted requirements through the audit of a product to its conformance. The Product Audit is a systematic and documented process for obtaining and evaluating objective evidence in determining the extent to which product criteria are fulfilled

Manufacturing Process Audits

A Manufacturing Process Audit will also provide a test of the supplier's Quality Management System (QMS) for its compliance to the contracted requirements. The audit shall consider the following aspects of the manufacturing processes: product's planning, equipment, materials, inspections, documentation and all the sundry processes that are used to produce the contracted product

Key Characteristics

The features selected as Key Characteristics (KC) are monitored to determine the need for process capability improvements. KC's should be identified in the design definition or should be selected by the manufacturer based on history. Supplier should ensure compliance with the KC process requirements and customer should monitor the KC process during the surveillance activities.

QMS Audit

Following the initial QMS approval audit, the buyer should perform periodic supplier quality system audits or rely on Third Party Certification Body Audit results to ensure continual compliance of the supplier's QMS.

If an "other party" / Certification Body is used, communication between the Buyer, supplier and the Certification Body is important to ensure records are aligned and accurate

Risk Analysis

Supplier surveillance method and frequency should be based on the results of the risk analysis. Supplier should develop and implement mitigation plans for the risk items identified during risk assessment or surveillance audit. The Buyer should monitor status of mitigation plans during future supplier surveillance activities.

Rate Readiness Review

Rate Readiness reviews are conducted to assess the ability of the Supplier to support the Buyer's requirements for the contracted rate of production. Rate Readiness Reviews are carried out between the Buyer and the Supplier. The reviews also evaluate the Supplier's capability to react to a Buyer's significant change in the production rate. It ensures the Supplier has the means and plans in place to manage changes, support the new production and minimize the risk.

Corrective Action

An effective Root Cause and Corrective Action process is needed to prevent reoccurrences of product and system non-conformances related to events such as:

- Internal Escapes (before the article is approved for return to service and released to the customer)
- External Escapes (after the article has been approved for return to service and released to the customer)
- Audit Findings (Regulatory, Customer, Registrar, Process and Internal Audits)
- Customer Complaints
- Sub-contractor Nonconformities/Supplier Discrepancies

Risk and Safety

Darren Rusling

Introduction

For a number of years now, many organisations have recognised the intrinsic link within their business between the Quality and Safety (both Product and Occupational) functions, and whilst some have chosen to merge these functions, an equal number have retained the traditional split, largely driven by the nature of their products and the need to maintain separation, although they acknowledged that there is similarity in both approach and techniques.

In respect of risk, it is the aim of a robust Quality Assurance programme is to provide a framework to effectively manage the business, safety and quality processes and demonstrate compliance to customers, third parties and regulators, thus mitigating quality and safety issues, associated with people, material and processes.

Standards

DEF STAN 00-56
DEF STAN 05-61 Part 9
DEF STAN 02-207 (replacing SSCP 25)

Safety

Due to the operating environment of modern military and defence platforms, systems and equipment it is essential to identify and manage the associated risks and ensuring the safety of personnel, equipment and the environment.

A number of methods can be applied either collectively or individually in order to provide the necessary evidence of compliance and assurance against regulatory/contractual requirements such as Def Stan 00-56, Def Stan 05-61 Part 9, Def Stan 02-207, JSP 430 (sea), JSP 454 (land), the MAA Air publications, EN 9100 and ISO9001.

These include:

Safety Cases

The safety case is developed to demonstrate that the proposed activity fulfils all relevant legal requirements and minimises risk to as low as reasonably practicable (ALARP).

Safety Audits (Independent)

These audits ensure that an organisation has protected the user of a product from potential hazards, and they are extremely important in the design and development stages of a product, system or platform. They enable and promote:

- Assessment of alternative solutions
- Development of a hazard risk index
- Classification and identification of product related hazards i.e. improbable, remote, occasional, critical or catastrophic

Accident and Risk Analysis

A qualitative accident and risk assessment are supportive of the overall Safety Case, and aim to identify major hazards, the means of reducing the risks there-from and the mitigation of the consequences.

FMEA

Failure Mode and Effects Analysis (FMEA) is a systematic technique for failure analysis and involves inductive reasoning (forward logic) single point of failure analysis and is a core task in safety engineering. A FMEA is mainly a qualitative analysis and involves reviewing as many components, assemblies, and subsystems as possible to identify failure modes, and their causes and effects. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet.

Underpinning the safety programme, is the application of basic quality procedures and processes by SQEP personnel, and is paramount in certain areas, e.g. flying control systems (air) or first level systems (maritime), with the associated accurate recording and validation of these activities.

The number one objective of any organisation has to be to establish robust safety arrangements within the organisation and their Supply Chain. The organisation's senior leadership team has to be 100% committed to delivering this.

Safety within the organisation and the Supply Chain is about understanding and adhering to existing procedures and related technical standards and specifications as they are focussed on safeguarding both quality and safety.
The organisations culture should allow individuals to raise concerns without fear and demonstrate a questioning attitude by challenging assumptions, investigating anomalies and considering adverse consequences.

The organisation must clearly understand the interaction between Quality, Cost and Schedule. This interaction will vary, and is dependent upon the complexity system and equipment. If we fail to recognise this interaction in design, the pressure will be transferred to the construction, manufacturing or installation phase, and the focus will invariably shift to Cost and Schedule at the expense of Quality.

Risk

The debate involving both risk management and quality assurance programs has led many to argue that the differences between these two activities are negligible. The relationship between a risk management plan and a quality assurance programme overlap and compliment the purposes of both. Risk management could be thought of in terms of "risk" to the reliability of a product, and that "assuring product quality" using a robust internal / external audit process is the most efficient method of risk mitigation, then the relationship between the two is clear.

Management intent and governance structure in relation to Quality and Risk should be clearly defined. If this is absent then the organisation could be exposed to risk in terms of legal exposure and compliance with its stakeholders' requirements, and have no capability to identify and implement corrective and mitigation actions, and without a mechanism for evaluating opportunities and measuring improvement.
In organisations where Risk Management is an embedded process, it is usual to find the existence of a Risk Plan. The plan should contain a set of sequential activities related to managing the organisations risk activities. These activities should reference out to the relevant procedures, and be assigned an owner, and the appropriate evidence to support mitigation, along with any agreed review points. In conjunction with the Risk Plan there should be an associated Risk Register, this captures and identifies relevant risks and applies a method that evaluates both impact and probability. A regular review of the risk register should take place in order to ensure the topicality of the information within it and an evaluation of progress.

Identification, Traceability, Fraudulent & Counterfeit Materials

Paul Bayley

Introduction

Identification of documentation, materiel, components, equipment and operations used in the manufacture, procurement and maintenance of products is required in order to ensure that due to unique marking and the retention of records it is possible to create a traceable historical path throughout the complete life cycle of defence equipment.

Traceability is the ability to verify the history, location, or application of an item by means of documented recorded identification.

Records Management underpins the other topics in this chapter; these are all essential to ensure Configuration Management is maintained. For more information on Configuration Management see Chapter x.

The spread of fraudulent and counterfeit materiel has increased across all industries and the globalisation of the supply chain has resulted in an increased risk that suspect fraudulent and counterfeit materiel may enter the defence supply chain, seriously impacting on the performance of defence equipment in terms of safety and reliability, and financial losses and loss of reputation for suppliers.

The implementation of identification and traceability and the elimination of fraudulent and counterfeit materiel provides safety, affordability, and improves operational effectiveness of defence industry products.

Regulatory Requirements

DEF STAN 00-970
DEF STAN 05-130
RA 5221

A Defence Standard and DEFCON are being developed for fraudulent and counterfeit materiel to (a) define the requirements that the supplier will undertake to minimise the risk of suspect material entering their supply chain (b) deal with issues when suspect materiel is identified post-delivery.

Standards and Guides

BS EN ISO 9001 and BS EN 9100C Section 7.5.3 - Identification and traceability and 4.2.4 – Control of Records.

BS EN 9120 Quality Management Systems -

Requirements for Aviation, Space and Defence Distributors.

ISO 30301 - Information and Documentation Management Systems for Records – Requirements

ISO 15489 - Information and Documentation Records Management

PD 5454 - Guide for the storage and exhibition of archival materials

ISO 27001 - Information Security Management

ISO 12931- Performance criteria for authentication solutions used to combat counterfeiting of material goods.

BS 10008 - Evidential Weight and Legal Admissibility of Electronic Information.

SAE AS5553 - Counterfeit Parts; Avoidance, Detection, Mitigation and Disposition

SAE AS6081 - Counterfeit Electronic Parts; Avoidance Protocol, Distributors

SAE AS6174 – Counterfeit Materiel; Assuring Acquisition of Authentic and Conforming Materiel.

SAE AS6178 - Fraudulent/Counterfeit Electronic Parts; Tool for Risk Assessment of Distributors

Identification

Identification is normally performed by assigning a unique part number, serial number or batch number for material.

Typical methods of identification are:

- Labels or tags
- Nameplates
- Permanent marker pens
- Bar Code
- Etching
- Dot Peening
- Radio frequency identification tags
- Ink jet
- Laser jet

However, the requirement for more secure methods of identification in order to prevent fraudulent and counterfeit parts is driving more advanced technological solutions, such as:

- Holograms
- Materiel biometrics (DNA)
- Nano codes
- Forensic Markers
- Security coatings

Parts that are too small or otherwise impractical to be marked may, as an alternative, be marked showing the required information on a tag or label attached to a container or bag.

When identifying parts, consideration must be given to the type of component and operating environment, for instance:

- No method of marking shall be used in such a manner or in such a place that it would reduce the strength or the life or affect the performance of the part.
- The method of marking adopted shall not increase the risk of corrosion. E.g. where a plate made from a different material to the component is affixed to it for marking purposes, precautions shall be taken so that no risk of corrosion is introduced.
- Details of identification markings used, the methods by which they are applied and their location shall be stated on the drawing of the part.
- Parts shall be marked so that they can be easily identified for maintenance purposes when assembled.

Typical component or equipment assembly identification markings should include:

- Part number
- Serial number, where applicable
- Batch number, where applicable
- Series, modification or strike off number
- Identification of life limited or critical parts

Traceability

Traceability through the accurate maintenance and retention of records provides the ability to identify and track a product or a component through its provenance to its point of origin. The point of origin may be a particular lot or batch, production line or time frame or supplier. This then enables operational

and economic benefits whereby component failure or fault occurrences can be traced and confined to identifiable material, components and equipment.
Traceability is critical for many reasons, for instance;

- Supply chain provenance
- Conformance to requirements.
- Monitoring of critical safety items
- Tracking of life limited items
- Monitoring maintenance requirements
- Identification of condition (e.g. new, repaired, altered or rebuilt)
- Product recall
- Failure rate analysis
- Interchangeable and replaceable parts identification
- Tracking critical to mission parts
- Identifying tooling used in manufacture
- Software standards
- Modification and upgrade status
- Measurement and test equipment calibration history
- Inspection stages, identification of which inspector and techniques used.
- Manufacturing stages, identification of which operator and techniques used.
- For an assembly, the ability to trace its components to the assembly and then to the next higher level assembly.
- The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap).
- Whether the item has ever been identified as scrap
- Whether the item has ever been identified for disposal and destruction.
- Return to service tags
- Certificates of conformity
- Airworthiness directive status
- Tracking operating hours or cycles

Traceability requirements should be maintained throughout the product life. Whilst software applications are typically used for this, the management of physical records is also important.

General Records Management

Defence Industry organisations need to establish effective records management arrangements as an integral part of their quality management systems. Records form part of the demonstration that equipment meets the design intent and safety requirements and therefore the identification, generation, completion and retention of records associated with the supply of products should form part of the contractual arrangements between purchaser and supplier at all levels of the supply chain.

Such arrangements typically have the following key features:

- Infrastructure, such as appropriate storage facilities and equipment.
- A clear definition of record keeping responsibilities and requirements. This is normally done through the production and implementation of one or more procedures.
- The clear specification of the records to be kept, their retention period and form. This is normally done through the production of a records retention schedule.
- Defined controls to ensure that the integrity and authenticity of records is maintained during organisational and technology changes. These controls are normally defined in procedures and project plans.
- Appropriate security arrangements to prevent inappropriate access and loss. This is particularly important in relation to sensitive information.
- As-constructed records should provide a fully referenced account of the work actually constructed and

should be produced in a timely manner as the information becomes available throughout the contract.

Physical Records Management

Physical records can take a number of forms, common examples are; paper documents, microfilms, photographs and material samples. Appropriate storage facilities and systems need to be established that ensure that records are:

- Categorised according to the retention schedule
- Registered upon receipt
- Readily retrievable
- Indexed and placed in designated locations appropriate to their use
- Stored in a controlled and secure environment
- Subject to periodic review
- Transferred to a secure archive at the appropriate time if retention times are prolonged
- Destroyed in a secure manner when no longer required.

Storage facilities for physical records should be maintained to prevent damage from causes such as fire, water, air, rodents, insects, earthquakes and unauthorised access. Consideration should be given to appropriate contingency arrangements including making copies of important records.

Physical records can normally be stored under conditions of ambient temperature and humidity for periods up to five years. Long retention times may require a special facility such as an archive that meets the temperature and humidity conditions specified in PD 5454. There are a number of specialist suppliers who can provide records archiving services.

Electronic Records Management

Records may exist in electronic form throughout their lifecycle or originate in physical form and be converted to electronic format. Electronic formats can offer some significant advantages but there are also challenges in maintaining the security and integrity of records.

Electronic records need to be subject to carefully defined procedural controls. This can be facilitated by the use of electronic document management system. Information security risks need to be carefully considered and this can be aided by use of ISO 27001.

Particular care is needed to ensure that the hardware and software that is used does not become obsolete. Periodic technology reviews are, therefore, very important particularly where records have retention times of 30 years or more. Risks can be minimised by selection of widely used software, file formats and hardware. Special care is needed when software or hardware is upgraded to ensure that records do not become corrupted or lost.

Special care to ensure that the authenticity of records is maintained during times of change. Changes include the conversion of physical records to electronic format and technology upgrades. BS 10008 defines the controls to be applied when scanning paper documents to help ensure that authenticity is preserved.

Fraudulent and Counterfeit Material.

For this topic, the term 'materiel' is used to define all material, components, parts, equipment, platforms and documentation.

There are many definitions for suspect, fraudulent and counterfeit materiel. The MOD uses the following:

Suspect Materiel: Materiel in which there is an indication by visual inspection, testing or other information that it may have been misrepresented by the supplier or manufacturer and may meet the definition of a fraudulent or counterfeit materiel.

Fraudulent Materiel: Any suspect materiel misrepresented to the customer as meeting the customer's requirements.

Counterfeit Materiel: Fraudulent materiel that has been confirmed to be a copy, imitation or substitute that has been represented, identified or marked as genuine, and / or altered by a source without legal right with intent to mislead, deceive of defraud

The provision of provenance is a key element in providing assurance that materiel is manufactured and supplied in accordance with the original design organisations and the delivery team and/or design authority's intent, as expressed by the equipment drawings and specifications.

The fitment of parts other than those authorised, presents the following risks to the defence industry:

- Schedule delays
- Legal – Criminal & Civil Actions
- Reduced Performance
- Poor Reliability
- Product Failure
- Damaged Reputation
- Decline In Mission Readiness
- Threat to Systems Security
- Risk to life
- Environmental – toxic waste

All materiel may be subject to fraudulent and counterfeit activities. However the most common are electronic, electrical, electro-mechanical parts for example but not limited to; Integrated Circuits, transistors etc. In particular, hard to find and obsolete parts have proved to be targets for this fraudulent activity.

Within the UK Defence industry the Counterfeit Awareness Working Group (CAWG) has been established; this group consists of MOD and Industry representatives and has the following intentions:

Aim:

- Provide direction, through policy & guidance on Preventing, Detecting & Responding to the threat of fraudulent / counterfeit product supply within defence acquisition.

Objectives:

- Raise awareness
- Determine & share good practice
- Propose continual improvement to current practice

Outputs:

- Policy & guidance
- Provide Support to Standards Committees
- Communication with UK Industry & other Organisations

Supply of misrepresented material introduces a potential of non-conformance as the detection can be hard, due to the complexities of the supply chain and the ever increasing replication of materiel by illegal organisations.

Identification of suspect material is as much about change of culture as it is change of process. Understanding/awareness of the issue and the vigilance of staff is the key to detecting and removing unapproved parts from the supply chain.

There are some key identifiers that may indicate suspect parts:

In the supply chain:

- Results of Supplier Evaluations.
- Quoted or advertised price significantly lower than that quoted by other distributors/suppliers
- Delivery schedule significantly shorter than that of others when stock is exhausted
- Sales quotes or discussions implying an unlimited supply

Acceptance / Inspection:

- Packaging identifies the supplier and is free from alteration or damage
- Part and delivery receipt are consistent and reflect purchase order information for part number, serial number and part history (if applicable)
- Part identification has not been tampered with (serial number over-stamps, label or part/serial numbers missing, vibro-etch or serial numbers located at other than normal locations).
- Visual inspection of part and documents to provide positive identification.
- Evaluate any visual irregularities (altered or unusual surface, absence of required plating, evidence of prior use on new part, scratches, new paint over old, attempted exterior repair, pitting or corrosion).
- Random Samples of Standard Hardware

Operational:

- Parts do not perform to the standard required.
- High failure rate.
- Failure of a particular batch from a supplier.
- Limited life.
- Unreliable.

An earlier topic in this Chapter included the need to provide total traceability – however on its own traceability is not authentication, as records can also be counterfeit. Effective traceability also needs to deliver positive authentication in the supply chain. Secure acquisition of this information needs to be available to inspection teams, customs, distributors and the end-user. Authentication needs to provide absolute proof of authenticity in court cases and situations where goods are seized as suspected counterfeits.

Anti-counterfeiting devices and identification markings in isolation cannot stop counterfeiting, but can aid in the quick and unambiguous identification of fake products (in a correctly designed system).

Configuration Management

Gerry Fice

Introduction

The MOD acquires and the Defence Industry produces large, complex products which are subject to alterations and updates throughout their project life-cycle from requirement setting through design, manufacture, operation and decommissioning. This life-cycle may last decades and it is essential that the product or system performance, physical and functional attributes are known and can be compared with the design and operational requirements at any time.

Configuration Management (CM) is a management activity that enables the documented status of the product or system to be known at any time. Changes will occur and it is essential that they are controlled; the application of through life CM can do this ensuring a disciplined approach for product development and maintain design integrity through life.

The identification of Configuration Items (CIs) within a product breakdown structure and associated product configuration information can provide the framework for structured arguments that underpin the product / system safety case.

Configuration Management supports the Requirements Management role for control, monitoring and administration of requirements; by tracking the implementation of requirements. The evaluation of CI Configuration Baseline information against requirements documentation and use of Functional and Physical Configuration Audits can help to assure that requirements are met.

The lack of Baseline configuration information can lead to the need for costly corrective action to establish the required information for the continued use, or further development, of a particular product or system. The investment for CM is returned by reductions associated with the costs for intervention, corrective action, risk and possible liability.

Configuration Management Responsibility

A Configuration Change (Dispositioning) Authority must be identified at all times throughout the product lifecycle to make decisions on product configuration as defined in the requirements for design, realisation, verification, operation and support.

The Configuration Change Authority can also be known as the Configuration Control Board (CCB) and should include all interested stakeholders.

Configuration Management Planning

Configuration Management (CM) planning should identify the processes, procedures, responsibilities and authorities for the effective application of the CM principles within the context of the contractual and project lifecycle requirements.

The programme complexity and nature must be considered by CM planning to enable the effective and efficient application of the following CM principles:

- Configuration identification and documentation
- Configuration change management
- Configuration status accounting
- Configuration audit

Configuration Identification and Documentation

The selection of the Configuration Items (CIs) is fundamental to the efficient and effective management of product development and system design integrity. CIs are those whose status will be recorded, managed and tracked through life. Typical selection criteria should consider:

- Legal and regulatory requirements
- Safety
- Interoperability with other equipment, including NATO nations for joint operations
- Maintainability
- Reliability

CIs are usually established at the end of the Assessment stage, from Supplier recommendations as a result of system engineering analysis of the initial Systems Requirements Document. Further CIs may be identified during product development up to the time that the product design Configuration Baseline is established at Critical Design Review

CIs are usually the deliverable and separately installable units of the system. Computer software items are normally recognised as CIs because of the control of systems functionality.

The selection of configuration items and their interrelationships should describe the product structure, including a list of assemblies, sub-assemblies and items that require configuration management. The diagram in Figure 1 is an example of a top-down product structure, highlighting the relationships of the assemblies, sub-assemblies and components that make up the system.

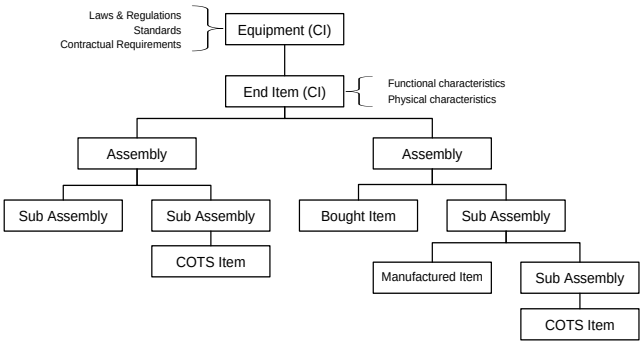


Figure 1: Example of a product structure

Within each level of the product structure reference should be made to product configuration information (e.g. – design data, operational information, maintenance procedures, storage requirements and training requirements).

CIs are defined within technical documentation that should also detail the interfaces between other product CIs. The release of approved configuration information establishes CI baselines.

CIs are usually identified by part numbers and naming convention. The Supplier – Designer will usually use its own numbering system and maintain traceability between the Supplier's identification numbering and the NATO Stock Number (NSN).

Where CIs are designated for the MOD Supply System, a NSN must be established for each item of supply. The contractual requirement for NSN support is invoked by DEFCON 117 - Supply of Documentation for NATO Codification. When a change to a CI affects the fit, form or function, it will affect the Configuration Baseline. The revised CI must be identified with a new NSN to differentiate this new CI from the earlier CI version.

Commercial off-the-shelf items are not to be considered as CIs unless these COTS

items are to be the subject of re-development under contract.

Configuration Baselines

Configuration Baselines are established where it is necessary to establish a reference for further activities / future change. A Configuration Baseline consists of the approved configuration information to satisfy the requirements for design, verification, operation and support.

Configuration Baselines provide stakeholders a mechanism for common understanding and an assurance that the product or system meets the contractual requirements. The level of detail for Configuration Baseline depends upon the degree of control required.

Traditional CM practices can recognise the following product documentation baselines:

- Functional Baseline – configuration documentation formally designated during the Assessment Phase.
- Design (Development or Allocated) Baseline - configuration documentation formally designated at the end of the Assessment phase and before Demonstration. When Configuration Items are formally allocated to the design.
- Product Baseline – configuration documentation formally designated at the beginning of the Production / Manufacture. The Product Baseline + agreed Concessions = Delivered Product / In-Service Baseline.

Configuration Change Management

Change Control - General

Configuration change management is applied through the process of establishing baseline reference points from which to control change. A Baseline reference point consists of a documented product definition baseline, which can include but not limited to; design information, software version documentation and associated validation and operational information
A change to a Baseline can be initiated by the need to implement regulatory, safety, quality, or performance improvements including supportability arrangements or a need to meet new requirements for improved capability.

The purposes of configuration change management are to ensure:

- Control of Configuration Baselines;
- Consistency between product and product configuration information;
- Communication of change information;
- Change decisions understand the impact of change;
- Changes are necessary or offer significant benefit;
- Stakeholder interests are considered;
- Product interfaces are controlled;
- Concessions - are recorded and managed;
- Products are supportable after change.

Change Control - Responsibilities through life

A supplier – Design Organisation will be required, under the terms of the development contract, to ensure that configuration change management is applied to product / system development up to the delivery of the product baseline for In-Service use.

Once the product design drawings are completed under contract and sealed

(design freeze) the supplier relinquishes Configuration Change Authority control, and therefore can no longer make changes unilaterally. At this point, the responsibility for configuration change decisions is transferred to the Authority's Delivery Team Leader responsible for In-Service design integrity.

The Delivery Team Leader is supported by a Configuration Control Board (CCB), subsidiary committee(s) and personnel with configuration management responsibilities.

The following is a sample of reasons for change:

- Improvements to safety / risk elimination.
- Changes to legislation.
- Improvements to product performance.
- Provide new capability requirements.
- Obsolescence of products or equipment.
- Availability of spares.
- Insertion of new technology.
- Correct defects (both preventive and corrective).
- Improve product support.

Change Control - Evaluation
Evaluations of proposed changes must be documented and consider the risk / potential impact. The extent of an evaluation will depend upon the product complexity and change category.

The Prime Supplier is responsible under contract, for configuration change during initial product development and for the integrity of the deliverable Product Baseline. Following delivery of the product baseline for In-Service use, the responsibility for configuration change control is transferred to the Authority.

In-Service configuration change approval / rejection is provided by a meeting of the Configuration Change Authority - CCB or subsidiary committee attended by the Industry Design Organisation and relevant sub-suppliers. The Authority's representatives can include Safety; ILS, Quality Management and the Front Line Command (customer).

Where configuration change is agreed then the change control process should consider:

- When the change can be incorporated – (Effectivity Date)
- How the change will be incorporated.
- Who will incorporate the change (Reference ISO 10007)

Change Control - Concessions
Concessions are contractual non-conformities and do not affect the product or system configuration baseline. A concession is generally limited to the delivery of the product that has nonconforming characteristics within specified limits for an agreed time or quantity of that product. (Reference ISO 10007)

Concessions form part of the Status Accounting records for a particular baseline, the management of Concessions should contractually invoked in accordance with the Defence Standard 05-61, Part 1 – Concessions.

Configuration Status Accounting
Configuration Status Accounting (CSA) is the activity that results in records and reports that relate to product and its product configuration information. Effective configuration management relies upon the availability of the up-to date products configuration information and the communication of change(s) to

product configuration information to the relevant stakeholders in a timely manner.

The depth and range of the information captured in the CSA system should be based the nature of the product, the environment in which the product will be operated, the anticipated volume and complexity of change activity and the information requirements of the project.

Configuration Audit
Configuration Audit is a formal examination to verify that the requirements of the product configuration information are realised by the product / system Configuration Items (CIs). There are two types of audit:

- Functional Configuration Audit (FCA)
- Physical Configuration Audit (PCA)

Benefits of Configuration audit include:

- Validation for the integrity of the configuration documentation.
- Verification of consistency between a product and its configuration documentation.
- Determination that an adequate process is in place to provide continuing control of the configuration

The configuration audit schedule should be compatible with the availability information e.g. engineering data, specifications, manuals, hardware / software product design information and reports.

Functional Configuration Audit
A Functional Configuration audit (FCA) consists of the formal examination of test data and quality assurance records for a CI, prior to acceptance of the Product Baseline, to verify that the CI has achieved the performance and functional characteristics specified in the associated requirements configuration documentation.

An FCA should be conducted for each CI, or group of CIs, for which a separate development/ requirement specification has been baselined.

Physical Configuration Audit
A Physical Configuration Audit (PCA) is the formal examination of the as-built configuration of a CI against its design documentation to ensure that the CI conforms to its specified physical requirements.

During the PCA any differences between the physical configurations of the selected production CI and the development CIs used for the FCA should be evaluated to assure no degradation of the functional characteristics of the selected CI.

Abbreviations

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FCA	Functional Configuration Audit
PCA	Physical Configuration Audit
CI	Configuration Item
CSA	Configuration Status Account
ISO	International Standards Organisation
CCB	Configuration Control Board
ILS	Integrated Logistic Support
CM	Configuration Management
COTS	Commercial Off The Shelf
NSN	NATO Stock Number
MOD	Ministry of Defence
NATO	North Atlantic Treaty Organisation
BS	British Standard
DEF STAN	Defence Standard
SQEP	Suitably Qualified and Experienced Personnel
ALARP	As Low As Reasonably Practicable
FMEA	Faliure Mode and Effect Analysis
QMS	Quality Management System
KC	Key Characterisitics
OTD	On Time Delivery
OQD	On Quality Delivery
PO	Purchase Orders
FAI	First Article Inspection
APQP	Advanced Product Quality Planning
KM	Knowledge Management
DQAFF	Defence Quality Assurance Field Force
AQAP	Allied Quality Assurance Publications
MAOS	Maintenance Approved Organisation Scheme