

# Common Findings – Common Challenges

## Presentation to FAA Global Manufacturing Meeting

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# Subjects

- Review of Production Findings
- Risk Based Approach to Supplier Oversight
- Shared Oversight with other Authorities

# Findings Reviews

CAA has undertaken periodic analysis of Part 21 Production findings since 2007 – why ?

- Feedback to Surveyors in Continuation Training
- Feedback to Industry Bodies (UK ADS/EAQG/IAQG)
- Feedback to the Third Party ISO9000/EN9100 sector including presentations to their assessment staff

# Background



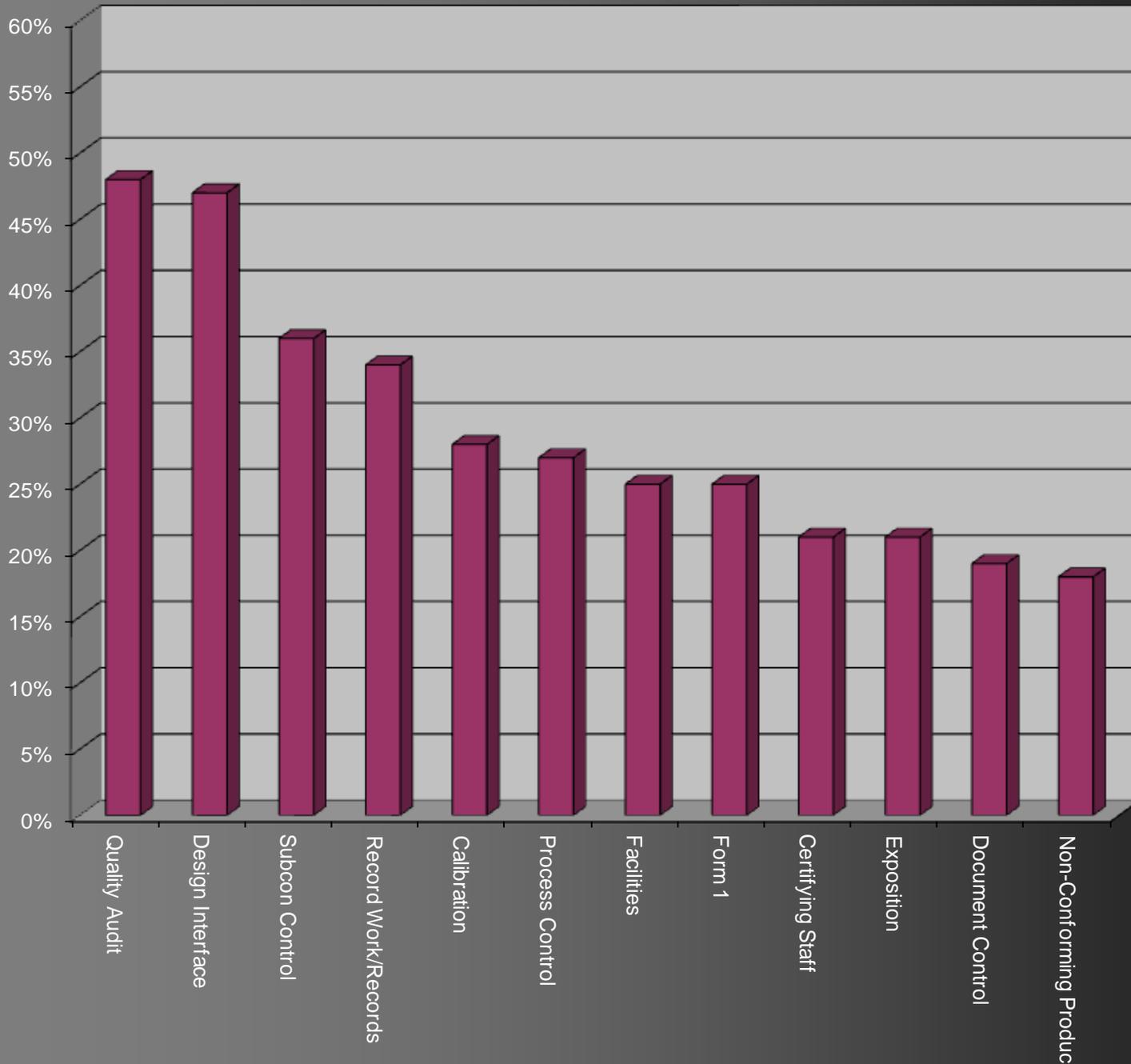
UK Part 21 POA population stable at 170-180 POAs

Each slide represents over 400 visits - current requirement is to audit annually as a minimum and review all Part 21 regulation elements within 24 months.

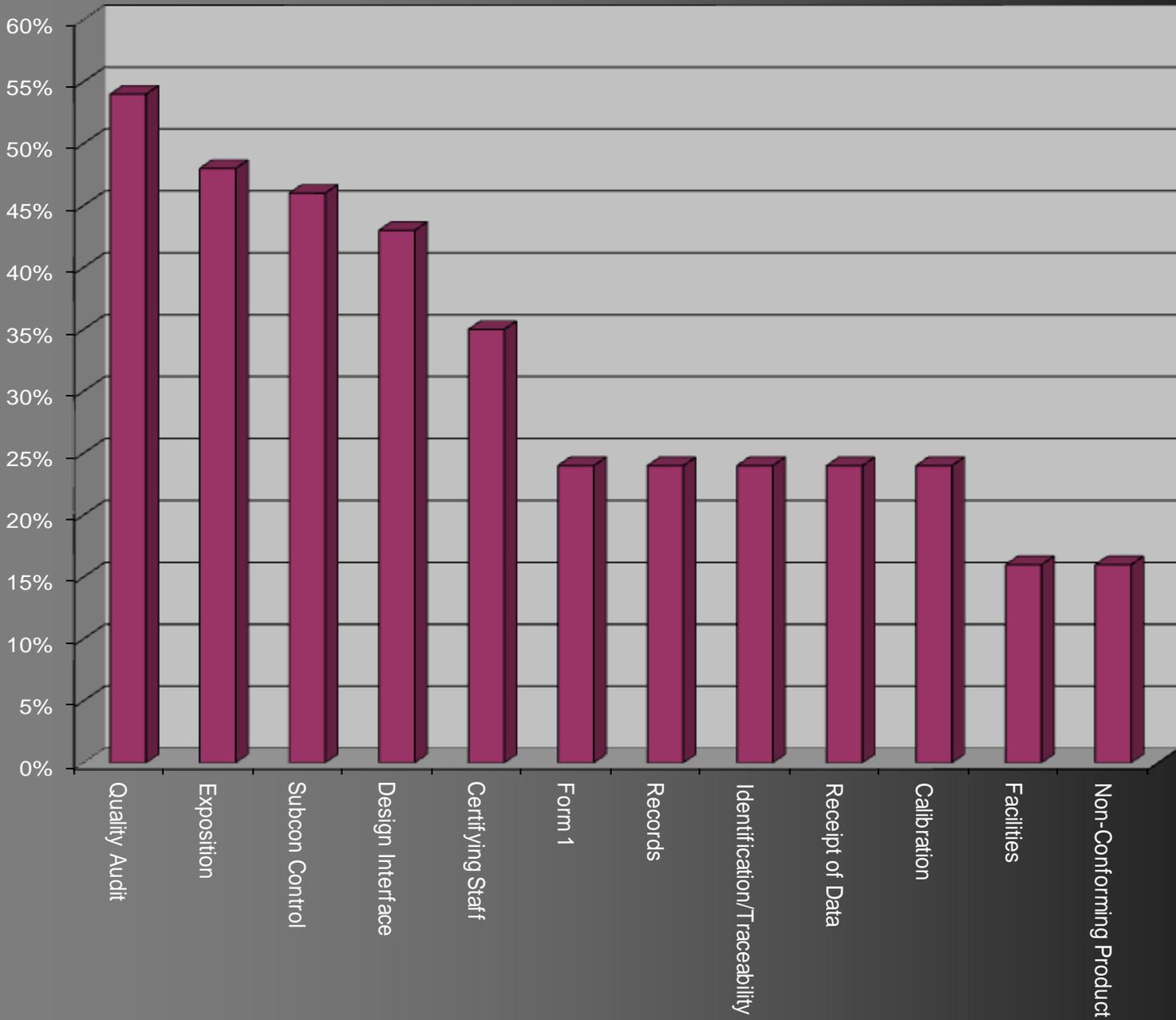
UK POAs generally seek to operate in accordance with the requirements and direct safety-significant findings are rare – focus is on identifying common themes and trends to advise industry and seek improvement.

2007

■ Issues Reports



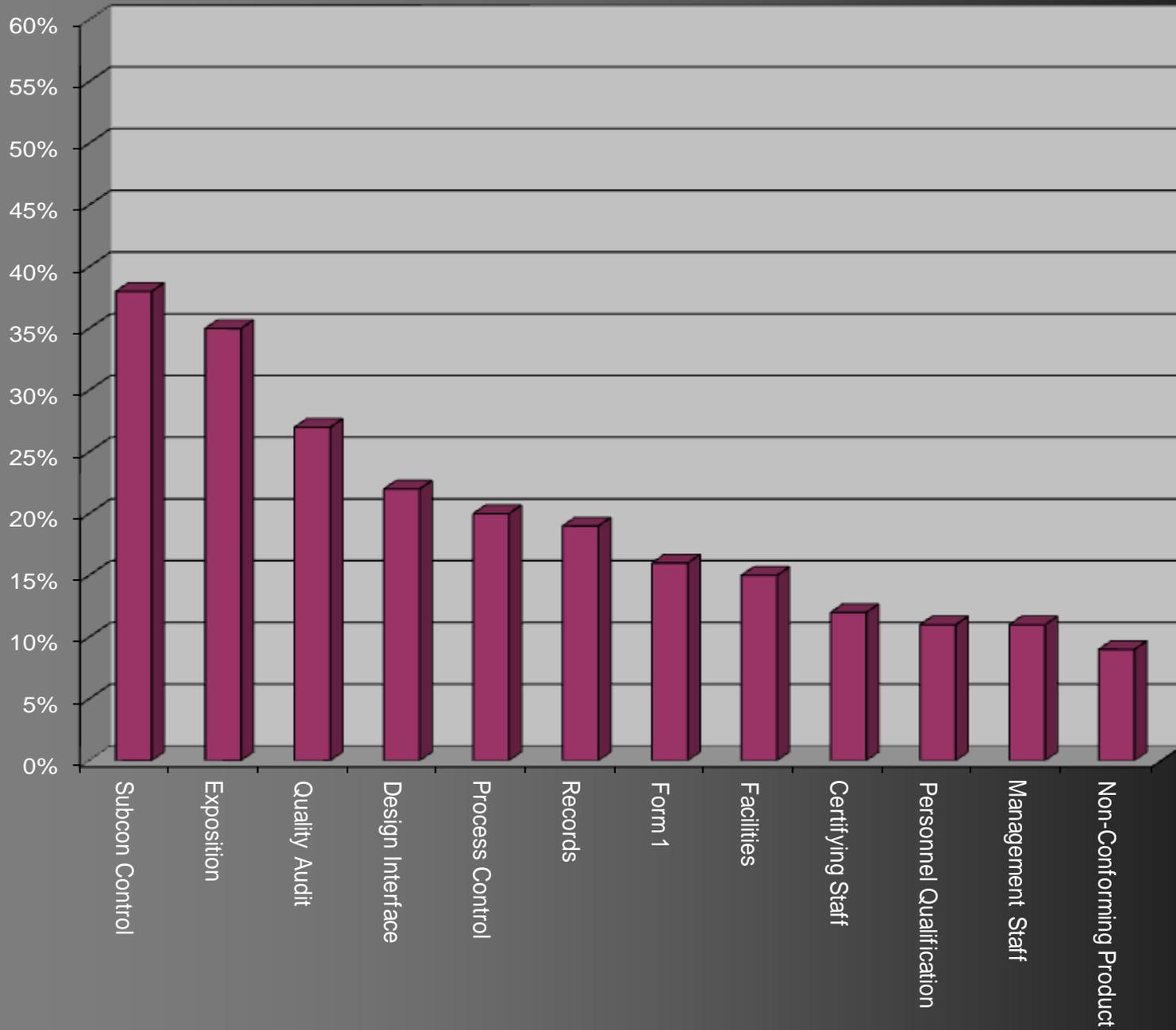
2009



■ Issues Reports

2011

■ Issues Reports



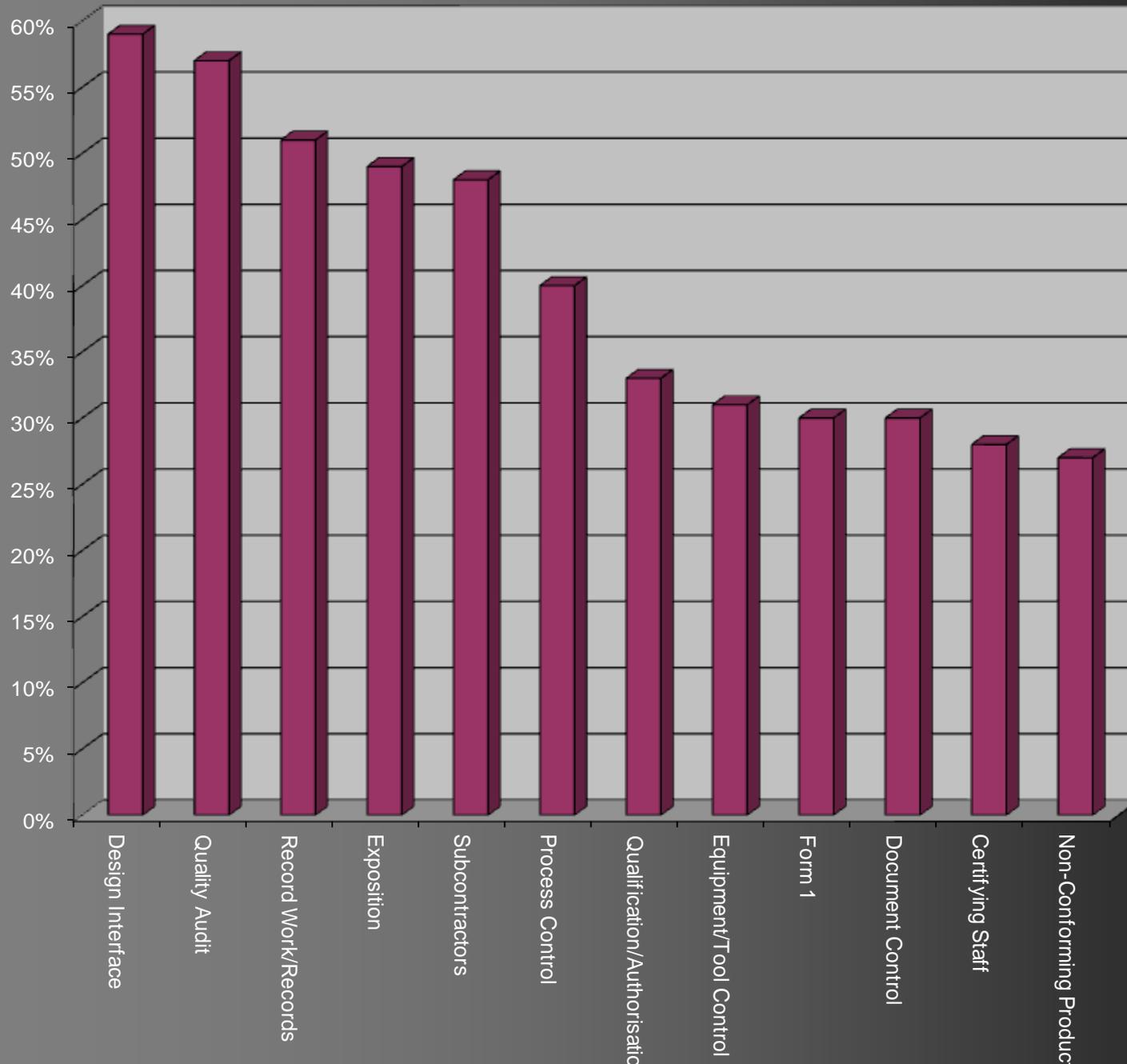
# Supplier Control

Consistently in the top three elements.

Contributory cause to several high-profile escapes.

Publication of additional CAA Guidance in 2012

More on this later ...



2013/14

■ Issues Reports

# Design Interface

- Evidence of controlled data from the design holder to support production release.
- Flow-down of direct delivery authorisation.
- Handling of concessions and non-compliances.
- Control of changes to production methods, processes and drawings.

# Quality Audit

- No evidence of consideration of the Regulatory Requirement (audit schedule ISO9000 based).
- Not carried out to schedule.
- Findings overdue with no evidence of feedback to Accountable Manager.
- Closure action only addressing specific failing, lack of root cause analysis leading to repeat findings.

# Feedback/Comments

- *“This is ‘low hanging fruit’ – easy to find.”*
- *“Part 21 is your requirement, we have to base our audits on ISO 9000 to satisfy our third parties and other customers.”*
- Why do we feel these elements are so important ?
- Let's take an example:-

# Example

- During oversight a CAA Surveyor samples an internal audit report on Process Control.
- The internal audit found that the specific corrosion protection on the drawing was no longer used.
- The product was no longer available due to changes in environmental regulations.
- An alternative treatment had been identified and was called up on the Bill of Materials, Process Layouts and the Production Travellers.

# Example

- The internal auditor reviewed the change documentation in accordance with the Company Procedures.
- It had been approved by the Manufacturing Process/Production Engineer who was authorised to do so in the company Quality Manual and the company Authorisation Matrix.
- The internal auditor recorded the sample as being in compliance on their ISO9000 based audit checklist.

# Questions

- Should the Internal Auditor have recorded compliance ?
- Can the CAA Surveyor record compliance ?
- Should the CAA Surveyor raise a regulatory finding ?

# Answer

- It depends ...
- Both the ISO 9000 Auditor (and the Surveyor) need one more level of information.

# EASA Part 21

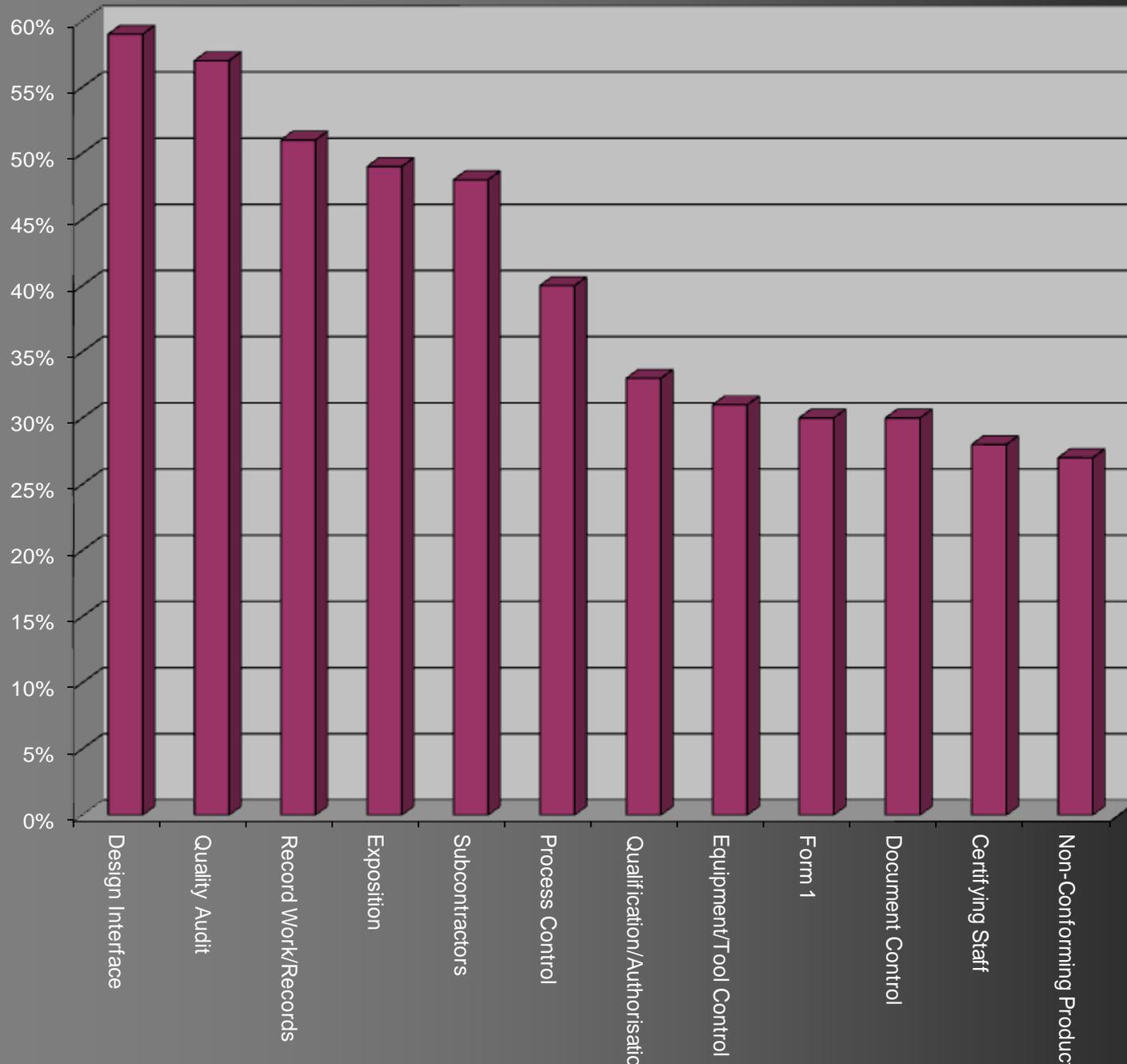
- The Design/Production Interface procedures should specify the extent to which the Production Organisation can develop and amend its own manufacturing data.
- Changes that affect any element of the airworthiness data package have to be approved by the Design Holder either directly or via delegated authority within the documented Design/Production arrangement.
- *Where is no evidence of this, then we have to raise a regulatory finding.*

# Quality Audit

- Audit schedules based on ISO9000 will not address:-
  - Co-ordination with Design
  - Incorporation of Airworthiness Data in Production and Inspection Data
  - Clear criteria for which items require traceability
  - Release Certification
  - Personnel training and qualification – certifying staff
  - Mandatory Occurrence Reporting
  - Work outside the approved Production Facility
  - Production Flight Test (where applicable)
  - Product Audits

# Quality Audit

- AS/EN 9100 audits would cover some of these elements, but both ISO9000 and AS/EN 9100 state that compliance with applicable regulatory requirements has to be addressed by the QMS.
- *Third Parties should not be accepting Internal Audit schedules from Production Organisations that do not show consideration of the regulatory requirements.*
- Procedure based audits alone are not sufficient, need to check that the procedure meets the requirements.



2013/14

■ Issues Reports

# Recording of Work

- Operations unsigned.
- Process conformity results not recorded.
- FAIRs not available, incomplete or showing non-compliances to drawing data that have not been addressed.
- Archiving ineffective to protect or recall records.

# Exposition Document

- Not maintained up to date.
- External Occurrence reporting procedures not included or out of date.
- No detail Scope of Work relevant to the Approval
- Design/Production Interface Agreement not in place to address all Parts identified in Scope of Approval.

# Process Control

- Lack of records of facility checks being carried out at intervals required within the process specifications. (daily checks, bath analysis etc).
- Routings and Work Instructions incorrect or not being followed.
- Substitute methods, equipment, process parameters and consumables used without design authority.

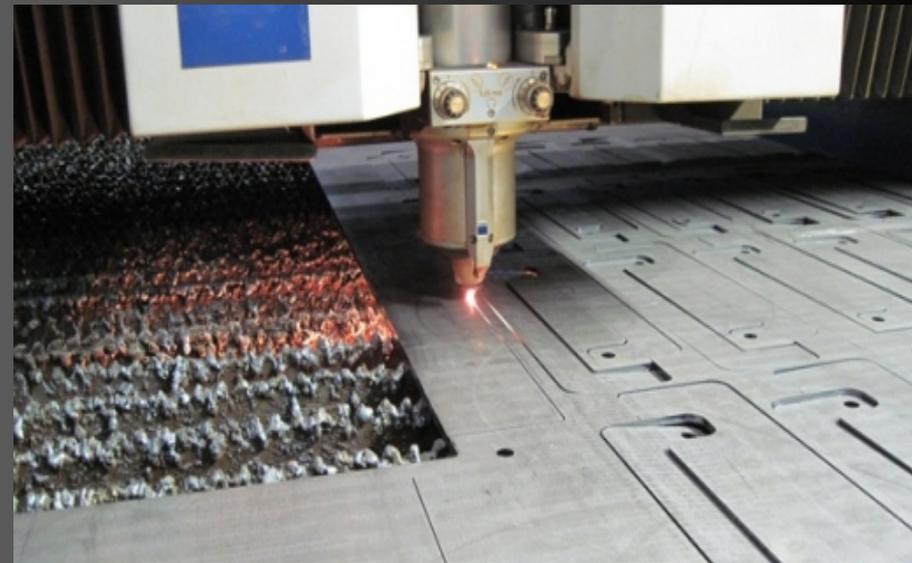
# New/Different Manufacturing Methods

- Production Engineering generally determine the manufacturing method.
- Does a change to the normal/traditional method introduce unforeseen problems ?
- Can the Production Engineering function anticipate potential problems including in-service issues that may result ?
- Liaison with Design ...

# New/Different Manufacturing Methods



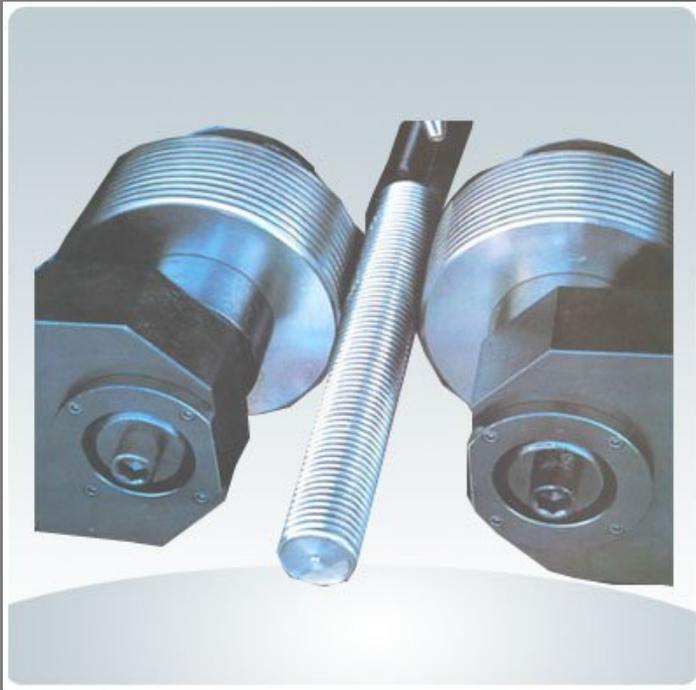
- Example 1



# New/Different Manufacturing Methods

- Laser Cutting
- Heat affected zone that would not be present when cold punching.
- What effect (in any) will this have on the service life of the component ?
- Still in compliance with the design data ?

# New/Different Manufacturing Methods



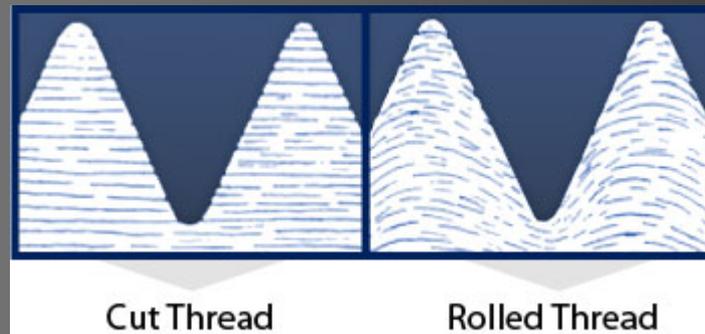
- Example 2



# New/Different Manufacturing Methods

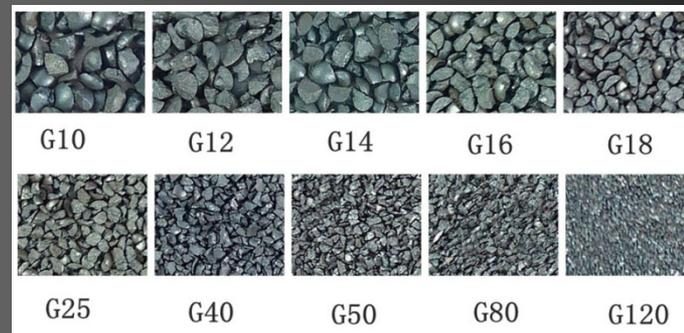
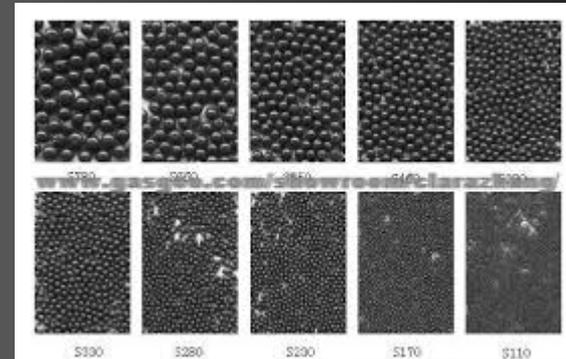
Result of single point cutting:-

- Reduction in the mechanical strength of the finished screw thread.



- Still in compliance with the design data?

# New/Different Manufacturing Methods

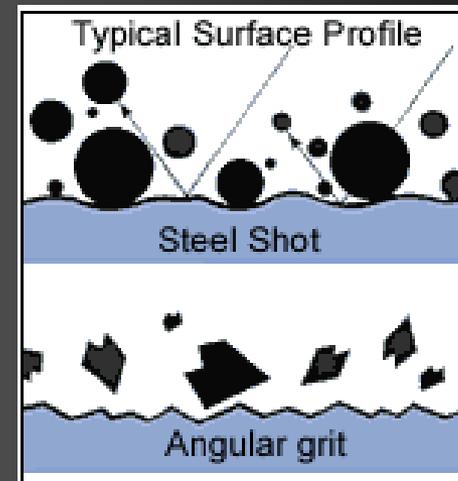


- Example 3

# New/Different Manufacturing Methods

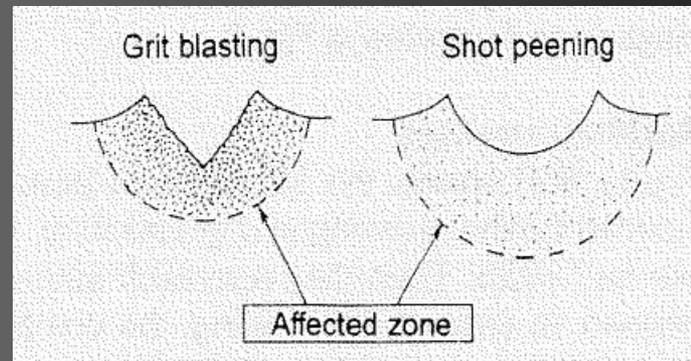
Result of using grit (not shot)

- Visually grit/shot blasting is same process using much the same equipment.
- Shot is used to reduce the propagation of micro-cracks from a surface by plastically deforming the material surface.



# New/Different Manufacturing Methods

- Grit Blasting
- Generally used as a cleaning process to remove scale from the material surface.
- Does not impart the same properties as shot blasting.
- Still in compliance with the design data ?



# New/Different Manufacturing Methods

- Importance of liaison/confirmation with Design Holder.
- Need for formal concurrence.
- *What about subcontractors ... ?*

# Common Factors

- All of these aspects only become apparent when audits take place at the product level.
- Progressive roll-back of authority from independent inspectors to authorised operator personnel.
- Must be accompanied by robust and resourced product auditing that the facilities and processes meet the design data and that if they do not, that there is authority to stop production until corrected.

# Common Factors

- The majority of recent production quality escapes requiring safety action have involved non-conformances that were already known within the production organisation via concessions, incomplete FAIRs etc.
- Repeated concessions against design data can create a culture of acceptance of “low level” non-conformance.
- Compliance ►►►► Performance

# What must we do ...

- Work together with industry and our regulatory partners to focus our audits on area of maximum risk and reduce duplication.
- More effective use of finite Industry/Regulator oversight resource maximises opportunity to detect escapes before they affect the travelling public.
- Once found, take every available lesson from them to minimise the chance of recurrence and continue to improve.

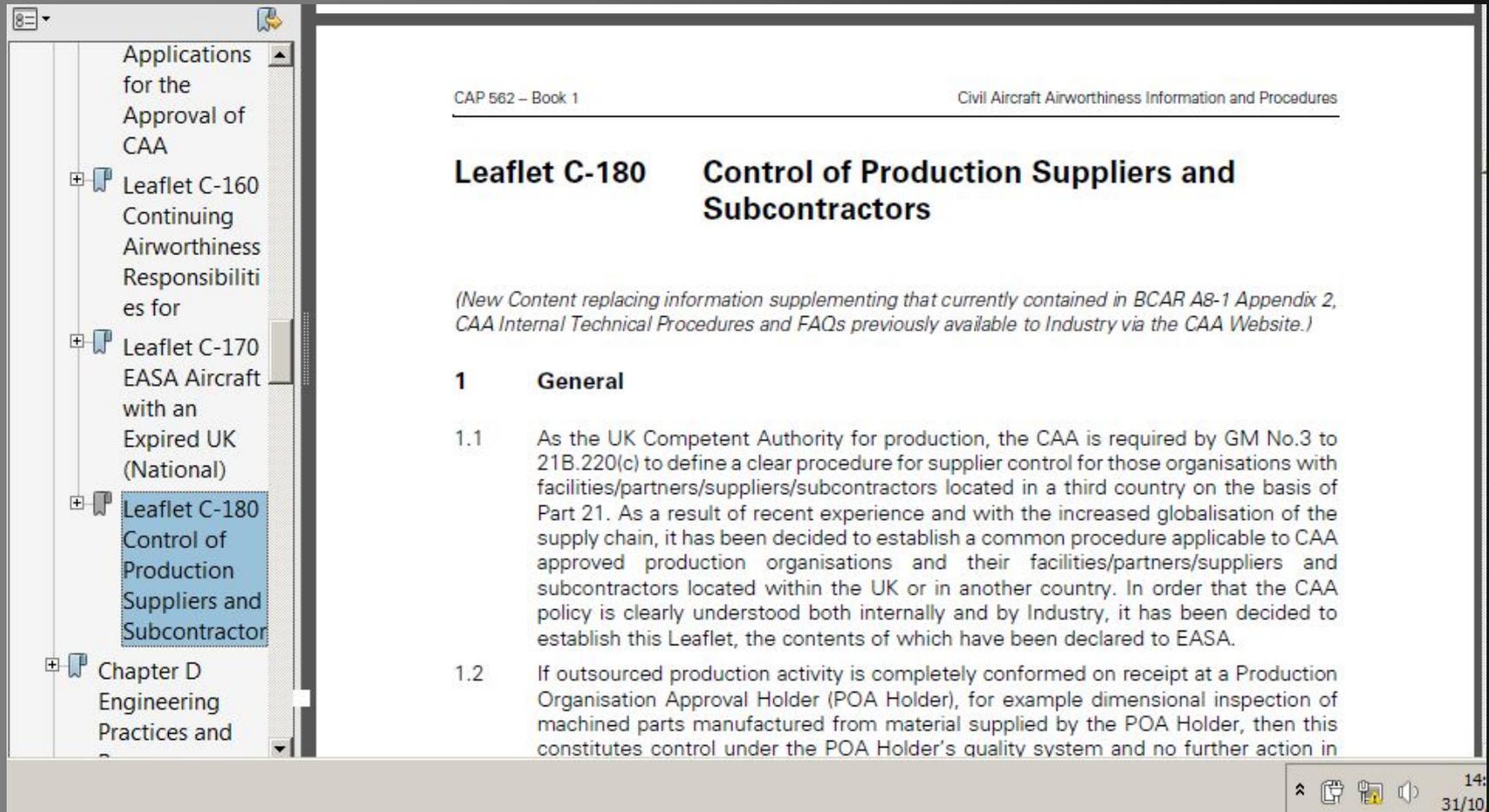
# Subjects

- Review of Production Findings
- Risk Based Approach to Supplier Oversight
- Shared Oversight with other Authorities

# Supplier Control

- Oversight of Suppliers/Subcontractors consistently in top surveillance findings.
- Subject to CAA Safety Advisory Group (SAG) review and need for action agreed at CAA Leadership level as part of our SMS approach.
- Leaflet initially published in October 2012 following Industry Seminar – subject to revision as our approach has matured.

# Leaflet C-180



Applications for the Approval of CAA

- Leaflet C-160 Continuing Airworthiness Responsibilities for
- Leaflet C-170 EASA Aircraft with an Expired UK (National)
- Leaflet C-180 Control of Production Suppliers and Subcontractors**
- Chapter D Engineering Practices and

CAP 562 – Book 1 Civil Aircraft Airworthiness Information and Procedures

## Leaflet C-180 Control of Production Suppliers and Subcontractors

*(New Content replacing information supplementing that currently contained in BCAR A8-1 Appendix 2, CAA Internal Technical Procedures and FAQs previously available to Industry via the CAA Website.)*

### 1 General

1.1 As the UK Competent Authority for production, the CAA is required by GM No.3 to 21B.220(c) to define a clear procedure for supplier control for those organisations with facilities/partners/suppliers/subcontractors located in a third country on the basis of Part 21. As a result of recent experience and with the increased globalisation of the supply chain, it has been decided to establish a common procedure applicable to CAA approved production organisations and their facilities/partners/suppliers and subcontractors located within the UK or in another country. In order that the CAA policy is clearly understood both internally and by Industry, it has been decided to establish this Leaflet, the contents of which have been declared to EASA.

1.2 If outsourced production activity is completely conformed on receipt at a Production Organisation Approval Holder (POA Holder), for example dimensional inspection of machined parts manufactured from material supplied by the POA Holder, then this constitutes control under the POA Holder's quality system and no further action in

14:31/10

# Leaflet Content

- Exposition
  - Manpower Planning
  - Manager
  - Resources
  - Visit Plan
  - Product Audits
- Extent of Supply Chain
  - UK
  - International
  - Critical Parts

# Leaflet Content

- Changes to Significant Subcontractor Work
- Control of Vendor Supplied Items
- Other Party Supplier Control

# Notification of Changes

- Transition Plan (minimum content defined)
- Based on information supplied and the overall risk considered, Surveyor decides whether to:-
  - Witness audit prior to subcontractor starting work
  - Include in future scheduled surveillance
  - Extent of activity does not require direct CAA witness

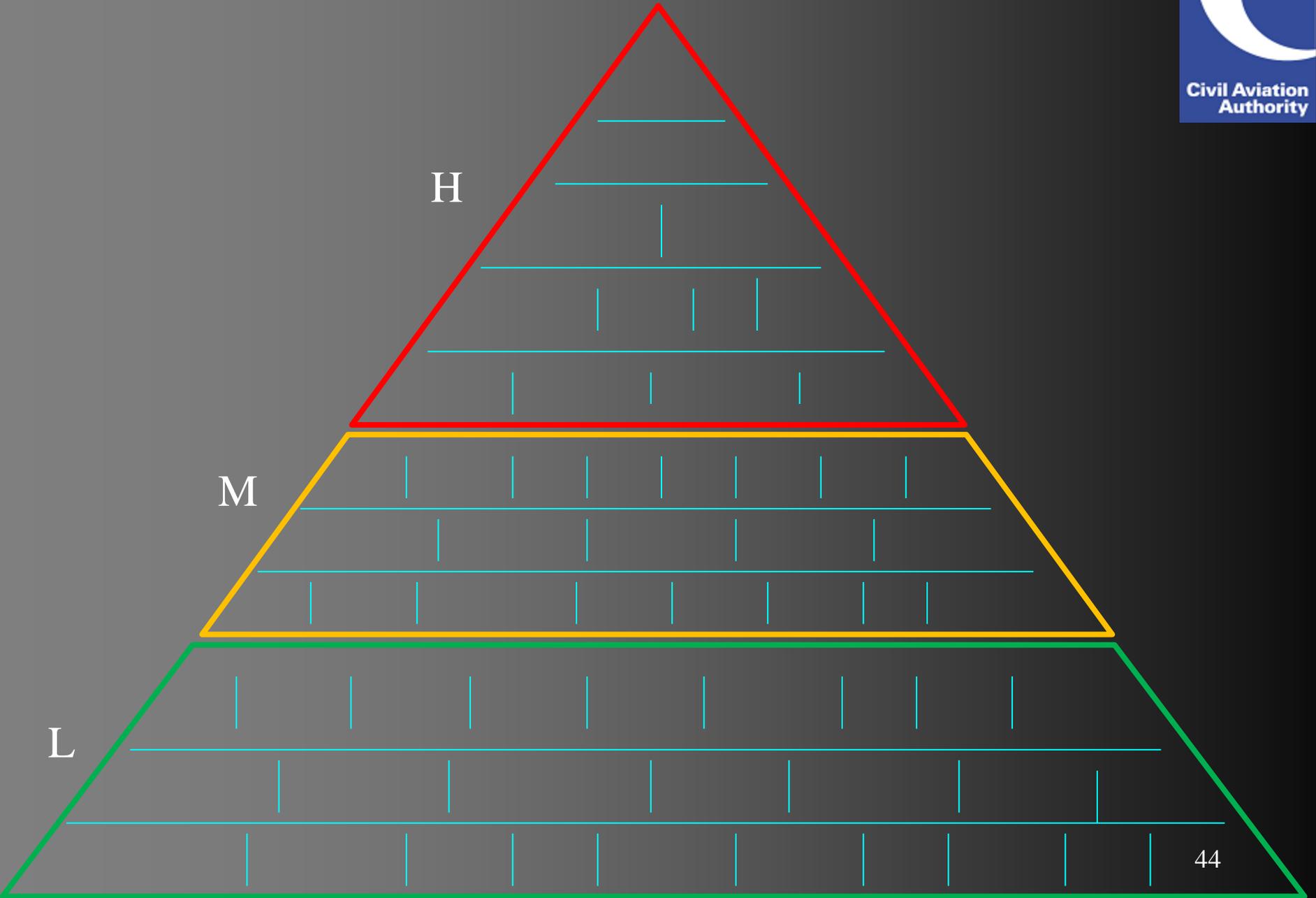
# Risk Based Approach

- All 180 UK Production Organisation Approval Holders were initially assessed on the basis of estimated product criticality and extent of supply chain exposure.
- Those provisionally classified Amber or Red were individually contacted by CAA team to progress responses to more detailed Scoring Criteria.

# Assessment Criteria

Approximate Percentage of Production Contracted	Approximate Number of Units produced by Subcontractors	Approximate Number of UK Subcontractors	Number Undertaking Critical Activity (UK)	Approximate Number of Overseas Subcontractors	Number Undertaking Critical Activity (O'seas)	FTE Personnel Undertaking Supplier QA Activity	Number of on-site audits undertaken annually
Result Score	Result Score	Result Score	Result Score	Result Score	Result Score	Result Score	Result Score
0 0	0 0	0 0	0 0	0 0	0 0	0 3	0 3
25% 1	100 1	100 1	2-5 1	10 1	2-5 1	2-5 2	2-5 2
50% 2	200-400 2	200-400 2	10 2	50 2	10 2	10 1	10 1
75%+ 3	400+ 3	400+ 3	50 3	100+ 3	50 3	50+ 0	50+ 0

- This is then used to generate the rating to determine the level of CAA Witness Oversight:-



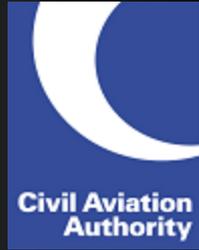
# Witness Frequency

- Supplier Level and Criticality:-
  - <11 **LOW**: Desktop review during 24 month cycle
  - 12-16 **MEDIUM**: +1 Witnessed Audit
  - 17+ **HIGH**: +2 Witnessed Audits
- Focus on Critical Parts and Overseas Suppliers

# Results

- Majority of initial risk estimates confirmed, in some cases extent of supplier activity was much lower than originally anticipated and these were reclassified to Green.
- Some individual organisations upgraded to Red due to activity in safety critical systems or wide participation in a significant number of programmes.
- Proportions remained largely unchanged:-
  - Green ~ 30 % (54 companies)
  - Amber ~ 60 % (109 companies)
  - Red ~ 10 % (18 companies)

# What needs to be reviewed ?



- Quality System elements of Part 21 - 21.A.139(a)
  - Technical evaluation of capability
  - Special Process Control
  - First Article Inspection
  - In process inspections and product acceptance testing
  - Completion of conformity documentation
  - Traceability
  - Incoming receipt of materials and parts
  - Personnel training and competence
  - Records control, including retention and archiving
  - Effectiveness of subcontractor's internal audit system

# Supplier Witness Visit

- Flow-down of Supplier QA requirements to meet design data
- Control of sub-tier suppliers (if permitted).
- Procedures to report non-compliance to the Production Organisation, including material/process changes, material substitutions, concessions and errors found post-delivery.
- General Requirements (adequate facilities, personnel, equipment etc) + regulator right of access.
- Product Audit – assessment at shop floor level that procedures and processes are actually being complied with.

# Product Audit

- Review Certificate of Conformity Release
  - Completed correctly ?
  - Receipt of Flow-Down Conditions
  - Review Assembly/Test Area
  - Work Instructions – available/controlled ?
  - Facilities – maintained/calibrated/housekeeping ?
  - Work Pack/Routing complete and signed ?
  - Sample check key authorisations

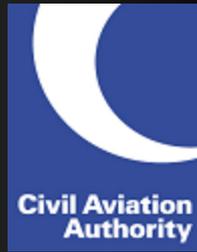
# Product Audit

- Evidence that the part conforms to drawing requirements (Inspection Reports, First Article Inspection Report – FAIRs).
- Have concessions been agreed by the Design Holder identified in the Interface arrangements ?

# Production Holder Actions

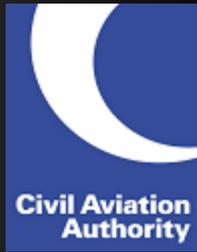
- Update Exposition with scoring information.
- For those rated Medium or High, CAA agrees which planned supplier surveillance visits it will witness.
- Expect to see consideration of airworthiness significance of the parts in generating the audit plan, not just vendor spend.

# Supplier Governance Board



- Meets quarterly.
- Chaired by Head of Airworthiness – John McColl.
- Reviews all Production Organisation approval renewals for extent of planned supplier activity.
- Reviews Top 10 Production Organisations for Supply Chain activity.

# Supplier Governance Board



- Challenges/Confirms Top 10 Surveillance Plan
- Reviews individual Surveyor requests outside the recommendation cycle to conduct supplier surveillance (Variations, Outcomes from other Surveillance, Intelligence).
- Reviews potential for combining external visits with other planned activities – second sites, overseas Maintenance Line Stations etc and the potential to involve regulatory partners.

# Subjects

- Review of Production Findings
- Risk Based Approach to Supplier Oversight
- Shared Oversight with other Authorities

# International Co-operation



- Currently exploring potential for mutual co-operation with other regulatory partners (both FAA and other European National Authorities) to undertake audits on each other's behalf.
- Best use of resources and minimise time lost to travel.
- Previously undertaken for FAA under the former ACSEP programme.

# International Co-operation



- Formal agreement reached in June 2015 between ENAC Italy and UK CAA for the involvement of UK CAA personnel in the surveillance of the AgustaWestland S.p.A. facility in Yeovil and in the general oversight of the single Italian Production Approval.
- Seen as first-in-class and a template for International co-operation and efficient use of oversight resources.

# International Co-operation



- Memorandum of Understanding at Senior Level
- Work Instruction regarding Interface and Exchange of Information
- Team Training and Liaison Visits
- Cost Recovery
- Programme Management Meetings

*Thank you for the  
Invitation ...*

*Questions ?*