

Introduction to Conformity of Production (CoP)

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Introduction to Conformity of Production

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Introduction to Conformity of Production

1. Introduction



Introduction to Conformity of Production - Introduction

Scope

- ▶ This presentation will only cover CoP requirements and will not include Type Approval Technical requirements
- ▶ It will not give you a definitive list of what is required to gain CoP clearance but will introduce the terms and elements that are required
- ▶ It will not cover how to create a QMS or control plan for your products
- ▶ VCA Audit procedures will not be covered

Introduction to Conformity of Production - Introduction

General housekeeping

- ▶ There is time allocated at the end for questions
- ▶ Copies of the slides will be added to the VCA website under the CoP section after these seminars

Introduction to Conformity of Production - Introduction

Relevant Legislation – EU / ECE

- ▶ Regulation (EU) 2018/858 European Framework Regulation (as amended)
- ▶ EU Reg (No) 167/2013 Approval and market surveillance of agricultural and forestry vehicles (as amended)
- ▶ Regulation (EU) No. 168/2013 Approval and market surveillance – motorcycles (as amended)
- ▶ E/ECE/TRANS/505/Rev.3 (1958 Agreement Revision 3)
- ▶ REGULATION (EU) 2016/1628 (as amended) on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery (NRMM) (CoP contained in Regulation (EU) 2017/654 Technical and General Requirements)

Introduction to Conformity of Production - Introduction

Relevant Legislation - UK

The Road Vehicles (Approval) Regulations 2020 (Statutory Instrument 2020 No. 818 (as amended))

The Motorcycle (Type Approval) Regulation 2018 (Statutory Instrument 2018 No. 235)

The Agricultural and Forestry Vehicles (Type Approval) Regulations 2018 (Statutory Instrument 2018 No. 236)

All UK legislation can be found on <https://www.legislation.gov.uk/>

Introduction to Conformity of Production - Introduction

Relevant Legislation

- ▶ Presentation will refer to 2018/858/EU and E/ECE/TRANS/505 rev. 3 for references but the basic principals are the same for all the aforementioned legislation
- ▶ Please refer to the applicable legislation for your product

2. The Basics

What is Conformity of Production?

- ▶ The ability to produce a series of products which conform to the specification and performance requirements of a relevant Regulation.
- ▶ Purpose is to ensure every vehicle/component is going to be the same as the one approved
- ▶ Type approval – test representative(s) within type and permit manufacturer to make the items without further checking subject to controls and checks in place.

TEST ONE MAKE MANY!

Introduction to Conformity of Production – The Basics

Legislation mentioned previously mentions two elements that are required for CoP

1. Quality system that covers the company process from design through to sales
2. “Control plans” for each type approval subject area showing how ongoing compliance will be demonstrated

Other items are required and these will be covered in detail later

Introduction to Conformity of Production – The Basics

CoP Clearance Duration

- ▶ Maximum three years
- ▶ May be dictated by legislation covered by clearance
- ▶ Risk rated
- ▶ May be linked to ISO/TS expiry in some cases
- ▶ Audit may be conducted at any point during the clearance

Introduction to Conformity of Production – Quality Management Systems and CoP

3. Quality Management Systems and CoP

Introduction to Conformity of Production – Quality Management Systems and CoP

Legislation does not state that ISO9001 or similar is held

- ▶ ISO9001 is a good indication of what is required of a QMS
- ▶ For CoP, the Quality Management System should be supporting the business in demonstrating ongoing compliance
- ▶ Elements that CoP audits will look into are centered around supporting the manufacture of products (i.e. calibration)
- ▶ On-site audits look at the end-to-end process of manufacture, from design through to labelling of the final product



QMS example – making a coffee!

Introduction to Conformity of Production – Quality Management Systems and CoP

QMS example – making a coffee!

I like my morning coffee to be made with:

- 1) 1 ½ scoops of filter coffee, strength 4
- 2) 1 teaspoon (4 grams) white sugar
- 3) 330ml mug
- 4) 300ml Boiling water
- 5) 30ml 1% fat milk at 3⁰C

But everyone says how much they like it so I need to make lots more to sell.....
but I need every cup I make to taste the same.....

Introduction to Conformity of Production – Quality Management Systems and CoP

Need to write down the specification and work instructions. Date and label the documents so I can make sure everyone uses the newest version

– This is **DOCUMENT CONTROL**

Need to understand what laws and rules there are around making coffee

– I need **ACCESS TO LEGISLATION**

Need to order in stock of coffee, milk and sugar. Must make sure it is the correct specification

– **APPROVED SUPPLIERS / PURCHASING PROCESS**

Introduction to Conformity of Production – Quality Management Systems and CoP

Need helpers to make the coffee who are trained

– **TRAINING PROCESS AND MATRIX**

Need the correct size scoop, spoon and mug and make sure the kettle always boils the water and the fridge is at 3°C

– **CALIBRATION PROCESS AND LIST**

Need to keep my milk cold, coffee and sugar dry, and put any ingredients that are no good away from the rest so they aren't accidentally used

– **STORAGE OF INCOMING PRODUCT / QUARANTINE AREA**

Need to check with my customers that they like the coffee. Record any complaints they may have

- **CUSTOMER SATISFACTION / COMPLAINTS PROCEDURE**

Introduction to Conformity of Production – Quality Management Systems and CoP

Check on the workers now and again to make sure they are doing what I ask them to

– **INTERNAL AUDIT**

Record what I do so I can identify trends to help improve

– **RECORDS**

Make sure I update all my paperwork if I change anything, and check the laws etc if I alter what I do

– **CHANGE CONTROL**

Test the occasional coffee and parts of the process to check all is as I wanted

– **TESTING**

THIS IS THE FUNDAMENTALS OF A “COP” QUALITY SYSTEM!!!

Introduction to Conformity of Production – Quality Management Systems and CoP

QMS example – making a coffee!

- ▶ Although a strange example, it illustrates how everyday tasks can be seen in terms of a CoP style quality system
- ▶ Most, if not all businesses, have these elements in place but may not document them or even be aware
- ▶ Thinking about your business in terms of inputs, controls and outputs (over a coffee!) should help form the documented procedures you will need

4. Control Plans

Introduction to Conformity of Production – Control Plans

Taking the coffee example further, it is easy to start drawing up a control plan:

The document will need:

- ▶ To be owned by me and have a document reference / revision number / date
- ▶ Reference what will be checked
- ▶ Identify who checks it
- ▶ Details how often to do the checks
- ▶ Gives a pass/fail criteria

Introduction to Conformity of Production – Control Plans

An element of the plan could look like this:

Process	What to check?	Requirement	What do I need	How often?	When?	Who?	Record
Sugar addition	Type of sugar	Granulated	Visual check	Every delivery	Shopping arrives	Storeman	Delivery note
	Amount of sugar	1 teaspoon (4g)	Calibrated scales	Every 10 cups	During making	Barista	Check sheet

And so on...

Control Plan Contents – Control Plans for CoP

Must:

- a. Be owned and controlled by the approval holder
- b. have a document reference, version level, be dated and be part of, or referenced within the Quality management system
- c. contain references to the legislation the item is tested / checked against
- d. explain what tests and checks are to be done including the inspection of marking
- e. outline the test frequency
- f. identify who conducts the test
- g. indicate the pass / fail criteria

Introduction to Conformity of Production – Control Plans

Control Plan Contents – Control Plans for CoP

Additional areas looked at:

- ▶ Does the control plan relate to the approval issued?
- ▶ Does it refer to the correct CoP legislative testing? (if applicable)
- ▶ Are the controls in place suitable to determine conformity in relation to the manufacture?
- ▶ Are the manufacturing processes the same as previously used for approval?
- ▶ Do they relate to the correct assembly site?
- ▶ Are component labels checked?

Introduction to Conformity of Production – Control Plans

- ▶ EU, ECE and National type approval legislation require documented control plans for each approval that specify intervals in which tests or associated checks necessary to verify continued conformity with the approved type are conducted.
- ▶ The frequency of the testing should be a suitable period based on risk, and not exceed any requirements contained in any of the pieces of legislation you hold approvals to.
- ▶ Although the nature of inspections and tests is partially indicated in the legislation, it will also be specific to the nature of your product and its method of production.
- ▶ Further information can be found on the VCA website

Introduction to Conformity of Production – Control Plans

- ▶ Some regulations have specific requirements: ie EU Regulation 715/2007, ECE R44
 - Test frequencies
 - Sampling regimes
 - Pass/Fail criteria

- ▶ Some are general:

The Type Approval Authority which has granted type approval, may at any time verify the conformity of production in each production facility. The normal frequency of these verifications shall be at least once per year. *ECE Reg 141*

- ▶ Some are halfway between!

“Conformity of production of the vehicle or component or separate technical unit shall be checked on the basis of the data contained in the communication form(s) for type approval set out in Annex 3A and/or 3B of this Regulation”. *ECE Reg 10*

5. Other Elements

Introduction to Conformity of Production – Other Elements

Other Specific Areas of Interest

Change Control

Access to Legislation

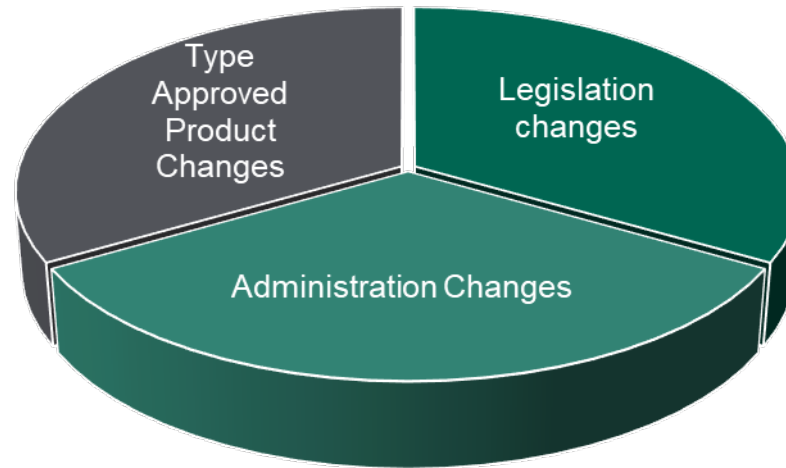
Assembly Plant Statement

Change Control

- ▶ Should be imbedded in the Quality System.
- ▶ Change control procedures must exist in relation to how your type approval(s) are managed and maintained.
- ▶ Expands on the change process typically found in a ISO9001 / IATF quality system
- ▶ Must including applying for CoP changes
- ▶ Requirements can be broken down into three areas:

Introduction to Conformity of Production – Other Elements

Change Control



Type Approved product changes

- ▶ Internal Factors – i.e. design changes
- ▶ External Factors – i.e. parts become discontinued – replacements sought
- ▶ Client requested Change
- ▶ Scope applicability – is your current clearance scope (type approval subjects) sufficient for the change you want to implement?

Legislation changes

- ▶ Have direct access to legislation
- ▶ Keep up to date on legislation changes
- ▶ Staff trained to assess the legislation changes against the approval for applicability

Administration changes

- ▶ Primary Contact changes
- ▶ Address changes Approval holder
- ▶ Address changes of assembly plants – Including Management of assembly plants

Assembly Plant Statements

- ▶ All assembly plants used that are not a direct part of the approval holder need to submit a signed assembly plant statement
- ▶ This document is a declaration that the assembly plant will not make any of the changes listed previously without contacting the approval holder first.
- ▶ The approval holders change control would then assess the proposal and notify the assembly plant if and when the change can be implemented.

Introduction to Conformity of Production – Other Elements

Access to legislation

- ▶ Must be an updated source
- ▶ Website address accepted
- ▶ Trade body membership not sufficient
- ▶ Use of consultant accepted but “contract” must be in place to cover duration of CoP clearance
- ▶ Sources will be checked as part of the audit process

6. Supplier or Assembly Plant?

UK CoP (GB / UK(NI)) – Supplier or Assembly Plant?

- ▶ Manufacturer (approval holder) responsible for CoP
- ▶ Manufacturer must own the control plans and change control
- ▶ CoP clearance must contain all assembly plants used
- ▶ Scope of clearance can vary site to site
- ▶ Any work done prior to registration must be considered for CoP

UK CoP (GB / UK(NI)) – Supplier or Assembly Plant?

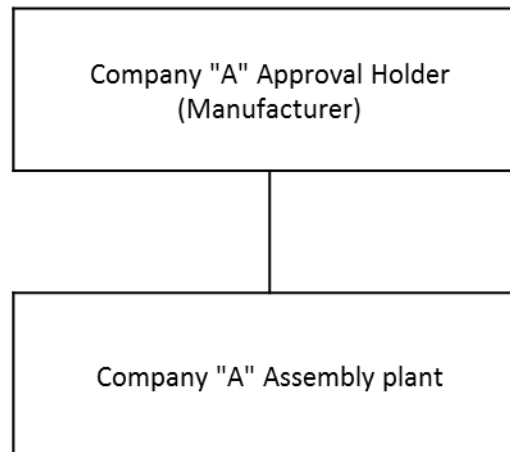
Suppliers

- ▶ Boundary between supplier and assembly plant not clear, depends on product
- ▶ Generally, if a supplied item can be approved in its own right it comes from an assembly plant
- ▶ Example of supplier – brake disc/caliper/pad assembly
- ▶ Example of assembly plant – trailer “A”frame with coupling and axle

UK CoP (GB / UK(NI)) – Supplier or Assembly Plant?

Simple relationships

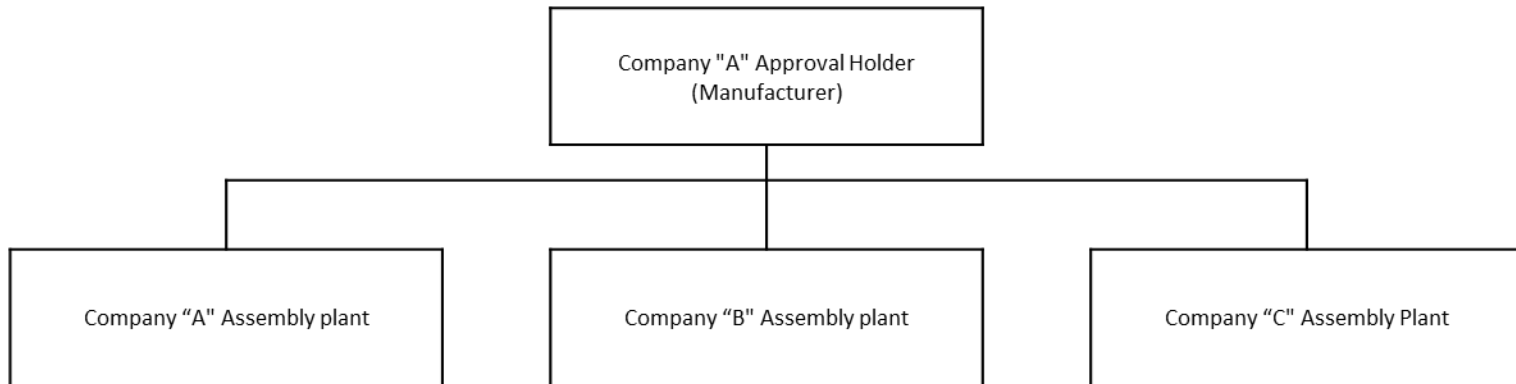
- ▶ Approval holder is also assembly plant



UK CoP (GB / UK(NI)) – Supplier or Assembly Plant?

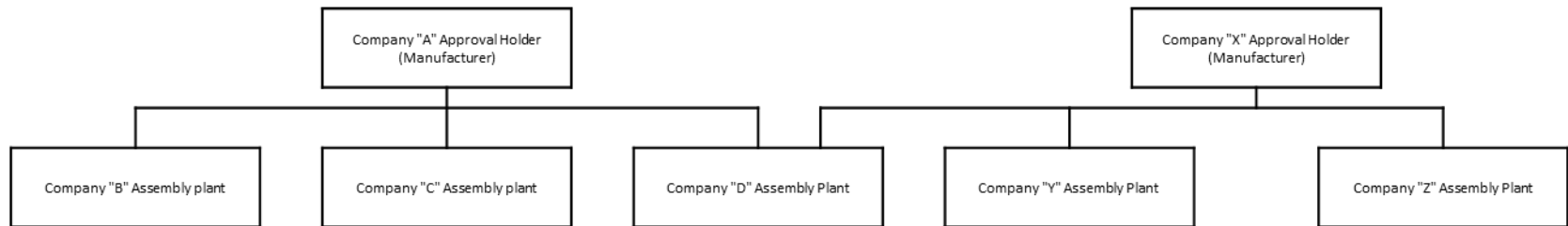
Regular relationships

- ▶ Approval holder uses numerous assembly plants



Complex relationships

- ▶ Assembly plant “feeds” more than one approval holder



- ▶ In this case, Company “D” are evaluated twice for CoP

7. Test Data

Introduction to Conformity of Production – Test Data

- ▶ Some legislation requires test data to be submitted periodically
- ▶ CoP team request data when needed
- ▶ Data evaluated by Engineer
- ▶ Follow up action may be needed
- ▶ Failure to supply data can result in approvals being withdrawn
- ▶ If incomplete result packs are received, approvals are at risk
- ▶ Facility appraisals may be carried out
- ▶ Important “Old” approvals are withdrawn otherwise data is expected
- ▶ Any tests conducted for CoP, whether mandated or part of your controls, may be assessed at audit

Introduction to Conformity of Production – Frequently Occurring Problems

8. Frequently Occurring Problems

Introduction to Conformity of Production – Frequently Occurring Problems

- ▶ No checks detailed on position and content of approval marking in control plan
- ▶ Control plans contain little or no detail
- ▶ Access to legislation reference not suitable
- ▶ Change control that does not consider type approval areas
- ▶ Approvals not being updated
- ▶ Change of location(s) and company names
- ▶ Assembly plants not covered
- ▶ ISO scope not relevant
- ▶ Subject listing does not cover approval subject applied for

9. Application Process



Introduction to Conformity of Production – Application Process

- ▶ If you are not an existing VCA customer you will need to set up an account with us. A Customer Account Application Form can be found in the publications area of our website
- ▶ Please direct all correspondence regarding CoP to copmailbox@vca.gov.uk

Introduction to Conformity of Production – Application Process

Type Approval Applications and CoP relationship

- ▶ When an application for approval is received, the VCA admin team will check CoP status
- ▶ Approval will not be issued if any parts of the CoP clearance have expired
- ▶ Scope (subject list) will be checked against the application
- ▶ If a new assembly plant is being used, this will need to be added to the CoP clearance
- ▶ If a new subject is being applied for this will need to be added to the CoP clearance
- ▶ Addresses must tally
- ▶ Process and requirements identical for approval extensions

10. Summary

Introduction to Conformity of Production – Summary

- ▶ CoP consists primarily of a Quality Management System and Control Plans
- ▶ Clearance duration is covered by legislation or risk (max. 3 years)
- ▶ Control Plans need to cover every type approval subject that you apply for
- ▶ Test data is required to be retained and may be requested
- ▶ Please contact copmailbox@vca.gov.uk if you have any questions

11. Questions