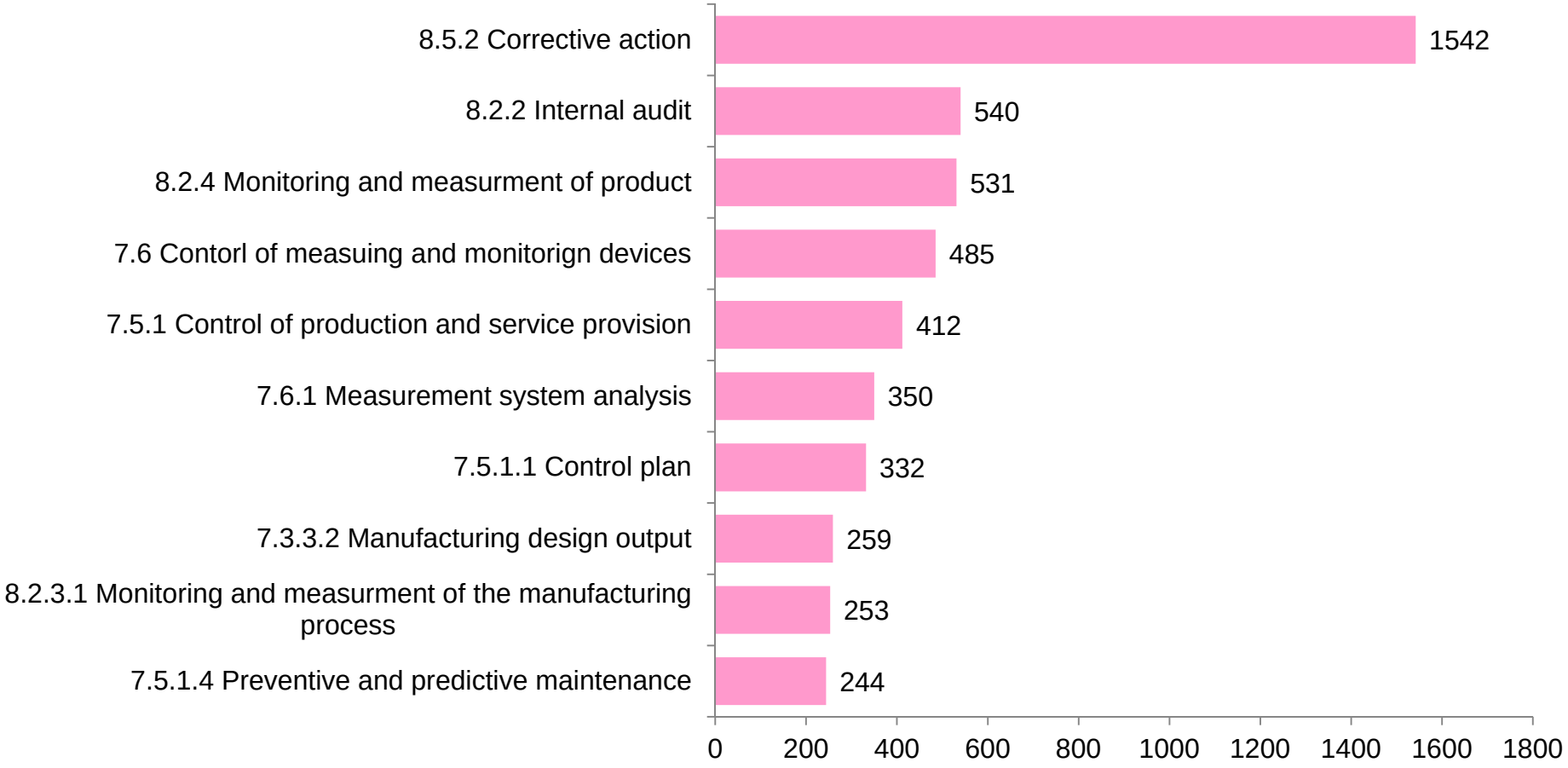
Effective closure of system based nonconformities Webinar

16th April 2015

- During presentation (11:00 – 11:30) everyone will be muted so that only the presenter will be heard.
- The presentation will be followed by a 30 minute Q&A session.

- Recording will be made available after the webinar on the Industry Forum website.
- If you are experiencing any technical problems please call us on 0121 717 6620.

UK Top 10 Major Nonconformities 2014



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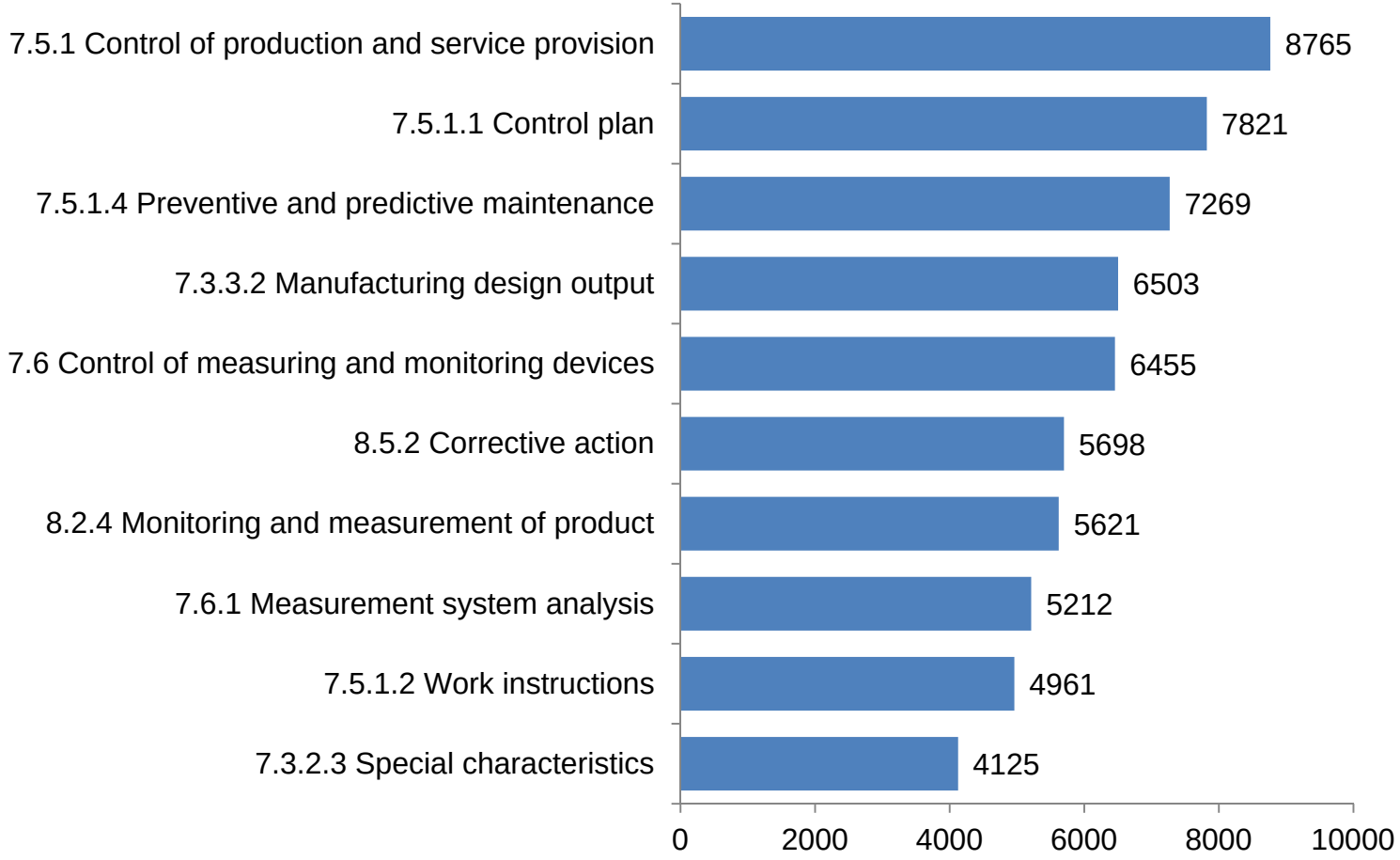
UK Top 10 Minor Nonconformities 2014



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Corrective action and the linkage to ISO/TS16949

TECHNICAL SPECIFICATION

ISO/TS 16949

Third edition
2009-06-15

Quality management systems —

Particular requirements for the application of ISO 9001:2008 for automotive production and relevant service part organizations

Systèmes de management de la qualité —

Exigences particulières pour l'application de l'ISO 9001:2008 pour la production de série et de pièces de rechange dans l'industrie automobile

ISO

Reference number
ISO/TS 16949:2009(E)

ISO/TS16949: 2009

8.5.2 Corrective action

The organisation shall take action to eliminate the causes of nonconformities in order to prevent recurrence, Corrective action shall be appropriate to the effects of the nonconformities encountered

8.5.2.1 Problem solving

The organisation shall have a defined problem solving process leading to root cause identification and elimination

Rules for achieving IATF recognition 4th edition

Surveillance and recertification audits

When a nonconformity is identified by the certification body, then the decertification process shall be initiated on the last day of the audit. For a major nonconformity the certification body shall require the client to identify the root cause and implement correction within 20 calendar days from the closing meeting date

For major nonconformity certificate suspended

Onsite follow up with 90 days

Rules for achieving IATF recognition 4th edition

Surveillance and recertification audits
Minor nonconformities

The certification body shall verify the effective implementation of the identified corrective action at the next audit.

In cases where the accepted corrective action plan is found not to be effectively implemented a new major nonconformity shall be issued against the corrective action process and the previous minor nonconformity reissued as a major nonconformity

Common issues

- Jumping to conclusions
- Impatience. Impatience leads to insufficient analysis
- Problem-solving effort is rushed to get a quick solution
- Lacking input from key functions
- Not using a team approach
- Poor team participation
- Not using a logical problem solving process
- Failure to collect data and complete a problem investigation
- Problem described incorrectly/incompletely
- Potential cause misidentified as real root cause

What problem solving format?

No IATF specified format
Responses must comply with CB requirements/formats

Must meet TS requirements:

- Determining the causes of nonconformities (8.5.2b)
- Evaluating the need for action to ensure nonconformities do not reoccur (8.5.2c)
- Determining and implementing actions needed (8.5.2d)
- Records of the results of actions taken (8.5.2e)
- Reviewing the effectiveness of the corrective action taken (8.5.2 f)

What problem solving format?

The organisation shall apply to other similar processes and products the corrective action, and controls implemented in order to eliminate the cause of a nonconformity (8.5.2.3)

Example: Minor nonconformity

Statement of nonconformity:

The process to review and update control plans is not effective

Requirement:

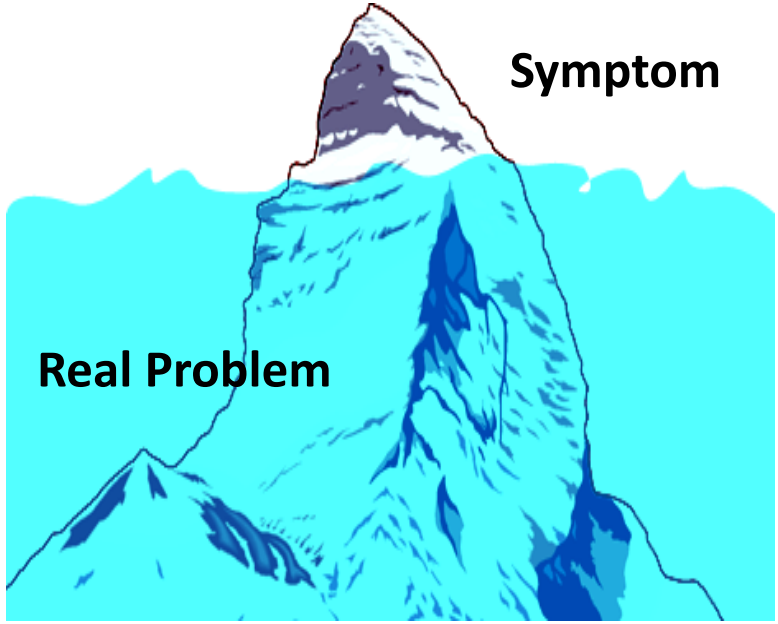
7.5.1.1 Control plans: Control plans shall be reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources or FMEA

Objective evidence:

Gauge A345 being used to measure product in the bending cell, process step 40, was not referenced on the control plan A347890.
FMEA for product 23468 stated that a 1 in 25 check should be undertaken at process step 40 but control plan stated 1 in 10 check.

Date 1st April 2015

Nonconformity was found based on a limited sample. How big is the problem?



20%

80%

Establish a team

Involve more than just Quality!

Could include:

- Production
- Engineering
- IT

Correction

Update control plan A347890 referencing gauge 345

Amend control plan to reflect 1 in 25 check for process step 40

Date 2nd April 2015

Correction

- Was there a review of other control plans?
- Was there a review of other FMEA's?
- How big is the problem?
- Why did existing verification processes pick up the problem (internal audits, FMEA/control plan reviews etc.)

Determining the cause of nonconformity

Gauge A345 being used to measure product in the bending cell, process step 40, was not referenced on the control plan A347890.

Why: Gauge was added to address a quality problem by line technician. Technician not aware of requirement to update control plan
Why: Lack of awareness of TS requirement
Why: Technician was a new employee
Why: Control plan awareness not verified during induction process

Root cause: Lack of an effective induction process to cover technical requirements of ISO/TS16949

Determining the cause of nonconformity

FMEA for product 23468 stated that a 1 in 25 check should be undertaken at process step 40 but control plan stated 1 in 10 check

Why: Control plan updated as a result of a quality concern but PFMEA not updated
Why: No formal process in place to review FMEA and control plan after internal/external nonconformities occur

Root cause: No formal process in place to review FMEA and control plan after internal/external nonconformities occur

Corrective action

Root cause:

- Lack of an effective induction process to cover technical requirements of ISO/TS16949

Corrective action:

- Add verification of competence relevant to ISO/TS16949 to annual appraisal of existing employees

Completed 12th April 2015

- Develop process of verification of existing competence of new hires, including identification of training needs, delivery of training and verification of effectiveness

To be completed 31 May 2015

Corrective action

Root cause:

- No formal process in place to review FMEA and control plan after internal/external nonconformities occur

Corrective action:

- Reviewed existing process (not documented but happening adhoc):

Complete 10th April 2015

- Develop documented process taking into account customer specific requirements

To be completed 31st May 2015

- Train employees in process and evaluate understanding

To be completed 31 May 2015

Verification of effectiveness

- Increase frequency of manufacturing process audits
- Implement an additional verification check by Technical Director on completion of action to address customer complaints to verify process for review of FMEA and control plan was effectively completed

Next visit

What are the consequences if repeat problems are found on the next Certification body audit?

Reviewer Checklist

Response Due Date:

	Y/N
Problem Investigation:	
Does the response answer what, who, where, how many, when and magnitude of the problem?	
Does it explain a systemic or process based breakdown and not just incident specific?	
Was a team identified and used to solve the problem?	
Problem Statement:	
Is a problem statement included?	
Is the problem statement clear to any reader?	
Does the problem statement support the results from the problem investigation? (e.g. statement should not restate the finding statement)	
Correction/Containment:	
Is there at least one action related to each piece of objective evidence in the nonconformity form?	
Are the action(s) clear?	
Is the verb past tense (changed...) or present tense (will change...)? If past tense, is evidence attached to show implementatian of the action and the date it was completed? If present tense, is a date provided to show when the action started and a target end date?	
During the problem investigation, were any more occurances found? Were they all corrected or containment plan in place?	
Is there evidence attached to show the correction (or containment) implemented?	
If correction/containment actions are not necessary is an explanation is provided?	
Root Cause:	
Is the analysis to determine the root cause documented, evidence provided (i.e. either detailed in the form or attached as a separate document)?	
Does the root cause show a systemic issue exists (i.e. "What in the system failed that such a problem occurred?")	
Is the analysis clear to any reviewer?	
Does the analysis and root cause statement make sensecompared to the problem statement?	
Corrective Action:	
Does the corrective action(s) address the root cause(s)? If more than one root cause exists, there should be an action for each root cause.Does the corrective action(s) address the root cause(s)? If more than one root cause exists, there should be an action for each root cause.	
Are the actions clear and written in past tense (*changed…*) or future tense (*will be changed…*). If past tense, is evidence attached to show implementation and the date it was complete? If present tense, is a date provided to show when the action started and a target end date?	
Do the corrective actions effectively change system?	
Is there evidence attached to show the change implemented? If so, does the attachment highlight (or identify in some way) where the change(s) occurred? Open each attachment to ensure it is correct and you can easily find the changes.	
Does the action(s) provide the effective date of the process or system change?	
Is there evidence of the communication of the change(s) to all affected personnel	
Verification Action:	
Does the verify action explain who, what will be done, and date(s) the verification will be conducted?	
Does the verification action align with the corrective actions implemented?	
Are the actions clear to any reader?	

Summary

- IATF putting pressure on certification bodies to ensure effective closure of nonconformities
- Effectiveness checked during office audits of CB's by IATF Oversight
- Use your proven problem solving processes to solve system related problems found in external audits
- Use your proven problem solving processes to solve system related problems found in external audits

- For a copy of the review check-sheet e-mail paul.hardiman@industryforum.co.uk

Training

1 Day Problem Solving Training (at Industry Forum Learning Centre or in-house)

- 8th May 2015
- 3rd June 2015
- 29th September 2015
- 18th November 2015

For details of this course, and other related training, visit www.industryforum.co.uk or contact +44(0)121 717 6614

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Thank you for attending

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A recording and pdf file of this presentation will be made available on the Industry Forum website at https://www.industryforum.co.uk/resources/webinar-archive/ from 12.00pm (GMT) on 17th April 2015

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