Experiences and Lessons of a Compliance/Certification Engineer/ Manager

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About the presenter

A member of the product compliance industry since 2004, starting in audio/video with radio modules, moving into power tools with radio modules and then back into audio/video and radio.

BTEC HND in Sound and Video Engineering and MIET.

Previously a member of UK, EU and International Standards Committees and EU/UK Trade Association Committees; Vice Chair of LVD, EMC and RED matters for the EGMF EU Trade Association for Garden Equipment.

Also, wrote an article on the NLF for the EMC Journal in 2010.

As part of internal ISO 17025 accreditation for the acoustic chamber according to the Outdoor Noise Directive (non-accredited testing for Machinery Directive), was an approved Noise Technical File expert (CE marking + DoC too) + CIG023/ISO 9001 etc. audits

What this presentation isn't/ is about

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- Not about details on the requirements of Directives/Regulations, but I will touch on some requirements where needed
- Not about CE/UKCA Marking, Notified/Approved Body, Harmonised/Designated Standards, DoC, FCC/ISED etc……(ish)
- The details of the above can be found via other sources, e.g., Test House webinars, e.g., Mike Derby recent webinar on FCC/ISED/RED

- This presentation is more about the real life experiences of what is required to get to the compliance of the above – The stuff that does not get talked about much in the training I have received over the years
- **JUST MY EXPERIENCES**, from someone in compliance, in the manufacturing/ engineering world

Firstly & Secondly

- Firstly, the title page showed all the job titles I have had since I started. The requirements of the job are inconsistent, especially without processes, RASIC/ RACI's – leading to confusion about what I am actually supposed to do, so have to find the holes and try to plug them (Shawshank Redemption inductions). **An agreed defined Compliance/Certification Engineer and Manager role in the industry would be a great help**

- Secondly, the lack of compliance training in the education system has had a huge impact on successful delivery of cost and time effective compliant products due to lack of design engineer experience/knowledge requiring hours of training/ support. Seen some developments but a long way to go – **a head start would greatly help!** Engineers embracing compliance has been tricky over the years too, or those with little knowledge that complain about regulations/standards

Saying that, there have been many debates about the different between a technician and engineer too!
I have had engineers be very vocal at the requirements, even when they are black and white - A little knowledge is dangerous

And....

- Compliance is not just for hardware, it is cross functional
- Therefore should be all encompassing across engineering/quality
- E.g., cyber security
- E.g., 60335-1 and 62841-1 safety critical software

Testing, testing, testing….
TF, TF, TF….

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- Testing is more important than the Technical File (TF)? – No!
- The TF is a legal requirement and the easiest to inspect
- The formatting of the technical file is critical, to the detail of the file names. In some regions and test houses, there are specific requirements covering some of these details.
- Time and care MUST be spent on documentation….
- Most Market Authority investigations I have seen reports of are User Manual and DoC related, and most fail!
- e.g., “UK” Declaration of Conformity – NI Protocol – GB or UKCA
- e.g., “CE marking”, NOT “CE mark”

Market Authorities wanting actual testing involves tendering labs, money and time. Documentational investigation (User Manual and DoC) is much easier and cheaper, not involving engineers in expensive test labs, but admin in offices, with procedures, a ruler (measuring marking) etc. Think of a police officer stopping you with a broken rear light is just a starter for 10…..

The TF - level of detail….

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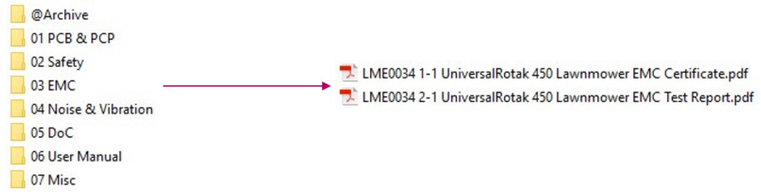
- Think multiple third parties - Test House, NB/AB, Market Authority, Judge…they are all human, if you make their life easier, they will do likewise for you example for certification:

Also, must keep a proper certification database for internal AND external use. Excel is fine, PLM is good (i.e., what is workable for all your stakeholders)



- LME0034 2-1 UniversalRotak 450 Lawnmower EMC Test Report

- **LME** (LawnMower EMC) **xxxx** (Technical File Sequential Number) y (document #) – z (revision)
- **UniversalRotak 450** (Product Name) **Lawnmower** (Product Type)
- **EMC Test Report** (Document Content) **.pdf** (Document Type)

Also, must keep a proper legislation and standards database for internal use - something workable for all your Stakeholders!

Note: Not even using a PLM – just plain old windows, and have full documentation control (OND, internal AND 17025 audit approved!)

The TF level of detail….

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- Test Houses, NB/AB/TCB/CB approved….example complete TF for radio:

I learnt this by talking to Test House lead engineers at a personal level and giving them the confidence to speak freely and not business-to-business – Speak your mind, tell me the real issue, e.g., Safety Critical Component List

01 RED-RER-FCC-ISED - Application	11/05/2022 16:00	File folder
02 RED-RER-FCC-ISED - Technical	11/05/2022 16:00	File folder
03 RED-RER-FCC-ISED - Marketing	11/05/2022 16:00	File folder
04 RED-RER-FCC-ISED - Test Reports-Certificates	11/05/2022 16:00	File folder
05 Radio Technology - GCF	11/05/2022 16:00	File folder
06 Radio Technology - Bluetooth	11/05/2022 16:00	File folder
07 Radio Technology - Other	11/05/2022 16:00	File folder
08 General - Clause-by-Clause, Functions-Reactions Analysis	11/05/2022 16:00	File folder
09 General - FMEA	16/12/2021 14:06	File folder
10 General - Discussions	16/12/2021 17:01	File folder
11 General - Declaration of Samples	15/12/2021 09:24	File folder
12 General - Schedule of Tests-Sample Submission to Test House	20/04/2022 16:07	File folder
13 General - Test Results	16/12/2021 17:02	File folder
14 General - PASS E-mails	11/05/2022 16:00	File folder
15 General - Draft Reports	14/01/2022 16:50	File folder
16 General - Sample Return or Scrap	15/12/2021 09:25	File folder

This is the level of detail and organisation required to have a successful certification process that is repeatable, by any compliance engineer across the global organisation, for EU, UK, NA approvals

The TF level of detail….

- Guidelines / Checklists
  - EMC-Radio Certification Content
  - Safety Certification Content
  - TF according to EU/UK legislation
  - An Agile TF for EU/UK/NA (previous slide extended)
  - Example Radio Document Checklist
  - Also, a good quality sample tracking sheet for internal & external testing

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Example Report Content - EU

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- What if OJ HS is old (withdrawn from CEN/CENELC) but new standard is not in OJ? OJ are HS's but NOT state of the art…..list both in the report!

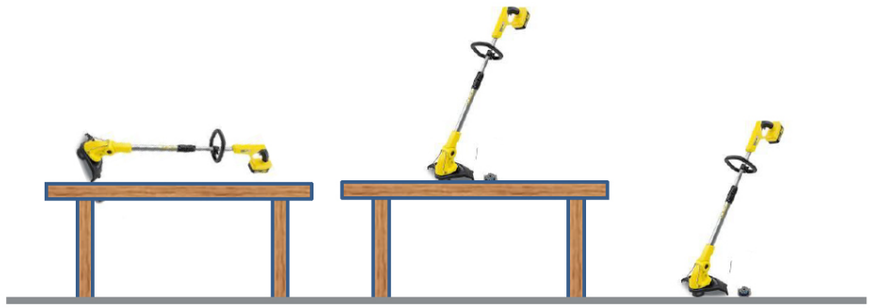
Standard	Year	Title
EN 55014-1	2006	Emission – Electrical motor-operated and thermal appliances for household and similar purposes, electrical tools and similar electrical apparatus
A1	2009	
A2	2011	
EN 55014-1	2017	
EN 55014-2	1997	Immunity - Household appliances, electric tools and similar
A1	2001	
A2	2008	
EN 55014-2	2015	
EN 61000-3-2	2014	Limits for harmonic currents emissions
EN 61000-3-3	2013	Limitation of voltage fluctuations and flicker

Example Test Setup

- Taken from EMC Directive:

> The electromagnetic compatibility assessment shall take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the essential requirements set out in point 1 of Annex I in all the possible configurations identified by the manufacturer as representative of its intended use.

- What is right?



I saw a report from an accredited test house for EMC testing of a line trimmer with no line and no guard lying flat on a table – NOT representative – engineers would argue it is from an accredited test house (see later)

Example Risk Assessment

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- Required for most Directives/Regulations
- Many say “Risk Assessment” on front cover but content….
- Look at guides from REDCA (TGN 30), CENELEC (Guide 32), RAPEX etc.
- REDCA TGN 30 Section 3 “Tasks of the Notified Body” is a good example
- Also ISO 12100 – Machinery yes, but the process is spot on and lets be honest, the process applies for everything!

Example Risk Assessment

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- Mitigating risks can be by standards and/or Harmonised standards but what if there is a gap with the standard(s)?
- A risk assessment should determine if standards/guides etc. are or are not suitable to mitigate the risk(s)
- If they are, nice one – keep clam and carry on – well done, the standards committee are ahead of the curve!
- ***If not***, the assessment should then determine the necessary steps to mitigate the risk(s) if the risk(s) are high enough to warrant it – Design, Guard, Instruct in that order, NOT INSTRUCT FIRST!"
- I have seen many RA's that miss this level of detail. You cannot rely on Harmonised Standards "covering all". You need to consider your product use case/conditions profile against the HS to determine if there are any gaps and how those gaps shall be reduced according to a probability and severity scoring method
- Example, EMC ESD 8KV air vs 15KV air discharge. My experience is 15KV as the company(ies) requirement (by procedure) sees 15KV as foreseeable use case – RA drives this
- In other words, never assume, always assess! – Highest battery capacity in the range must be worst case – Wrong! Proven by measurement, and procedure changed for the whole division, I was involved in driving this

The standards are the baseline minimum and even if harmonised, might not be sufficient for your product, in those particular use cases/conditions for that product, to actually give presumption of conformity!

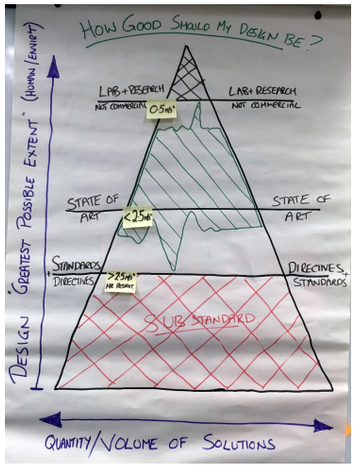
Summary Thus Far….

- Certification Plans and Test Plans are critical to successful Compliance
- Even better if you review both in advance with the third part test house chosen to perform the testing – Include their knowledge and experience
- If you are doing internal testing, accredited or not, ISO 9001/ISO 17025 are your friends. Using the principles within will help to achieve better, repeatable measurements (and looks better if the results are ever needed as evidence!) – Also reduces audit times

Example audit 2 days to half a day using ISO principles in presentation of documentation

Also....

- Consider State of the Art and Greatest Possible Extent
- This is often missed!



Supporting Your Stakeholders

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- Compliance Procedures/Processes with RASIC/RACI
- Templates
- Training
- (and coaching)
- All peer reviewed and agreed with critical stakeholders

- Bonus – For those that are in Agile organisations – Guilds, such as, Compliance Teams, Marketing, Engineering, Distributors

Communication

- Face-to-face where possible, teams if needed, e-mail only where necessary – no reply to all! Subject heading actually about the subject at hand!
- Ensure documentation presentation is for intended stakeholders and not for you. Dyslexic? Autistic? Easy to read?
- Write documentation not in the here and now (project nickname) but for a stakeholder new to the topic in 5 years time, and perhaps even with a language barrier
- This means, as standard English as possible (with technical language where needed of course)

We are not Shakespeare and you are not trying to get a degree – No essays here!

Communication

- Meetings – Clear chair, minutes AND OPEN ACTIONS WITH DELIVERABLES! – Oh, I thought you were doing that task!
- Network with experts and sign up to multiple sources of information to cross check facts/accuracy
- Examples, Compliance and Risks, Test House Seminars/White Papers, R&S Demystifying EMC, join Trade Associations & Standards Committees

Trade Associations & Standards Committees are often missed (cost and time) but the best way to integrate with your peers to determine the industry position and therefore state of the art plus steering the future of the industry you currently work in!

and finally…Test Houses

- Are only human. They are not perfect and accreditation does not mean perfection. Some of the best performing Test Houses I have worked with are not accredited! It all depends on what you want
- DO NOT KNOW YOUR PRODUCT!
- You are not the most important customer
- You delaying/changing/adding scope to projects is not profitable (profit is in big projects with quick turnarounds and no delays!
- SLA, Rate Card, Management Review of Performance (both ways!), Weekly Reviews of project status (Gantt chart in excel is fine). If you want it done quicker, then the rate card should cover your requirements

To Summarise

- By employing these systems and relationships, I have been able to maintain global Compliance Certification for varying types of products from easy (standard hi-fi amplifier) to complex (Robotics – Lawnmower)

- Going from 7/8 Market Authority topics a year to zero
- “Most Professional Company” - Test House Principal Engineer
- “Biggest consumer product contract” – Test House UK Operations Manager
- “Best Compliance department in the whole group” – Group lawyer for EU Member State
- “Trustworthy” – Test House (EU) Project Manager and Battery Testing expert (Now has set up his own test house!)

The End….

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ANY

QUESTIONS?

There is a whole theory on human reciprocation