

MIC MRA Workshop - Tokyo

Report Checking - Information validity and integrity
Guidance for Notified Bodies
DRAFT R&TTE CA Technical Guidance Note 20

Pieter Robben

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Your Certification Resource

American Certification Body, Inc.

Introduction

- History and background
- Draft Technical Guidance Note 20 (TGN20)
- Other relevant documents
- What's next?
- Important note



History and background

- May 2014 R&TTE CA meeting
 - Discussion about the possibility of creating a Technical Guidance Note (TGN) of how to deal with the issue of checking test reports from sources which are outside the control of the reviewer of a Notified Body for the R&TTE Directive.
 - It was agreed to prepare a draft Technical Guidance Note and make this available at the next meeting in 2014.



History and background

- December 2014 R&TTE CA meeting
 - Document “DRAFT TGN 20 Guidance for Report Checking – Information Validity and Integrity” was made available for review and discussion.



Draft TGN20 (summary)

- Introduction
 - The guidance is intended to help Notified Bodies to confirm the integrity and validity of test reports submitted by agents, manufacturers or test laboratories with which the Notified Body does not have consistent experience.



Draft TGN20 (summary)

- Introduction (continued)
 - The guidance in the draft TGN20 document is not exhaustive and simply contains suggestions for checking the validity of test reports.
 - It should help to guide the certification body in the decision of whether to accept the test report and/or test results or not.



Draft TGN20 (summary)

- Introduction (continued)
 - It is accepted that this guidance would not apply to all projects and all activities, especially in those cases where the Notified Body already has a good working relationship with the applicant.
 - The guidance applies primarily to those cases where the Notified Body has concerns about the validity and integrity of the test report which was submitted for review.



Draft TGN20 (summary)

- Guidance
 - Develop a good relationship with the applicant by discussing the project, not just accept the money without any questions.
 - Request a meeting or conference call with all associated parties; including the Notified Body, manufacturer, test laboratory and agent in order to eliminate concerns that one party has created data which is not supported by any of the others.



Draft TGN20 (summary)

- Guidance (continued)
 - Ask the test laboratory questions about how they tested the device and how it functions. Speak with the engineer directly.
 - When communicating with an agent; ask to copy the test laboratory and manufacturer on all correspondence.
 - When communicating with a test laboratory; ask to copy the manufacturer on all correspondence.



Draft TGN20 (summary)

- Guidance (continued)
 - When communicating with a manufacturer; ask to copy the test laboratory on all correspondence.
 - Ensure that the test report does not contain conflicting names of multiple test laboratories.
 - a report may be written by one test laboratory but measurements were performed at another.
 - It is acceptable to contract work from one test laboratory to another but this must be clear in the application and the test report.



Draft TGN20 (summary)

- Guidance (continued)
 - Look for different fonts or character styles throughout the report. Look for evidence of suspicious document editing or modification.
 - Check that the type of test results do match the type of device. Not just conclude “does it pass or fail” but also conclude “does it look right, for this product”. If the results are taken from another device, the clues may be found in the test results.



Draft TGN20 (summary)

- Guidance (continued)
 - Check that the (test setup) photographs are in focus and that they do clearly show the device under test. Verify that the device which is depicted in the photographs is indeed the device which was actually tested.
 - Check that the list of test equipment matches with the (type of) plots in the test report.



Draft TGN20 (summary)

- Guidance (continued)
 - Ensure that the test equipment listed in the test report does match with the equipment that was actually used for the test.
 - Check that the test setup photographs and the test parameters do match with the test equipment list.



Draft TGN20 (summary)

- Guidance (continued)
 - Check the calibration dates of test equipment and that the test dates fall within the calibration interval. Also check that the calibration dates do not appear to have been edited, changed or manipulated.
 - If you notice a mistake in a test report and report back to the applicant, how quickly is it fixed? A test laboratory should take time to investigate and even re-check their results.



Draft TGN20 (summary)

- Guidance (continued)
 - Ensure that changes and modifications to test reports are correctly inserted (ideally accompanied by a revision history and number).
 - Look for modifications that appear to have been edited on, or appear to be an editing modification of a document (e.g. modifications which were directly inserted in a PDF document).



Draft TGN20 (summary)

- Guidance (continued)
 - Do a thorough review and ask questions about anything of concern.
 - Feedback from market investigations does indicate that agents, manufacturers or test laboratories who create fraudulent documents or falsify test data do tend to seek out Notified Bodies who ask fewer questions.



Other relevant documents

- R&TTECA Technical Guidance Note 18 on the requirement for real results in test reports.
- Do not accept test reports which only contain the verdict “PASS”, “FAIL” or “NOT APPLICABLE” for all test results but do not contain any actual test results.



What's next?

- The R&TTE CA will continue to discuss this document with its members.
- After the final text of Technical Guidance Note 20 is approved, the document will be published on the R&TTE CA website (www.rtteca.com)
- Members of the R&TTE CA also have access to all relevant draft/discussion/final documents and meeting reports.



Important note

- R&TTE CA Technical Guidance Notes (TGN's) do not replace the text of the R&TTE Directive 1999/5/EC and are for guidance only.
- In legal disputes the text of the Directive, or its implementation in national legislation, takes precedence.



Questions?

- Contacts:
 - michaeld@acbcert.com
 - pieter@acbcert.com
 - www.acbcert.com

