AMERICAN COUNCIL OF INDEPENDENT LABORATORIES

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Timely Updates on Critical Standards

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In this issue we continue to focus on "news you can use"- i.e., new and pending changes to EMC standards that will cost EMC laboratory owners and managers money, test time, and/or will impose new or altered testing and staff training procedures.

Following our normal procedure, this issue first presents a brief review of the latest updates to some key EMC standards. Next, this issue covers the impact to laboratories on the complex subject of laboratory accreditation *corrective action documentation.* Specifically, we address those items that test labs need to submit to their Accrediting Bodies [ABs] in order to clear "findings", "discrepancies", or "nonconformities" that result from an ISO/IEC 17025:2005 audit. At the end of this newsletter is a list of upcoming standards-related workshops that may be of interest to our members.

Latest EMC Standards Updates

IEC 61000-4-4 Edition 2, Amendment 1 published 2010-01

Standards Alert Vol. 2, No. 1 described the proposed amendment to the second edition of IEC 61000-4-4. The amendment was published with no change from the document reviewed in the previous Standards Alert. So, what was indicated in Vol. 2, No. 1 continues to be accurate.

IEC 61000-4-3 Edition 3, Amendment 2 published 2010-03

This amendment adds a new informative Annex J to the third edition of 61000-4-3. The entire focus of this new annex is the measurement uncertainty (MU) resulting from the test instrumentation used in the electric field strength calibration process and in the testing process. The purpose of this annex is to assemble MU budgets that clearly state which influence quantities (i.e., contributors) are taken into account. The objective of this Annex is to ensure consistent usage between test labs so that stated MUs will be comparable.

Items considered include the influence contributors to MU such as: field probe calibration, antenna and absorber location, and power amplifier output level uncertainties. There is also an example of MU for establishing the text level. All the terms used in the example are then described in some detail.

A strong statement at the end of the annex says that the MU calculation is not intended for adjusting the test level applied to the EUT. That does leave open the question as to what to use the uncertainty for. Perhaps, the intent was to allow someone to examine the MUs from different test labs as an aid to deciding which lab to use based on having the lowest level of instrumentation MU and thus most repeatable results.

Interpretation sheet No. 2 [IS 2] for CISPR 22, 6th Edition

The IEC has issued a new interpretation sheet for CISPR 22 dealing with the selection of impedance stabilization networks (ISNs) applications on multi-pair cables when performing conducted emission tests.

First of all, it needs to be understood that an Interpretation Sheet [IS] is NOT a change to a standard. Rather, it is intended to clarify the meaning and/or intent of some portion of a standard if it can be misread.

IS 2 first addresses the question of which ISNs to use in the case of measuring a multi-pair cable. Specifically, should it be an ISN that connects to all pairs, even those that are not actively passing signals to be measured? Or, should only the active pairs be terminated in an ISN? IS 2 then gives examples of which ISN (out of the many listed in annex D of the standard) should be used based on all pairs in a cable being active or only some of the pairs being active in a multi-pair cable. That decision then has to be stated in the test report, which must specifically state which ISN was selected when performing the test.

The test labs should carefully read this interpretation sheet so that the test plan identifies which pairs (or all) of a customer supplied cable has signals transmitted as part of the normal application. This has to be sorted out before starting the test.

The last issue discussed in IS 2 is the length of the cable to use between the telecom port and the ISN. Other than keeping that cable 40 cm above the reference ground plane, there is no length stated. The clarification presented in IS 2 indicates that the lab is to use a cable length as short as possible, such that no cable bundling is necessary.

Correcting lab audit findings

Introduction

Many of the ACIL CAS Member Laboratories are (or plan to be) accredited to ISO/IEC 17025:2005 with a Scope of Accreditation that includes EMC testing. A key aspect of obtaining and maintaining an ISO/IEC 17025:2005 Accreditation is the bi-annual on-site audit. During these audits, the assessor (who is sent to the laboratory by the Accrediting Body [AB]) reviews the competency of the laboratory using ISO/IEC 17025:2005 ("General requirements for the competence of testing and calibration laboratories") and other AB-specific and/or test-specific checklists.

As a result of his/her audit of the laboratory, the assessor identifies “findings” (sometimes called "deficiencies" or “non-conformities”) in those areas where the laboratory was found not to comply with some specific portion of ISO/IEC 17025:2005, or some specific clause in a standard, etc. It is up to the laboratory then to separately address (in writing) each of these "findings" with a document or a set of documents that details what they will do to correct their process and/or test activity (as applicable) to meet the requirements of ISO/IEC 17025:2005 and/or a standard. The laboratory must provide these "corrective action" responses to the AB (and possibly to the assessor) in a timely manner. These "corrective action" responses are then used by the AB (and/or the assessor) to determine the adequacy of the laboratory’s response. In addition, those "findings" that are judged by the AB and/or the assessor to be not critical to the operation of the laboratory and to the tests performed by the laboratory are then reviewed generally at the next audit. In contrast, if one or more "findings" are judged to be critical by the AB and the assessor, a re-audit of the laboratory may be required. This is in addition to the "corrective action" responses documentation provided by the laboratory and is done to see if the underlying problem has been adequately resolved.

It is thus imperative for a laboratory to respond to each "finding" with a degree of urgency that is appropriate to the issue, and to ensure that the "corrective action" response is adequate. An adequate response would typically include, for example, a root cause analysis of the problem, and the issuance of revised work procedures or the issuance of new procedures that are written for those areas not previously addressed. Merely stating that something will be done as a corrective action without objective evidence (i.e., documented proof) may well be judged to be an inadequate response.

Major areas of non-conformities

Most ISO/IEC 17025:2005 on-site audits last from two to five days. Within those time constraints, there are many areas where non-conformities can be found. Remember that during the on-site audit, the assessor is looking at tests being performed, test reports that have been previously issued, calibration certificates, business processes, results of internal audits, etc. in addition to the contents of the Quality Manual and the test processes. This is a daunting task, and one where there has to be focus in “selected” areas with the expectation that the next audit will cover those not addressed during the present audit.

Listed below are six of the major areas where assessors frequently find non-conformities:

Calibration of test equipment
ISO/IEC 17025:2005 Clause 5.4 Test and calibration methods and method validation

Calibration Traceability
ISO/IEC 17025:2005 Clause 5.6.2.1 Measurement traceability-Calibration

Using accredited calibration laboratories/Calibration performed by test lab
ISO/IEC 17025:2005 Clause 5.6 Measurement traceability

Test Methods
ISO/IEC 17025:2005 Clause 5.4.2 Selection of methods

Test Equipment
ISO/IEC 17025:2005 Clause 5.3 Accommodation and environmental conditions and 5.5 Equipment

Uncertainty
ISO/IEC 17025:2005 Clause 5.4.6 Estimation of uncertainty of measurement

For each of the above six (6) areas, here are typical findings/ non-conformities.

1. Calibration of test equipment.

Laboratories have choices in sending out their equipment for calibration either to an accredited calibration lab, or to perform the required calibrations in-house. When equipment is sent out for calibration, a typical non-conformance is one where the purchase order for the calibration does not state exactly what is needed. For instance, the required values of impedance over the entire frequency range of use, or a statement about which calibration standard must be used, or a statement requiring that a measurement uncertainty statement be included on the cal certificate. When equipment is calibrated in-house, a typical "finding" is one where the laboratory has failed to satisfy either the AB's requirements for personnel training and/or the AB's requirements for the calibration of reference instrumentation (which must be traceable to a national standard to perform the calibration), all of which are integral parts of the laboratory's quality program.

2. Calibration traceability

Laboratories that use either calibration laboratories or do in-house calibrations need to show that their results are traceable to some authoritative source. Normally this authoritative source is a national laboratory, such as NIST in the US. That does not mean NIST does the calibration. It means that the calibration instrumentation must have what is called an unbroken chain of calibration traceability that link to a primary standard such as the volt or ohm. In ISO/IEC 17025:2005, the link must be to a primary standard given in SI Units (*Système international d'unités*). This traceability link must be available to the assessor, so that he/she can determine its suitability. What is found at times is that the instrumentation used to locally (by the test lab itself for example) calibrate test equipment loses its traceability back to the primary standard as it instead is traced back to only a locally used instrument such as a spectrum analyzer or power meter that itself was not calibrated with a traceable source.

3 Using accredited calibration laboratories/calibration performed by test lab

In most cases, the easiest way (and the way that AB's most commonly prefer) to meet ISO/IEC 17025:2005 traceability requirements is to use an ISO/IEC 17025:2005 accredited calibration lab that has within its Scope of Accreditation the parameters and/or instruments that are required to be calibrated. A common "finding" is that one or more of the Calibration Certificates/Reports obtained by the laboratory are not endorsed with the AB-specific "ISO/IEC 17025:2005 Accredited Calibration" symbol.

Nothing in ISO/IEC 17025:2005 precludes a laboratory from conducting its own calibrations for those items of test equipment that need only general-purpose laboratory equipment for their own calibration. If this is done, it places more constraints on that piece of general-purpose lab equipment - i.e.., that it has to have its calibration traceable to a national primary standard and generally has specific additional requirements by the AB. Failure to establish adequate proof of traceability for the equipment used to perform the in-house calibrations is a common "finding".

4. Test Methods

Following the test method standard is, of course, the best course of action. Assessors are trained what to watch as they witness a test in progress. A common "finding" is that laboratories tend to miss making records of the environmental conditions where the test is performed. For example, if an ESD test is being performed, is there a record on the data sheet of the relative humidity level as measured using a calibrated hygrometer? Another example: If a test is performed outside of a shielded enclosure / RF Anechoic environment, has the level of the RF ambient been recorded to show that there is adequate headroom to measure a quantity above the noise floor? Another common "finding" is uncontrolled test software. - For instance: When the tester can modify the software to speed up the test. Why is that allowed?

5. Test Equipment

Test standards provide a lot of detail about the equipment needed to perform tests. Equipment must be available (and must actually be used) which meets the required test para-

parameters and specifications. For example, an FCC Part 15B Section 15.107 conducted emission test cannot be performed if there is no Line Impedance Stabilization Network (or Line Voltage Probe) attached to the input power line of the EUT. A more subtle example is the case of an antenna that cannot be used if the emission being measured is out of the antenna frequency range (this is especially a concern at frequency band breaks where the antennas need to be changed). Although these examples seem obvious, failure to have or use the required equipment is a common "finding".

6. *Uncertainty*

This is a subject that has been met with skepticism at one extreme and enthusiasm at the other extreme. For calibration laboratories, ISO/IEC 17025:2005 is clear that uncertainty must be reported along with all other relevant information in order to have a traceable equipment calibration. For test labs, the ISO/IEC 17025:2005 requirements on the use of Uncertainty Statements contains ambiguous wordings such as:

- Where applicable
- When relevant to the validity or application of test results
- When client's instructions require
- When uncertainty affects compliance to a specification limit

Recently, as reported in the last Standards Alert, the 5th edition of CISPR 11 (*Industrial, Scientific, and Medical equipment—RF disturbance characteristics—Limits and method of measurement*) states that compliance is determined by measurement results, taking into account consideration of measurement uncertainty. In the 6th edition of CISPR 22 (*ITE -radio disturbance characteristics-limits and methods of measurement*), measurement uncertainty (MU) shall be calculated and both measurement results and MU shall appear in the test report, but MU will not modify the test results. So it is clear "where applicable" applies, "when relevant to the validity or application of test results" and "when uncertainty affects compliance to a specification limit".

It is rare that a client instructs the test lab to explicitly require MU be considered in the test plan. This reminder is not needed if the test is for CISPR 11 5th Edition or for CISPR 22 6th Edition because, as noted above, the MU considerations are already embedded. But for other tests (including but not limited to immunity tests), the client may not know what "considering MU" means, but the test lab should.

The method and standard to use in computing MU should typically be one that is internationally applied. This is because most products are sold internationally and hence any test report that is scrutinized is on firmer ground if the MU reference is an internationally accepted one, such as CISPR 16 -4-2 (*Uncertainties, statistics and limit modeling—Uncertainty in EMC measurements*).

In CISPR 16-4-2 there are several influence factors (terms in the MU equation) taken into account. For radiated emission measurements, these factors range from antenna factor uncertainty to the reading on a receiver or spectrum analyzer. There are about a dozen factors that are shown as examples. Non-conformities arise when all the major factors are either not present in the MU calculation or the values given are suspect. One such suspect shows when the test laboratory simply repeats the example values shown in CISPR 16-4-2. What must be done is to determine fresh values applicable to the measurement instrumentation chain of the laboratory being audited, which is almost impossible to be identical to that in CISPR 16-4-2. Another finding occurs when the laboratory personnel cannot explain how they arrived at the values used for each influence factor. The importance of the correct way to calculate MU cannot be overemphasized, as for example, it is needed to determine how to apply MU in the 5th edition of CISPR 11.

Corrective actions taken by labs

How do labs respond to findings/non-conformities is quite diverse from a few words to detailed modifications of the quality manual to even appeals that the finding was not warranted. There are simple "rules" to use in responding. The corrective actions should:

1. Cover only the "finding", "non-conformity" or "deficiency" and not ramble into other topics.

2. Provide objective evidence that corrective action was actually taken. This objective evidence might include the text of the modification of the quality manual, minutes of staff meetings where the corrective action was discussed (signed by who gave the talk and who was in attendance), providing copies of missing calibration certificates, and so on.

3. Determine the impact of the non-conformity on testing performed *before* the assessment found that non-conformity.

4. Not only indicate that corrections will be made in the future, but in fact when will it be accomplished. This is particularly critical if the finding impacts test results up to the time of the audit. If test data are impacted, the laboratory must not wait for the next audit to describe the impact as that audit might be as much as two years later. Thus this corrective action has to be documented and provided to the assessor for acceptance quickly.

5. Provide all proof in the language that the AB uses to assess competency.

6. Ensure that any new procedures and processes are entered

into the quality system and that process itself is documented.

7. Deliver clear evidence if the "finding" is not supportable by a specific clause in ISO/IEC 17025:2005 or a clause in a testing standard. All findings need to be written against a requirement. Note that ABs may also have specific requirements when auditing particular test methods in the scope of the test laboratory that must meet regulatory needs. These are generally in the form of a separate checklist for the assessor to use in the audit over and above that of 17025. At times laboratories confuse which edition/version of the standard to use as it may not be only the latest version that the regulatory checklist is invoking. Finally, ABs may have particular policies on what they require. There are, for example, different policies on how to use MU or not to use MU as there are still some questions on how to calculate MU including all applicable influence quantities.
8. Where relevant, show that the customer involved with the "finding" agrees with the corrective action.
9. Where relevant, indicate not only the approved vendor/ supplier list, but if it is a calibration vendor/supplier, indicate that it is (or is not) accredited to perform the calibration requested.
10. Where relevant, provide not only classroom/OJT for a test in an area found needing training during the assessment, but have the results of an examination or practical proof of competency test showing that the person trained is competent. Those results should then be placed in the person's training records.
11. Where relevant, compute measurement uncertainties so that they include *all* the key influence contributors/factors that are indicated in such references as CISPR 16-4-2. There must not be any incidences of omitting key components in the measurement instrumentation chain.
12. Where relevant, provide proof that the laboratory knows what the differences are in similar (e.g. ,different editions with amendments) standards. This is critical as it has to be clear to the assessor that the laboratory knows what is required when an older edition of a standard is used for testing as required/requested by the customer.

Looking Backwards While Moving Forwards

We have reviewed the various items needed when addressing audit "findings". One other key point needs to be stressed: Specifically, if there are "findings" that are substantially addressed by, for example, statements such as: "... the problem with the testing will be fixed", or "... the equipment instrumentation will be recalibrated using the correct method or by an accredited cal lab", then the laboratory has to determine the impact of these "findings" on tests performed before the audit date.

For example, if a test was performed with an antenna that was subsequently found to have been calibrated using an inappropriate standard (or was found to have been incorrectly calibrated, or was calibrated by a cal lab that was not accredited), what is the impact on all of the tests that were performed with a questionably-calibrated antenna? If the impact would be that, for products with small compliance margins, they may now potentially fail (even though a pass was achieved with the questionably calibrated antenna), the question then becomes: "How will the lab notify their customers about this issue?", and "Will a retest be required using a properly calibrated antenna?"

Remember the changes in CISPR 11

In the August 2009 edition of the ACIL EMC Standards Alert Newsletter, we identified that the latest (i.e., 2009) edition of CISPR 11 contains the full implementation of CISPR 16-4-2 on measurement instrumentation uncertainty. This goes beyond simply calculating MU. It now indicates how MU is to be used in modifying the actual measurement result, which is then compared to the emission limit (s). The next edition of ACIL EMC Standards Alert Newsletter will provide more information on the application of MU as expressed in CISPR 16-4-2. The important point to note is that under certain conditions, simply having a measured result under the limit may not be an "unequivocal" pass when MU is taken into consideration. This obviously greatly affects the test laboratory's relationship with its customers, especially if an initial measurement is a "pass" but when taking into account MU, it becomes a "fail" by a "calculation", rather than as a result of a "visible" measurement.

So, be aware of the impact of MU on whether or not you can unambiguously state "pass" or "fail", especially for products having small EMI margins with respect to the applicable limits. Failure to correctly account for the effects of MU on statements of compliance will, no doubt, become a common "finding" in the future.

Upcoming Workshops

1. A workshop on ANSI C63.10 wireless transmitter measurements to meet the FCC Unlicensed Transmitter Rules will be held on 15-16 June 2010 at UL in Northbrook, IL. Information on registration is posted at the top of the home page of the iNARTE web site (www.narte.org).

2. The ANSI C63.4/C63.5 Time Domain Workshops will be held on 23-24 July 2010 - i.e., the Friday and Saturday before the start of the IEEE EMC Symposium in Ft. Lauderdale, FL. Registration information is provided as part of the advance program for the IEEE EMC Symposium (www.emc2010.org) or in the printed version on page 27.

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