Life & Health

Q&A WITH UL

IEC 60601 3RD EDITION – RELEASE 2*

CONTENTS

*New & revised items identified with an asterisk (*)

Underwriters Laboratories Inc.
333 Pfingsten Road, Northbrook, IL 60062-2096 USA
T:: 847.272.8800 / F:: 847.272.8129 / W:: ul.com

IEC 60601 3rd edition and existing 2nd edition products

Q1: **What do I have to do when 3rd edition goes into effect for devices already on the market?**

A1: Because the regulatory requirements vary from region to region, it depends on where the product is being sold. Presuming the device has been cleared for the market, once the transition dates for regulatory approvals are here, for each regulatory submission, the regulators will be looking for use of recognized consensus standards in technical files/product submissions (such as 510(k)) including revisions to existing products. In some markets, including the EU, any existing products will also need to demonstrate conformity with the 3rd edition.

- EU requires compliance with state-of-the-art – even considering existing products
- FDA traditionally doesn't require recertification. The organization is revising this
- UL will support and maintain the 2nd edition as long as market needs it and it's legal

It's always best to confirm requirements with the regulatory authority regarding the specific region of interest.

For devices already with the UL classification mark, UL can provide a gap review of the previous test data to avoid duplicate tests, and then work with our customers to see whether you want to maintain dual certification to both the 2nd and 3rd editions to support requirements in multiple markets. We will then prepare a test plan to meet your needs for the applicable country differences. If the product is going into a market that recognizes the 3rd edition, then we will complete a distinct 3rd edition test report form in addition to the 2nd edition test report form.

Q2: Will we have to maintain 2nd edition certification on a product as it is being upgraded to the 3rd edition?

A2: If you already have a product that has been tested and classified to the 2nd edition and are in the process of upgrading to 3rd edition, the 2nd edition certification remains valid unless you make changes to the device. Once you complete the transition to the 3rd edition, you can decide whether or not to maintain the 2nd edition classification.

Note: This will be dependent upon the regulations for the target markets in which the device will be sold. That is, the timing of the dates for implementation of the new standard do not necessarily align in all geographies. Therefore, you will need to determine the status of the acceptance of the different editions of the standard in the markets you wish to sell to.

Q3-Q5 Available for download by UL customers only through **MyHome @UL.**

Q6: I have an existing product with no safety issues or field problems for 10 years. Can we use field history as justification for 3rd edition submittals?

A6: Field experience can be used, but it cannot be the sole basis of establishing compliance with the 3rd edition. For 3rd edition certification, the manufacturer's risk management process will be assessed, i.e., field history alone is not a presumption of compliance.

Q7: What are the specific differences in requirements between the 2nd and 3rd editions?

A7: This question requires a very detailed response. Given the risk management allowance, this can vary from product to product. If you have product-specific questions, please contact UL for a gap assessment. For general standards training, UL University offers courses in 3rd edition requirements, and UL also offers a 1 hour webinar highlighting the major changes to the standard.

General risk management & post market surveillance

Q1: Am I required to have a risk management audit to receive a UL mark to 3rd edition?
A1: No. UL offers manufacturers the option of a desktop assessment to 3rd edition.

Q2: How do we demonstrate a lower level of risk compared to the standard?
A2: You can demonstrate it by showing that your risk acceptability criteria are lower than those established in the standard.

Q3: What is different between what I do now for risk management versus what will I have to do for risk management with IEC 60601 3rd edition?
A3: It depends on your current processes. Most manufacturers have some of the pieces in place. The risk management file is key to completing a 3rd edition assessment and will need to capture the outputs of your risk management process that are applicable to the product as per ISO 14971.

Q4: Regarding the risks involved with off label use of my product, how proactive do you need to be for risk assessment?
A4: The guidelines call for foreseeable misuse, which could include some off-label usage. If it becomes very common, a manufacturer could apply for approval of the off-label use indication which may also qualify them for reimbursement.

Q5: When we develop risk acceptability criteria, theoretically, management may sign off on it but the certification body might not. How do we plan for that?
A5: By using recognized, harmonized standards, single fault failure criteria, and including robust documentation to show the certifier why the risk acceptability criteria is appropriate. Use documentation to show the "how" and the research you did.

Q6: What option do I have to learn about risk management as it pertains to my product?
A6: UL University offers public ISO 14971 training courses. These are also offered privately to explore specifically how the standard applies to your product. UL also offers gap analysis to ISO 14971 and 3rd edition to review your product's compliance and non-compliance with the standard.

Q7: My company is registered to ISO 13485, what are we auditing against right now?
A7: ISO 13485 is the internationally recognized standard for "Quality Management System – Requirements for regulatory purposes." There is a reference to ISO 14971 for risk management in clause 7.1 of ISO 13485 under "Planning of product realization", and in clause 7.3 "Design and development". Please note, however, that the reference in clause 7.1 is in a "Note". As such, this is considered an "informative" reference (use for guidance but not required) as opposed to a "Normative" (mandatory to use for compliance) reference. Therefore an ISO 13485 registration is no guarantee of full compliance with ISO 14971. There are many more requirements in ISO 14971 that are clearly not contemplated in ISO 13485.

Q8: Is there a preference to using ISO 14971 registration/on-site versus desktop assessment of risk management clauses?
A8: It depends on what makes sense for your business situation. For several reasons, many manufacturers choose the desktop assessment as their certification path and UL is ready to support that option. The 3rd edition makes over 100 references to the risk management file, and for each of those references, multiple clauses from ISO 14971 must be assessed for compliance. Objective evidence (documents) must be provided to demonstrate conformity with each of the clauses of ISO 14971. This may represent a significant documentation burden. As a result, many manufacturers

may find it advantageous to meet with their certification engineer on their premises where it will be comparatively easy to locate the required documentation and populate the TRF with the various references. Some manufacturers that produce multiple devices within a year have elected to pursue the registration as a means of eliminating redundant documentation efforts, even though this is not a UL requirement to do so.

Also note that just as with 2nd edition assessments, the manufacturer can also have an engineer come to their location to do the 3rd edition "desktop assessment without a formal audit and ongoing registration.

Q9: How do we determine what the international markets require for post market surveillance and how do we reach resolution to satisfy conflicting requirements?

A9: Post market surveillance is not a requirement of the 3rd edition, but is required by some regulatory agencies throughout the world. The regulatory agencies determine the regulatory requirements for each device type. See the UL white paper titled "A REVIEW OF MARKET ENTRY REQUIREMENTS FOR RISK MANAGEMENT, WITH SPECIAL EMPHASIS ON FDA AND ISO 14971 COMPLIANCE" which can be downloaded on the thought leadership pages of UL University website at **www.uluniversity.com** .

Q10: When and how would this issue of post-market surveillance interpretation of the 3rd edition come up?

A10: As part of the regulatory legal market entry process as noted above.

Q11: What is the manufacturer's responsibility for resolution?

A11: It is the manufacturer's responsibility to insure that they conform to, and can demonstrate compliance with legal market entry requirements.

Q12: Residual risk – most companies look at worse case, but residual risk is in all degrees. How do you assess this or handle this?

A12: Manufacturers must demonstrate they are working as state-of-the-art (SOTA) by some of the following methods:

- Demonstrating compliance by using SOTA standards such as ISO 14971
- Comparing their risks with other products on the market to see what other companies and competitors are doing
- Demonstrating this through documentation which the certifier will review

CB Scheme and the 3rd edition

Q1: How do you insure cross country acceptance of CB reports?

A1: The CB Scheme (IECEE) is set up for the mutual exchange and acceptance of test data. The work the IECEE Risk Management Task Force committee team members are doing is focused on insuring the test report data generated by one NCB is accepted by the other NCBs. The IECEE is now providing support to other member laboratories for the understanding of the requirements as evidenced by the September meeting in Milan to train NCB staff on these requirements. Note that this is supported directly by several UL staff members presenting at the September Milan meeting.

Q2: Are there changes in follow up services for CB Scheme?

A2 The CB scheme does not require follow-up services. Once you receive your CB test certificate, there is no additional surveillance activity by the NCB. Manufacturers should be aware, however, that regulators in various countries may have specific requirements related to follow up that are not covered by the CB Scheme. Manufacturers are encouraged to check with the regulators in the countries where their devices are to be sold to identify any specific requirements that may apply.

Q3: How will the IECEE 3rd edition Guidance Document be available to manufacturers?
A3: The IECEE has issued a guidance document explaining what is expected when populating the Risk Management clauses of the TRF. We expect that the Guidance document will be available on the IECEE website in the near future. When it becomes available, we will let you know.

Q4: Is a new CB scheme report required and when? What data would be required?
A4: As noted above, the CB Scheme is an agreement by member test laboratories for the mutual exchange and acceptance of test data. As such, any CB report is strictly voluntary for a manufacturer i.e. a CB Report is not required by regulators for market entry.

Q5: Knowing that the CB scheme certificate must be refreshed every 3 years, would a current CB report to the 2nd edition be an Appendix for a new report to the 3rd edition when the new TRF is in place, so that tests would not have to be redone?
A5: In renewing an expired 2nd edition CB license for a product that has undergone no changes (many manufacturers typically utilize the license renewal timing to introduce some product changes for a previously certified device), wherever possible UL will leverage any 2nd edition test data when creating a 3rd edition TRF to avoid any duplicate testing between the 2nd and 3rd edition. That is, when the existing CB Scheme rules for renewal of certificates have not changed with issuance of the 3rd edition. It must be recognized that there are differences in the technical content of the 2nd and 3rd edition, and as such, some additional work and testing may be anticipated in renewal of a certificate.

Q6: Would a supplemental TRF be used to tie to the original test done but that meets requirements for the 3rd edition?
A6: The intent of the question is not fully clear. However, if the intent of the question is to determine acceptable formats for a CB scheme 3rd edition TRF where a particular device already had in place a 2nd edition CB TRF, then it is possible that a supplementary 3rd edition TRF could be added to a 2nd edition TRF. This may be a question of practicality though. To create the supplementary 3rd edition material in a TRF style would require a detailed review of the entire TRF. And because of the many references to the risk management file and supplementary references and detail that are required, the resulting combined 2nd and 3rd edition TRF may be too large to be of practical value. Instead there may be more benefit to simply referring to the 2nd edition material in a single consolidated 3rd edition TRF.

Q7: Will testing to the 3rd edition be allowed under the Supervised Manufacturer's Test Program (SMTP) in the near future?
A7: Formal guidelines have been drafted and submitted to the IECEE for review and adoption; in the interim, UL is following the approach developed for UL's Data Acceptance Program (DAP) which the UL DAP team can provide upon request. Erik Sorensen of the UL DAP team is available to provide additional guidance.

Notified bodies and the 3rd edition

Q1: Does the RM file become part of the notified body (NB) technical file?
A1: Yes

Q2: If I have a class 1 device, would in-house testing work for MDD?
A2: Yes, for class 1 devices under MDD no notified body intervention is required (assuming that the product does not perform measuring functions or placed on the market in a sterile state)

Q3: What is the DOCOPOCOSS for ISO 14971?
A3: The DOCOPOCOSS for ISO 14971:2007 was 31 March 2010. This means that in EU the use of the 2000 edition of ISO 14971 will not provide a presumption of conformity to the essential requirements of Annex I.

Q4: Where can I find the DOCOPOCOSS online?
A5: See this link:
http://www.cenelec.eu/Cenelec/CENELEC+in+action/Horizontal+areas/ICT/Collateral_standards_under_MDD_AIMD.htm

Q5: Do requirements apply to AIMD?
A5: 60601-1 3rd edition is a recognized consensus standard and a product assessed to the 3rd edition would provide a demonstration of conformity to the AIMD.

Q6: When will I need to comply with the 3rd edition for the IVD and AIMD directive from an essential requirements perspective?
A6: The DOCOPOCOSS is June 30, 2012. At that time, it will be state-of-the-art in the EU for any applicable directives.

Q7: The MDD was recently revised. What if a device is covered under two directives?
A7: The manufacturer must still demonstrate conformity to the MDD and the rules for use of harmonized standards are unchanged.

Q8: CE assessment, MDD, DAP audit – is it a combined audit with the CE mark?
A8: UL can provide a combined assessment and integrate "like" clauses for one or all of these programs.

Q9: Does the NB expect us to have an ISO 14971 compliant system in addition to ISO 13485? Is it a requirement?
A9: Both ISO 14971 and ISO 13485 are harmonized standards and the NB will accept these. It is not necessary to have an ISO 14971 registration for MDD application but it would demonstrate that the manufacturer has met the standard requirements, in much more depth than can be given as part of an ISO 13485 or CE assessment.

Amendment 1 to IEC 60601-1 3rd edition

Q1: Amendment 1 – what has changed?
A1: Amendment 1 is a comprehensive and pervasive proposal affecting most of the 3rd edition. Significant items include but are not limited to the following:

- Eliminated reference to IEC 61558
- Clauses 8 and 9 of ISO 14971 would not be assessed
- A new clause has been proposed that requires compliance with IEC 62304 for software

Note: When the Amendment 1 is issued for public comment, we encourage manufacturers to review the many proposals in detail and provide comment as appropriate, as the changes are of a significant nature.

Q2: Once Amendment 1 is complete/approved, how long to issue the TRF?
A2: A TRF is typically published about 4-6 months after publication of the revisions as part of the international standard.

Test report form (TRF) and the 3rd edition

*Note that UL University offers a workshop "Documenting Required ISO 14971 Risk Management File Elements in the IEC 60601-1 TRF."

Q1: Are there reductions in work required in the TRF for the 3rd edition?

A1: The 3rd edition has more clauses than the 2nd edition and also incorporates risk management. Therefore, the 3rd edition TRF is longer than the 2nd edition and will most likely require more time to complete.

Q2: Are the risk management tables the same as other tables?

A2: The risk management tables are intended to serve the same purpose: as a method for documenting decisions.

Q3: When will the final version of the TRF be adopted?

A3: The TRF is a work in progress that is constantly under review and subject to revision for improvement. Refer to the current version that has been released and is for sale on the IEC website **http://webstore.iec.ch/** (Search for IEC/TRF 60601-1).

Q4: How does existing test information get recorded in the TRF when the test doesn't have to be redone?

A4: The 3rd edition TRF is filled in with an explanation of where the data came from. In some instances, this level of detail can be included as an attachment.

Q5: How does a certification body complete the TRF?

A5: The TRF has check boxes for pass / fail / not applicable (N/A). It will be completed much the same as a 2nd edition TRF, except for the guidance document used to clarify what is expected when populating the risk management fields in the TRF. The certification body will need to work closely with the manufacturer to review the risk management file and identify the objective evidence demonstrating compliance with 3rd edition risk management clauses.

Q6: Where can I get the TRF?

A6: The TRF is a copyrighted document published by the IECEE. It is available for sale on the IEC website at **http://webstore.iec.ch/** (Search for IEC/TRF 60601-1).

Q7: I would like additional detailed information on use of the TRF with 3rd edition risk management requirements.

A7: This information has been drafted by the IECEE Risk Management Task Force (RMTF) as a guidance document and it is available only to NCBs and CBTLs at this time. UL will provide information as it becomes available through our email subscription and LinkedIn Group.

Q8: Where can I learn in detail about the 3rd edition elements; test report form, risk management and the question/answer approach?

A8: In support of our customers, we provide regular updates via email, LinkedIn, and our website. UL Health Sciences experts are also active in industry, presenting papers, writing articles and participating in panel discussions on the 3rd edition.

For more formal training, UL University (ULU) offers a variety of options for learning the details around 3rd edition, including intensive multi-day technical training, custom training designed around your needs, products, and schedule, overview webinars and online learning options, and industry papers. Visit **www.uluniversity.com** for more information.

Q9: With respect to instructions for use, what do you put in the technical file?

A9: For the CB Scheme, the instructions for use (IFU), requirements for the 3rd edition are the same as the 2nd edition. Each regulator may have its own requirements.

Q10: Which version of the TRF is current?

A10: *As of January 2011, Version "F" is current.

Q11: When a certification body finds the reference in the risk management file, does the certification body interpret or judge the reference?

A11: A certification body will look at the risk management file (RMF) and other supporting documentation to assess the manufacturer's risk management processes against the requirements of the standard. Note that manufacturer "A" can establish one way to manage risk, and manufacturer "B" can have a different way.

Particular and collateral standards for the 3rd edition

Q1: Will certification to collateral standards be mandatory for CB-Reports?

A1: The IECEE CMC continues to review and address this question. For the most current information, please see the table issued by the IECEE named, "Use of collateral standards in the IECEE system for 2nd and 3rd Editions of IEC 60601-1", found at this link http://www.iecee.org/60601_collaterals.pdf . .

Q2: Are collateral standards required to issue a UL Mark?

A2: In reference to 3rd edition submittals, collateral standards are not required for issuance of the UL Mark at this time. However, as noted in Q1 before, some collateral standards such as 60601-1-11 are required for NCBs to issue a CB Test Certificate to IEC 60601-1, 3rd edition. Please see the table issued by the IECEE named, "Use of collateral standards in the IECEE system for 2nd and 3rd Editions of IEC 60601-1", found at this link http://www.iecee.org/60601_collaterals.pdf .

Q3: Where can I find more information about the adoption of particular and collateral standards?

A3: The regulatory agencies will generally list the standards they recognize as they are adopted. The best way to confirm what is adopted / accepted is to visit the source:

a. European Union go to **www.cenelec.org** - Search "60601"
b. CB Scheme go to **www.iec.ch** - Search "60601"
c. FDA visit recognized consensus standards database **http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm**

Q4: Will there be TRFs for all particular standards associated with IEC 60601-1 3rd edition?

A4: The IECEE will generate TRFs for 3rd edition particular standards according to industry demand. As a point of reference, TRFs do not now exist even for all 2nd edition based particulars.

Q5: If my company is releasing a product with a particular standard that references the 2nd edition and there is a conflict in requirements between the 2nd and 3rd editions, how do you make the decision with which to comply?

A5: The particular standard is the standard that has priority. You have the option of maintaining a version of the device that complies with the 2nd edition and another version that complies with the 3rd edition. We recommend you discuss any decisions with any involved regulatory agency to insure the agency agrees.

Q6: Will UL be supporting the collateral standard for home use, IEC 60601-1-11?

A6: UL has been involved in developing the IEC 60601-1-11 for home use standard and will be actively certifying medical devices for use in the home. We are also involved with FDA's home use initiative.

Q7: What environmental concerns are there with 60601-1-11?

A7: While 60601-1-11 addresses hazards in the home environment such as cleanliness, power integrity, etc., environmental concerns are primarily covered in the collateral standard IEC 60601-1-9. There is, however, an additional requirement. Specifically, sub-clause 7.4.9 of IEC 60601-1-11 requires that the instructions for use include information concerning the proper disposal of the equipment, its parts or accessories as may be applicable, as well as a statement that the lay responsible organization is to contact local authorities regarding the proper disposal of potentially biohazardous parts and accessories.

Usability and the 3rd edition

Respectfully answered by and published with permission of Michael Wiklund, co-author of AAMI HE74:2001, Human Factors Process for Medical Device Design

Q1: If my product meets the human factors expectations set forth in ISO/IEC 62366:2007, does it essentially meet the expectations set forth in ANSI/AAMI HE74:2001?

A1: This is a fair assumption, specifically because the core content in AAMI HE74:2001 is provided as Annex D in IEC 62366:2007. However, to satisfy FDA, be sure to place a sufficient focus on identifying use errors in the course of summative, i.e. validation, usability testing and then perform follow-up risk analysis. FDA provides substantial guidance on this topic in "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management," by Ron Kaye and Jay Crowley. Moreover, to satisfy the EU's notified bodies, be sure to establish usability goals and acceptance criteria during the design process and then test against them during the summative usability test.

Q2: Is it accurate to say that the FDA is concerned about a medical device's use-safety but not usability per se, but that the EU's notified bodies are concerned about both attributes?

A2: This is fairly accurate. The FDA has made a point on several occasions that their interest is focused squarely on use-safety while usability is usually more of a commercial concern for manufacturers. However, they have also made the point that a preponderance of usability problems, and particularly those that could delay a time-sensitive therapy, do concern them to the extent that they could have safety ramifications. So, manufacturers' usability test reports need to clearly differentiate among use errors that pose a risk to users/patients and use errors that are not would only influence users' satisfaction with the device. Meanwhile, the EU's notified bodies are looking for manufacturers to establish quantitative usability goals and associated pass/fail criteria. Examples of such goals are described in IEC 62366:2007, Annex G.

Q3: Suppose my company is adding a few new functions to an existing medical device's software user interface. Now that validation usability testing is a virtual requirement, can my company test the changes alone, or does my company have to test the device's entire user interface?

A3: Dr. Wiklund believes the FDA has rejected the notion of grandfathering pre-existing portions of a medical device's user interface that did not previously undergo usability testing. As such, a manufacturer would need to test a newly updated device's entire user interface if new functions have been added. In other words, the device will be subject to current design controls that call for validating that the device meets users' needs, which is typically achieved through summative usability testing. Clearly, this need poses a dilemma for manufacturers that are selling an approved device and want to enhance it without re-engineering pre-existing portions that do not meet the contemporary standard for user interface design quality. For this reason, he expects that some manufacturers might choose not to update their devices, but rather retire the devices at the appropriate time, sensing that the older portion of the device might not pass a re-validation effort.

Software and the 3rd edition

Q1: In the 3rd edition, are there new, changed or more stringent requirements for software when compared to IEC 60601-1-4?

A1: The intent was for the IEC 60601-1-4 requirements to be integrated into the body of the general standard. It was not intended for there to be a significant upgrade in requirements, although additional requirements for networking have been introduced.

Q2: How should manufacturers address IEC 60601-1 clause 14 (software) for designs previously released under 2nd edition that were not developed in the way mandated by 3rd edition. For example, they have little to no iterative milestones, architecture documentation, or formal development life cycle?

A2: The differences between clause 14 of the 3rd edition and IEC 60601-1-4 for use with the 2nd edition are not dissimilar. They both rely on a documented risk based development process for the software.

However there may be some software that would not have been assessed under 2nd edition certification yet requires evaluation under 3rd edition (for example meeting an item of essential performance), then a retro-active development process will need to be created and perhaps the some of the software redesigned. But such instances of this would be rare as most software in medical devices will likely have been developed through some kind of risk based process as this would have been required by medical regulations for many years previous to the introduction of the 3rd edition.

Q3: What is required for UL and/or CB in terms of IEC 62304, if a UL/CB approved product shall be upgraded to the 3rd edition? e.g., is it necessary to establish software development plans retroactively?

A3: IEC 62304 is not required for 3rd edition submittals. Clause 14.4 of the 3rd edition provides an informative (non-normative) reference to this standard. Therefore IEC 62304 is not criteria for certification under the CB scheme. However, particularly for high risk software, the assessing engineer may refer to IEC 62304 in his assessment as a guide to assist in the assessment. But again, this does not meet the IEC 62304 assessment criteria. IEC 62304 is a recognized standard in some economic areas, and it is likely one of the methods used to demonstrate conformity to regulatory requirements.

Q4: If my device is on the market without any complaints, what is necessary to complete IEC 62304 for the 3rd edition?

A4: This would not be sufficient to meet clause 14 of 3rd edition or IEC 62304. The integrity of a software development process cannot be substituted for an evaluation of previous complaints.

Q5: What if we purchase software as an off the shelf component (OTS), does SOUP apply in this situation?

A5: Yes, off the shelf (OTS) software meets the definition of SOUP (Software of Unknown Provenance) and should be addressed accordingly.

Q6: Is it expected that countries may adopt national deviations to software requirements in the 3rd edition?

A6: As noted above in the discussion of OSHA acceptance, with any newly issued document there is always some risk that the new standard will not be accepted as written by all involved parties. Typically the individual national committees will meet and determine if national deviations are necessary.

Q7: How should we handle the Declaration of Conformity (DoC) for new product where software complies and the product is certified with the 3rd edition but the country only accepts the 2nd edition?

A7: There is always the option of a dual certification to both the 2nd and 3rd editions where there is a genuine concern. In this fashion, the most stringent requirements form the two versions would be applied and the device would be in compliance with both. It may also be prudent to consider the likelihood of Amendment 1 to introduce changes in this area, and in particular the addition of a reference to IEC 62304, since this standard had not been published at the time the 3rd edition of IEC 60601-1 was published. That is, it may be worthwhile to consider also including an assessment to the requirements of IEC 62304, in addition to the clause 14 requirements of 60601-1 3rd edition and 60601-1-4 (2nd edition).

Q8-Q9 *Available for download by UL customers only through* **MyHome @UL.**

EMC and the 3rd edition

Q1: Are there questions in the 3rd edition TRF about EMC?

A1: EMC is addressed in the collateral standard 60601-1-2. The collateral has been aligned with the 3rd edition general standard and has very minor changes from 2nd edition. The general standard TRF does not include the EMC requirements.

Q2: What are the differences between the EMC 60601-1-2 standard definition of essential performance between Amendment 1 and the 3rd edition?

A2: The definition of essential performance is not directly defined in IEC 60601-1-2. Rather the definition for essential performance is referenced back to IEC 60601-1

Q3: Can EMC reports be separate from CB reports?

A3: The EMC report is a separate report from the safety TRF. Either a CB Style report without a CB certificate or one with a CB certificate can be issued. Both require a review of the user/installation manual to ensure compliance with the documentation requirements in IEC 60601-1-2 which differ from those in IEC 60601-1-1.

Other questions – IEC 60601 3rd edition

Q1: What would be my requirement to get access to Switzerland with 3rd edition?
A1: It is recommended that particular needs for legal market entry requirements be researched through UL's Global Market Access department. Contact UL for more information.

Q2: What do we do if we want to sell to European countries not in the EU?
A2: We recommend that particular needs for legal market entry requirements be researched through our Global Market Access Department. Contact your UL Account Executive for more information.

Q3: Is there a risk that OSHA will not accept the 3rd edition?
A3: As with any newly issued document, there is always some risk that the new standard will not be accepted by all involved parties. However we do know that this is under active consideration by OSHA. In the interim, manufacturers may want to consider maintaining a dual classification to both the 2nd and 3rd editions of IEC 60601, For the latest information from OSHA on accepted standards please see: **http://www.osha.gov/dts/otpca/nrtl/allstds.html**

Q4: Is clause 4.2 required for power supplies?
A4: Please see the Addendum attached below for a detailed response.

Q5: Is it possible that ISO will issue a TRF for ISO 80601-2-35?
A5: ISO is a standards writing organization and TRFs are basically templates used to share a common format for test data. It is possible that IECEE will generate TRFs to share test data for ISO/IEC test standards such as the IEC/ISO 80601 series. At this time, we have no specific information on ISO plans. If your device falls under the scope of an ISO standard, please contact UL and we will work with you on your test report formatting needs.

Q6: Each country seems to have its own rules for whether the 3rd edition is required for old products or new products. Please clarify the requirements in US, Canada and EU.
A6: FDA has not issued guidance, but typically FDA will require recognized consensus standards to be used for any new submissions. Existing products can still be manufactured and distributed with the standard and test data under which they were originally approved.

In Canada, it is similar. Any new products up for license will need to provide assessment data for the latest recognized standard. Any new products seeking license in Canada after June 2012 will need to have been evaluated to the 3rd edition.

For Europe in general, after June 2012, any existing product will also need to be reassessed to 3rd edition before it can be placed on the market. However there are exceptions to this general rule. To determine the date that is applicable to a given device, it is necessary to refer to the CENELEC website (**http://www.cenelec.eu/Cenelec/Code/Frameset.aspx**) for the date of publication of the 3rd edition aligned Part 2 Standard that is applicable, and the Date of Withdrawal for the 2nd edition aligned Part 2.

UL and the risk management file

Q1-Q5 Available for download by UL customers only through **MyHome @UL.**

Q6: **What are the advantages of having UL certify my product over versus other notified bodies?**

A6: UL has been working with the 3rd edition and its risk management requirements as they were being developed. UL has a strong system to support you through the transition and can integrate audits so that you can have one UL expert on site to assess your QMS and RMS for multiple regulatory schemes. UL is the top CB Scheme provider for the "MED" category, and our customers tell us that UL CB Scheme reports are accepted worldwide as the gold standard. When your certification body has the respect of the regulators, this saves time in approvals. Not all notified bodies are test agencies nor do they have the broad spectrum of accreditations necessary to gain access to multiple markets.

Q7: (A) For ISO 14971 and ISO 13485 would we need separate evaluations? (B) What would be the benefit of having both?

A7: It is important to note that UL offers the option of classification to IEC 60601 3rd edition using a desktop assessment approach. The ISO 14971 registration is a voluntary registration the manufacturer will choose based on their business needs/situation.

(A) If you choose to have an ISO 14971 registration and an ISO 13485 registration, there are many "like" clauses between the two standards that can be assessed together by an auditor who is qualified in both standards. This saves time in duplication of questions and review. For example, both standards require management review. It is possible that management review of the QMS and RMS occur during the same meeting, such that one auditor can review meeting minutes/documentation as a record of management review and it will satisfy requirements in both standards. If you were to host a separate audits each for ISO 13485 and ISO 14971, the management review would be assessed twice; once at each visit.

(B) The benefit to having both an ISO 13485 and ISO 14971 system is that the ISO 13485 registration can be used to demonstrate conformity to quality system requirements when applying for global market approval. An ISO 14971 registration can help demonstrate conformity to IEC 60601 3rd edition and also to help demonstrate to regulatory agencies that your risk management system has been assessed by a 3rd party.

UL Process

Q1-Q2 Available for download by UL customers only through **MyHome @UL.**

Q3: How do you insure engineers don't become design consultants but remain certifying body representatives?

A3: This is not a new issue associated with the 3rd edition as our engineers must maintain the role of a certifying body representative for all investigations we perform. As an independent, third party, certification body, UL does not provide product design consultation. This is a key element of training that all engineering staff receive when becoming UL employees.

Q4: What are the differences between ISO 14971 registration vs. certification?

A4: Registration to ISO 14971 is a 3rd party assessment that your risk management system conforms to the ISO 14971 standard. In this regard it is very similar to an ISO 13485 registration.

On the other hand, a 3rd edition certification is issued to the product. That is, the product and its accompanying documents are assessed for conformance with IEC 60601-1 and applicable particular standards. To the extent IEC 60601-1 makes reference to ISO 14971, whether done in person or by desktop assessment, objective evidence will be reviewed to determine a risk management process was employed in the development of the device. This does not assess all elements required by a full ISO 14971 risk management system, such as management commitment, provision of resources, post-production information and others.

Q5: What are the lessons learned around 3rd edition?

A5: We have a team working on identifying key learning points and sharing them with our staff and also with our customers. One of the things we have learned so far is that industry will hesitate to embrace a new standard unless the regulator makes it mandatory.

Q6: What is the major hurdle with the risk management in the 3rd edition? Why is it different than what was being done?

A6: The question on how to consistently assess a product from one certification body to another and from one regulator to another, in particular with respect to Clause 4.2 (ISO 14971 compliance) and risk management. The motivation for the change in the standard was to establish a uniform basis to allow manufacturers the flexibility to assess new designs incorporating new technology while still providing a level of safety acceptable to the user community.

Q7: Are customers needed for a 3rd edition pilot program of proactive review? How do I engage UL to initiate these types of projects?

A7: Yes. Please contact your Account Executive or local UL office.

Q8: How do you see the breakdown of service delivery around these new proactive review models? Will most people move to this or will the other service offering still exist?

A8: We will always have transactional customers that request certification after all the design work has been complete. As proactive review helps our customers get to market more quickly, we anticipate word will spread and it will become more common to bring UL in for certification assessment earlier in the design process.

Q9: How will that information about lessons learned and misinterpretations be communicated to customers on an ongoing basis?

A9: UL has several methods of communication to fit our customers' preference. Our webpage contains a lot of valuable information and information sheets to download. We have a Health Sciences email subscription database where we send out information regularly on UL events, regulatory updates, and new survey results. We also have a LinkedIn group open to the public where we share information. Some information is also sent via postal mail.

Q10: Can an evaluation be done from scratch to cover both the 2nd and 3rd editions?

A10: Yes, we can provide a concurrent test plan and integrate tests to produce two reports.

Q11 Available for download by UL customers only through **MyHome @UL.**

Q12: When you have essential performance (EP), do you expect more testing to demonstrate compliance?

A12: UL will work with the manufacturer to review the risk management file to assess the impact of essential performance. Because there will likely be new aspects to consider, it is anticipated that some additional work will be required.

Q13: If the product has no essential performance (EP), what should be recorded?

A13: UL will work with the manufacturer to understand the application of the device and the expectations of the various users, state of the art and other new concepts introduced by the 3rd edition of 60601 and ISO 14971. This would then be reviewed in the total context of the risk management file to determine elements needed to be recorded, as well as any gaps that may exist.

Q14 Available for download by UL customers only through **MyHome @UL.**

UL-EU Mark

Q1: What are the benefits of the UL-EU mark?

A1: The UL-EU mark is awarded when a manufacturer's product has been assessed to the applicable EN standard. It can be used as a mark of distinction to show that a 3rd party has assessed your device to the EN standards such as EN 60601-1. It can also be applied to products that use IEC components with CB Scheme reports. When the components are UL recognized, it also can be integrated with your Canada and US requirements as a "global" mark.

Q2: The UL-EU mark audit is that an audit of quality of test or audit of customer complaint resolution? Specific details of EU audit approach.

A2: The UL-EU audit is a CIG 23 audit that is required one time per year.

Q3: If I have a product for sale in the US and EU, which mark should be on the product? UL or UL-EU. Is the UL-EU mark for North America also?

A3: UL offers the option of a combined UL mark with the EU, C (for Canada) and US (for US) or any combination of the three marks. For the UL-US mark, your product needs to have been assessed to US based standards which require UL recognized components. More information on the UL -EU mark is located online at:
http://www.ul.com/global/eng/pages/offerings/services/marketaccesssolutions/uleumark/

UL Follow-Up Services (FUS) options for the 3rd edition

This section available for download by UL customers only through **MyHome @UL.**

NEW Addendum 1 – Specific information regarding power supplies

As you may be aware, there has been ongoing discussion regarding assessment and licensing of power supplies to the 3rd edition of IEC 60601-1. Much of this discussion has centered on the need for performing a risk management assessment for these devices.

It should be noted that the 3rd edition of IEC60601-1 includes provisions for components which have not been previously assessed for risk management following the requirements of ISO14971. Specifically, Clause 4.2 of the 3rd edition of IEC 60601-1 has the following (informative) note:

> "NOTE 3—It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in this standard for each constituent component of the ME EQUIPMENT or ME SYSTEM, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER should take special account of the need for additional RISK CONTROL measures."

As the Standard further empowers the manufacturer to integrate IEC 60950 based components, it is likely that some of these components may not initially comply with Clause 4.2. In effect, the note therefore assigns the necessary risk management activity for the power supply to the end-product manufacturer.

UL's recognition program supports application of these requirements. That is, under our Recognition program, power supply manufacturers have the option to recognize their power supplies to the 3rd edition of ANSI/AAMI ES (IEC) 60601-1 without performing a risk management assessment. When this option is chosen, the UL Report will specifically note that the risk management assessment was not performed, as well as any other Conditions of Acceptability that may be necessary based upon the scope of the work performed. This information will also be noted on the QQHM2 Recognition Card for the power supply in question.

Many of our customers also desire a CB License for power supplies certified by UL. At the present time, the IECEE CB Scheme policy is that a risk management assessment is required for a power supply to be eligible to receive a CB License. Therefore if the power supply manufacturer elects for UL Recognition without a risk management assessment, the power supply will be ineligible for a CB License. We will continue to provide updates on this point should this policy change in the future.

Of course, there may be business implications associated with a power supply manufacturer's choices for a risk management assessment. These business implications extend to the end-product manufacturer. To provide insight into the potential business ramifications of any certification decisions that may be considered, the following "Q & A" has been developed. Should you have any further questions on this topic, please feel free to contact your local UL representative.

Q1: If the power supply manufacturer does <u>not</u> include a Risk Management assessment with the power supply certification, what are the implications for the power supply manufacturer?

A1: The power supply manufacturer can expect some or all of the following:

- May have less up front overhead needed to develop the certification
- Risk Management relevant information may be requested by each end-product manufacturer using the power supply involved
- Design information may need to be shared with each end-product manufacturer
- End product manufacturer may consider other vendors due to the lack of Risk Management assessment
- End product manufacturer may require tighter supplier controls for the power supply as determined necessary by their Risk Management plan
- Potential for duplicate risk management assessments by each certification agency and or each end product manufacturer

Q2: If the power supply manufacturer does <u>not</u> include a Risk Management assessment with the power supply certification, what are the implications for the end product manufacturer?

A2: The end product manufacturer may expect some or all of the following:

- Must demonstrate that the power supply is in compliance with clause 4.8 (and others) of IEC 60601-1 where the RISK MANAGEMENT PROCESS is called out to define, supplement, modify etc. the requirements of the Standard.
- Will need RISK MANAGEMENT relevant information from the power supply manufacturer to complete their Risk Management file
- Must perform analysis to determine the need for any supplemental actions or end-product design changes to maintain acceptable risk on an ongoing basis
- May need to impose vendor requirements (such as supplier controls) on the Power Supply manufacturer to maintain acceptable risk
- An additional Certification burden due to the need to support the power supply risk management assessment

Q3: What can the power supply manufacturer expect if a risk management assessment is included in the power supply certification?

A3: Power supply manufacturers may expect the following:

- The ability to provide direct objective evidence of compliance with relevant parts of Clauses 4.2 and 4.8 (and others) of IEC 60601-1
- End product manufacturer may prefer the vendor vs. competitors because of the reduced burden in providing risk management relevant information
- Improved clarity and control over power supply related risks in medical applications
- Greater control of the scope of risk management activities

Q4: What can the end product manufacturer expect if they choose a power supply that has included the risk management assessment with the certification?

A4: The end product manufacturer can expect the following:

- Simplified Risk Management File development supporting 3rd edition certifications
- Reduced effort required for identification of component characteristics that may have an impact on safety and essential performance
- Clear identification of features/characteristics for supplier control
- Less detail needed to complete the end product Certification Report (TRF)
- Simplified process for certification of overall system

Q5: Is risk management absolutely necessary to certify a Power Supply to IEC 60601?

A5: No. Please see questions above

Q6: Can UL provide information on IEC 60601 and ISO 14971 so a Power Supply manufacturer can make the best business, technical and relevant decisions?

A6: Yes. UL has many forms of information, from downloads, to instructor led standards training in all areas of IEC 60601 and ISO 14971.

Contact UL Health Sciences:

Email: Medical.Inquiry@us.ul.com
Phone: See regional phone #s at: http://www.ul.com/global/eng/pages/corporate/contactus/
Website: www.ul.com/medical

LinkedIn Group: http://www.linkedin.com/groupRegistration?gid=3153188
Register for Email updates: http://visitor.constantcontact.com/d.jsp?m=1101528895193&p=oi

Common Acronyms:

3rd ed. or Third Edition - 3rd edition of IEC 60601-1
AIMDD -Active Implantable Medical Devices Directive
AM1 - Amendment 1
CB - IECEE CB Scheme
CBTL - CB Test Lab
CIG - CENELEC audit report style also known as CIG-23
CMC - Management body over the CB Scheme
DoC - Declaration of Conformity
DOCOPOCOSS - Date of cessation of presumption of conformity of superseded standard
EMC - Electromagnetic Compatibility
EN – European Norm
EU - European Union
EP - Essential Performance
FUS - UL's Follow Up Services program under United States OSHA NRTL requirements
IVDD - In Vitro Diagnostics Directive
MDD - Medical Devices Directive
NB - notified body
NCB - National Certification Body
OSHA - U.S. Occupational Safety & Health Administration – www.osha.gov
OTS - Off the Shelf (reference software)
QMS - Quality Management System
RM - Risk Management
RMS - Risk Management System
RMTF – Risk Management Task Force
SOUP - Software of Unknown Provenance
TRF - Test Report Form
U.S. – United States of America