Medical Device Communiqué

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IEC 61010: DOCUMENTATION REQUIREMENTS

UL EduNeering has developed eLearning courses based on our popular workshops on IEC standards (60601, 62304, and 61010) for medical device engineers and product design personnel.

The International Electrotechnical Commission (IEC) published the third edition of the IEC 61010-1 standard in June 2010.

Because measurement, control, and laboratory equipment is crucial to the quality and consistency of medical products, IEC 61010 exists to ensure that this equipment meets certain standards.

Our two new IEC 61010 eLearning courses focus on the standard for measurement, control, and laboratory use equipment.

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IEC 61010: DOCUMENTATION REQUIREMENTS *(Continued)*

IEC 61010 requires that equipment be accompanied by certain general documentation for safety purposes as follows:

- intended use of the equipment;
- technical specification;
- instructions for use;
- name and address of the manufacturer or supplier from whom technical assistance may be obtained;
- definition of the relevant measurement category if marking of terminals is required on the equipment;
- If applicable, warning statements and a clear explanation of warning symbols marked on the equipment shall be provided in the documentation or shall be durably and legibly marked on the equipment.

Equipment ratings

Documentation must include:

- the supply voltage or voltage range, frequency or frequency range, and power or current rating;
- a description of all input and output connections;
- the rating of the insulation of external circuits;
- a statement of the range of environmental conditions for which the equipment is designed;
- a statement of the degree of protection, if the equipment is rated according to IEC 60529 (the International standard for degrees of protection provided by enclosures).

Installation

Documentation must include installation and specific commissioning instructions such as:

- assembly, location, and mounting requirements;
- instruction for protective earthing;
- connections to the supply;
- supply wiring and external switch/circuit-breaker/overcurrent protection device requirements for permanently connected equipment;
- ventilation requirements;
- requirements for special services (e.g., air, cooling liquid);
- the maximum sound pressure level produced and any precautions related to sound pressure level.

Operation

Instructions for use shall include, if applicable:

- identification of operating controls and their use in all operating modes;
- an instruction not to position the equipment so that it is difficult to operate the disconnecting device;
- instructions for interconnection to accessories and other equipment;
- limits on intermittent operation;
- an explanation of safety symbols;
- instructions for replacing any consumable materials;
- cleaning and decontamination instructions;
- a statement that lists any potentially poisonous or injurious gases that can be liberated from the equipment, and possible quantities;
- detailed instructions about risk-reduction procedures; relating to flammable liquids and hot surfaces;

Instructions should indicate that if the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Maintenance

Instructions concerning preventive maintenance and safety inspection should be provided, and include inspection and replacement of any parts if their failure could cause a hazard. Also, documentation shall include any tests necessary to check that equipment is still in a safe condition.

If you have any questions about our IEC 60601 or IEC 61010 workshops and eLearning programs, and would like more information, please contact Pat Thunell at pat.thunell@ul.com.

ISO 13485:2016

INSIGHT ON KEY CHANGES

The following excerpt is from the UL whitepaper, "ISO 13485 – Change? Do I have to?" - written by Linda Chatwin, Esq., RAC, Business Manager and Regulatory Affairs Consultant - UL LLC, and Walt Murray, MasterControl. UL EduNeering will be updating our two ISO 13485 coures (DEV48 and DEV50) based on the ISO 13485:2016 changes. To download the full article, please visit http://web.ullifeandhealth.com/ISO13485

Risk

There are many revisions within the standard. The most prevalent change that one can readily identify is risk. The standard expects manufacturers to apply a risk-based approach to the control of the appropriate processes needed for the quality management system.

Risk is mentioned some 15 times throughout the standard, to account for the specific issues being addressed. Risk is to be considered in outsourcing and supplier controls, with respect to software validations, and in the training of personnel commensurate with risks inherent in the processes they perform. Risk is to be taken into account in product planning processes. Risk management activities should also be incorporated during the processes of:

- Verification, validation, revalidation
- Documentation of risk management in product realization

Alignment With FDA Terms

The revised standard sports the converging alignment with FDA terms, such as establish, implement and maintain documented processes, while clarifying that regulatory requirements include statutes, regulations, ordinances or directives, relative to the safety and performance of the medical device.

In order to comply with ISO 13485:2016, the company must now maintain a medical device file much like the European requirements. The elements of the file are to demonstrate conformity with the standard (essentially, the technical file).

1. Records that show changes are appropriately controlled (where applicable);
2. Records that show appropriate software, system, and quality requirements were established and provided to the vendor, if developed elsewhere. The vendor must be qualified, and the purchasing data and validation results should support that the requirements were met;
3. Records of testing and verification activities, including proper installation;
4. Validation Report that summarizes the activities and documentation as described in the validation protocol/plan, including issues during development and testing.

New Subclauses

- A design and development transfer sub-clause has been added. The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications. Results and conclusions of the transfer shall be recorded. This makes explicit the input of manufacturing into design considerations.
- Complaint handling is added as a completely new sub-clause to the standard, and requires much the same complaint handling process as FDA for recording, investigating, communicating and moving to CAPAs when indicated or justifying why they are not. The requirement to report to the appropriate authorities is also expanded.

MEET UL AT MEDCON, MAY 3 - 6

Meet FDA Officials and Leading QA Executives

UL is proud to once again be a sponsor at MedCon, which is being held at Xavier University (OH) on May 3 - 6. This event brings together global Medical Device executives and FDA officials to openly discuss pressing issues facing the industry.

Both Rob Sims and Richard Robbins from UL EduNeering will be in attendance, and we will be providing access to attendees to our new QSIT Essentials eLearning program.

Representatives from Compliance Insight, Inc., will also be in attendance. Compliance Insight is our subject matter expert for many medical device eLearning courses, including our QSIT Essentials program, which includes these five courses:

- QSIT 1 - Beginning the Inspection
- QSIT 2 - Subsystem
- QSIT 3 - The Design Controls Subsystem
- QSIT 4 - The Corrective and Preventive Actions Subsystem
- QSIT 5 - The Production and Process Controls Subsystem

Learn more about Compliance Insight at http://compliance-insight.com/

Other Quality & Compliance Essentials sets are available, each focused on specific topics. Content is provided as SCORM files to host on your own learning management system. Other delivery methods are available, including AICC or hosting on our own industry-standard LMS – ComplianceWire®.

STANDARDIZING LEARNING WITH GOVERNANCE POLICIES

The following excerpt is from an upcoming UL whitepaper that will focus on LMS/DMS integration best practices.

As medical device companies face increased globalization, expanding supplier networks and internal harmonization requirements, they seek to build consistency and standardization into their learning and compliance programs.

UL Advisory Solutions has conducted a number of "Learning and Compliance Governance" projects for clients, which is the process of defining the roles and steps required to make sure the enterprise system is used and managed effectively. A governance policy focuses on these activities:

- Captures Industry Best Practices
- Defines Enterprise System Ownership & Oversight
- Defines Procedural/Process Control
- Defines Administrative Control
- Describes the Roles of Training & Administrators
- Outlines System Use and Operation
- Captures Integration Processes (DMS, HRIS, MES, etc)
- Defines Monitoring and Metrics

Why Governance Is So Critical

There are several major risks that companies face if they haven't formalized their governance policies. One risk centers on "lost knowledge." When so much process and operational knowledge resides in a few people's heads, the organizations lose best practices when the people who implemented the learning system move to new functions. We have seen a new team take months to understand the process, but a governance policy would have made for a near-seamless transition.

Another risk occurs when companies expand rapidly, either through organic business growth or through acquisition. As new teams are added, they start to build their procedures for how to manage qualifications and training.

For example, a department may start defining their own nomenclature for SOP training items. They may create their own policies around training management visibility for department managers. And at some point these siloed practices generate friction when senior management is seeking a consistent view across product lines and facilities.

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STANDARDIZING LEARNING WITH GOVERNANCE POLICIES (Continued)

The Governance Policy's Impact on Culture

With a governance policy in place, our clients have told us that this is how the policy builds a culture of quality:

- The policy develops a clear and scalable enterprise vision for the LMS, leveraging all feasible synergies;
- Drives regulatory compliance and/or business efficiency;
- Resolves issues and finds common ground;
- Recognizes and encourages the entrepreneurial culture by acting as a business partner via collaboration with learning communities;
- Promotes harmonization, standardization, continuous improvement and knowledge management across the wider organization.

Core "Governance" Procedures

Here are just four "core" policies and procedures that our clients are using as part of their governance programs:

- Training Policy – this policy touches on scope, training responsibilities, procedures for GxP training and non - GxP area personnel, training curricula, training documentation, Annual GxP Training, External Training;
- Use and Operation Procedures – general use and operations instructions for Users and User e-signature certification;
- System Administration Procedures – including security roles, system admin roles and responsibilities, maintenance (including system releases), configuration changes requiring change control;
- Computer System Change Control – including standard operation procedures for system configuration changes, addition of new functionality, handling system releases.

We should point out that the UL Advisory Solutions team can provide procedural templates that help clients with controlling and maintaining the enterprise learning system.

An Example of Training Governance

Training policies detail how training is conducted, but also how activities are recorded. The training policy typically serves these purposes for department managers, employees and of course, quality assurance and auditing teams:

- Establishes that personnel must have the education, training, and experience (or any combination) to enable that person to perform his or her assigned functions.
- Notes that personnel must be trained in an operation before they perform these functions.
- States that personnel must be trained in the current good manufacturing practices (CGMP).
- Requires that training must be conducted on a continuing basis with sufficient frequency to assure that employees remain familiar with CGMP requirements.
- Defines the role of the employee and their manager when it comes to training activities.
- Defines the minimum elements/requirements for management of the training program.
- Explains the process that qualified individuals (or Qualified Persons, as defined in the EU) must use when conducting training.
- Explains the steps needed to conduct training effectiveness verification.
- States that training must be properly documented and maintained (e.g. date, content of training, trainer, length of training, etc).
- Refers to a separate "Training Record Retention Policy" in which the company's policy on record retention is defined.
- Identifies or points to a document that states Electronic Signature Policy (applicable if utilizing e-Signatures).

To learn more about UL Advisory Solutions and our Governance Policy services, contact Pat Thunell at pat.thunell@ul.com

COMBINATION PRODUCTS: GMP BASICS

Last year, US FDA released GMP Requirements for Combination Products draft guidance, which was added to our foundational "GMPs for Combination Products" course (see sidebar for course summary). We wanted to summarize the critical compliance options that combo product makers have to make.

FDA recognizes that there is much overlap between drug and device regulations. Efforts by firms to apply all the specific regulations for all combination product components could result in redundant work, so FDA offers a more streamlined approach to compliance.

For "single-entity" or "co-packaged" combination products, the manufacturer must follow one of two requirements. Firms must comply with either all requirements applicable to each constituent part, or all the manufacturing/compliance requirements applicable to one constituent part, and certain provisions noted in section 4.4(b) applicable to the other constituent part.

Co-packaged drug-device combination

A manufacturer of a "co-packaged" drug-device combination product may choose to fully implement both the drug cGMPs (21 CFR Parts 210 and 211) and device QSR requirements.

Alternatively, the manufacturer may choose to comply with the drug cGMPs, but would be required by the new regulations to also comply with specific QSR requirements (e.g., the requirements in 21 CFR 820.20 on Management responsibility, 820.30 on Design controls, and 820.200 on Servicing).

Compliance Options

The production of any combination product whose constituent parts include both a drug and a device must comply with one of the options set forth in section 4.4(b). Firms may choose any one of the options presented to be compliant.

- Full constituent part compliance: a firm may choose to fully comply with all requirements applicable to each constituent part, as if each were manufactured separately.
- Full drug compliance: a firm may choose to fully comply with all drug cGMPs. They must then follow the additional provisions of the QSR, as noted in section 4.4(b).
- Full device compliance: a firm may choose to fully comply with all QS regulations. They must then follow the additional provisions of the drug cGMPs, as noted in section 4.4(b).

For example, a manufacturer of an insulin pump decides they are going to satisfy the drug component's cGMPs and be in full compliance. The firm must then make sure that, according to section 4.4(b), they comply with the relevant QS regulations pertaining to the device constituent part.

UL's GMPs for Combination Products course introduces individuals to cGMP requirements and FDA rules that relate to combination products. Written by GMP expert Dave Peterson, the course covers these topics: Background, Final Rule, Compliance, The Office of Combination Products, and Post-Approval Modifications. Regulations and Guidance noted in this course include:

- 21 CFR Parts: 3, 4, 210, 211, 600-680, 820, 1271
- Draft Guidance: Submissions for Post-approval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA, issued January, 2013
- Guidance for Industry and Staff: Current Good Manufacturing Practice Requirements for Combination Products DRAFT GUIDANCE January, 2015
- Proposed rule: Post Marketing Safety Reporting for Combination Products, Federal Register, September 30, 2009

To learn more about our GMPs for Combination Products course, contact Pat Thunell at pat.thunell@ul.com.

About UL EduNeering

UL EduNeering is a division within the UL Ventures business unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®. In addition, UL offers a talent management suite that provides companies the ability to improve workforce skills & competencies within established role-based talent training programs to drive business performance.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory solutions, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university.