



# LAMPIRE BIOLOGICAL LABORATORIES

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Date: June 1, 2018  
Subject: Change in LAMPIRE's ISO Certification  
Recommended Action: Please Notify Appropriate Personnel

The International Organization for Standardization has recently revised both the ISO 9001 and ISO 13485 standards. ISO 9001:2015 has changed its focus slightly to be more user-friendly for service and knowledge-based organizations. The standard no longer requires a quality manual or quality representative and includes a flexible approach of allowing organizations to determine what processes should be documented within their Quality Systems.

ISO 13485:2016 continues to focus on Quality Management System (QMS) requirements for organizations that provide medical devices to ensure that they not only meet customer requirements but also applicable requirements of countries and regions where medical devices are distributed. This new version focuses on an expanded global alignment of regulatory requirements, enhancement of requirements for a risk-based quality management system, more detailed validation, verification, and design requirements, as well as additional requirements for supplier management.

LAMPIRE is currently certified to both ISO 9001:2008 and ISO 13485:2003. Based on our review of the ISO revisions, the strength of our quality systems, and our commitment to conformance with medical device regulations, we have concluded that we will **not seek certification to ISO 9001 after expiration of our current certificate on September 14, 2018.**

LAMPIRE's QMS is closely aligned to both standards, with a focus on continuous improvement and customer satisfaction, as well as regulations that pertain to medical devices, and will continue to maintain these principles. LAMPIRE is not a medical device manufacturer yet this is the appropriate standard for LAMPIRE. As ISO 13485:2016 has added to the requirements for certification, this change will enhance LAMPIRE's QMS ensuring that we continue to focus on quality and offer products and support that reflect this focus.

Please forward this notification to the appropriate members of your organization. If you have any questions or concerns, please don't hesitate to contact us.

Regards,

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