

Date: 05 Sep 2018

Dear Sponsor,

The purpose of this letter is to explain Nelson Laboratories, LLC (NL) change management policy.

Since we provide lab testing services, and not a manufactured product or material, our change management process differs slightly from a manufacturer. Our process applies to changes made to validated processes, qualified equipment, software changes and upgrades, testing location, organizational changes (executive responsibilities, company ownership, and company name change), regulatory scope/compliance, business critical systems, and significant facility changes.

We define “change” as an event likely to have an impact on data, quality, business, or system attributes, a change outside of the design scope of the validation/qualification, or something that is not like for like. Generally, if there is no change to fit, form, or function, change management is not required.

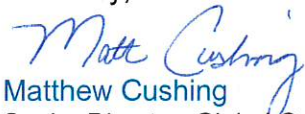
Since most of our testing services are based on standard testing protocols (STP) we provide the ability to have an additional “Customer Specification Sheet (CSS)” which provides customer specific instructions for testing (if necessary). The Customer Specification Sheet or STP are reviewed and approved by Nelson Laboratories prior to implementation. Customer approval is not required and is performed only upon request.

Additionally, all changes made through our change management process are assessed for the potential impact to you as a customer. We make every effort to contact our customers when it is appropriate so that your company may evaluate impact of such changes. You may refer to our web site at www.nelsonlabs.com (Secure portal log-In) for a posting of our most recent changes with the most up-to-date information.

Changes to procedures are controlled within an electronic document control system. You may refer to our web site at www.nelsonlab.com (Secure portal log-In) for a posting of our most recent standard testing protocol (STP) revision history report.

We will continually strive to be the best service laboratory for all of your testing needs. Please do not hesitate to contact me if you have any questions. Thank you for testing with Nelson Laboratories.

Sincerely,



Matthew Cushing
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