



27 January 2011

The purpose of this letter is to explain Nelson Laboratories, Inc (NLI) 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/hardware changes and upgrades, vendor changes for primary supplies, organizational structure changes, regulatory scope, 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 procedures, we provide the ability to have an additional Protocol Detail Sheet (PDS), which provides customer specific instructions for testing (if necessary). These Protocol Detail Sheets are reviewed and approved by the NLI Study Director and your company prior to implementation. Any revision to a test method using a PDS will trigger an update to the PDS which requires review and approval by your company.

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. You may refer to our web site at www.nelsonlabs.com for a posting of our most recent changes.

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, Inc.

Sincerely,

A handwritten signature in blue ink, appearing to read "J. Walton". The signature is stylized and written in a cursive-like font.