

NUMBER	CHANGE CATEGORY	2018 REQUESTED CHANGE	REASON FOR CHANGE	IMPACT	APPROXIMATE DATE IMPLEMENTED
CC01484	Organization	VP of Operations, North America. Jeff Hills will move to role of VP of Global Facilities and Systems. Lane Jensen will now oversee both Sales and Marketing. Jeff Hone will move to role of VP EMEA and Global Quality	To better align with NL's expanded scope of operations, growing global footprint	No impact- Organizational Change	29-Jun-18
CC01485	Major Software	Upgrade CRM to Dynamics 365 2.0. Current revision is CRM 2013, Service Pack 1.	To allow the S2 project access to CRM, tracking leads and opportunities with external facing mobile devices. This cannot be done with current system. SLC and Itasca locations will be on same version of CRM.	CRM will be offline after business hours for approximately 6 hours Saturday 06 Jan 2018	6-Jan-18
CC01486	Organization	SteriPro Laboratories (Itasca, Ontario) will be changing company names to Nelson Laboratories	Name change anticipated and planned since NL was acquired by Sterigenics International.	No impact- Organizational Change	1-Feb-18
CC01487	Cleanroom	Cleanroom maintenance will be performed. BSC hood removed and replaced with laminar flow hood and camera installed on it.	Maintenance improves testing environment and usability	Downtime to cleanroom operations 18-21 Jan 2018	26-Jan-18
CC01488	Other	Citations listed in reference section of an STP, no changes will be made. Citations listed within the resources section will not have the year and revision number nor any citations listed within SOP, MAN, or WI.	Significant number of global documents not in the NL system, it is no longer practical to have frequent minor updates to procedures to change revision numbers of references.	Documents within system will be updated as they revise to reflect new citation style.	9-Apr-18
CC01489	Final Product	the Nelson logo to one Sotera/Nelson logo, change table coloring from green to navy blue with white text. (not limited to)	Align the new Sotera name logo and color scheme changes	No impact- Templates will be manually set in MasterControl to auto-release 01 Mar 2018	01 Mar 2018 (SOP updated 04 May 2018)
CC01490	Equipment	Fridge E-2602 in BET lab will be replaced with Fridge E-2382.	Fridge E-2602 has been making loud noises. MMO has not been able to pinpoint the cause.	Fridge E-2602 will be in place until Fridge E-2382 is qualified for use	18-Jan-18
CC01491	Other	Removal of RDW 5 surface monitoring from the monthly in-house environmental monitoring. (rooms 103, 104, 106)	Microbial testing is not performed in these rooms.	While no impact expected, any impact to testing should be captured through the test system controls. Other cleaning methods for the equipment will be implemented by section outside scope of this change.	01 Feb 2018 (SOP effective 12 Apr 2018)
CC01492	Business Critical	Build out Redwood 4 warehouse space for Packaging Distribution and Shipping test. (new test offering)	Increase capability of Packaging section to offer new test offering	MMO/Facilities, QA/QC, applicable lab areas impacted by change. No downtime to operations	31 Oct 2018 (Val/Qual approval form)
CC01493	Other	through UNIFlow for studies that were completed prior to 12 Mar 2018. UNIFlow will be updated to include LOD for rinses 2,3,4 that are used calculating recovery efficiency	harmonization of internal procedure and standard to include guidance on limits of detection.	Minor change is captured through SOP0147.	27-Mar-19

CC01494	Other	Location of Login will move from E155/E136 to room 308	Itasca renovation	No impact to any operational process	12-Mar-18
CC01495	Other	Change the amount of 30 day timeframe datapacks are held before shredding. (currently held for 30 days, perform an audit on a certain percentage of the datapacks and then shred them) Dataacks will be retain (hard copy datapacks) until the appropriate amount of sampling has been performed.	Reducing datapack (boxes) storage timeframe from 30 days allows Document Imaging to store reduced amount of boxes stored can be stored in Document Imaging room in RW3 rather than 100 boxes stored in RW4.	There will not be any change to our shredding and auditing processes.	07 Apr 2018 (Procedure effective 24 Apr 2018)
CC01496	Engineering/Bui	Change general lab floor mopping from 3 times per week to 2 per week. Handwash stations and showers from daily to weekly.	Critical surfaces are cleaned by lab personnel during test, operations. Floor are mopped regularly, Handwash stations and showers are not within lab testing areas. Additional microbial monitoring is performed for all buildings, high risk areas on monthly frequency.	Change is not expected to impact general cleanliness of lab areas. Cleanroom areas are outside the scope of this cleaning process.	25-Jan-19
CC01497	Testing Location	Itasca-BET lab will be moved from room E207 to room 302L.	Itasca renovation project, newly constructed area of facility.	No impact to any operational process. Move can occur in single day.	25-Apr-18
CC01498	Engineering/Bui	Add a vacuum port in the B/F lab room M04.	Vacuum port needed to connect to BSC type of hood.	No impact.	16-Jul-18
CC01499	Equipment	to the basement and will be listed as available. e-2602 (2 - 8 C) currently in the basement and available (not out of service) will be moved to M26 at the location that e-2349 was.	Protective Barriers .ab area is in need of more fridge space.	Once fridge is moved will need 24 hour monitoring before use	23-May-18
CC01500	Other	Discontinuation of Vitek 2 testing in SLC location	Vitek 2 equipment in SLC has been inoperable since February 2018.	Testing will still be officered in Itasca location.	1-Aug-18
CC01501	Cleanroom	Cleanroom maintenance and qualification after maintenance	Shower in the sterilizer room will be removed, door handles will be installed on the door between the sterilizer room and the media storage room, the hood in CR5 will be raised, new camera mounts will be placed on hoods in rooms 4,6,7 and 8, replacement of telephone port and the cleanroom floor will be buffed.	Testing will be stopped approximately 12-16 Jul 2018. No effect on TAT.	27-Aug-18

CC01502	Other	<p>the following ways: Separate STP approval and CSS approval (revision number is remaining in approval forms). Remove STP revision number from the CSS document. GLP studies will require approval of the STP, not the CSS. Currently, both are approved in a single approval form. The STP is considered the "test protocol" Sponsor will receive separate communication for STP and CSS approval.</p>	Approval process was overly cumbersome and redundant	No impact- System can easily be switched on. Customers will continue to have option to request approval of CSS and / or STP.	8-Oct-19
CC01503	Major Software	Upgrade UNIFlow that supports UTC and multiple locations we will move from release 4.3.5 to 5.0.0	LMS (UNIFlow) system will need to be used at other locations other than SLC. An upgrade is required for this to take place.	Downtime to operations during upgrade approximately 8 hours.	10-Nov-18
CC01504	Organization	are intended to increase focus on two key priorities for our business: EMEAA growth and integration, and global quality. The following is a summary of the changes and rationale: Jeff Hone, focus on EMEAA operations across our seven sites in Belgium. Matt Cushing assume leadership of Global Quality (SLT). Michalina Adamski transition to DOLO responsibility for all EMEAA labs except Leuven. See	Reporting and responsibility changes ensure that we have specific responsibility, accountability, and focus on the EMEAA region and global quality, which are both important for our ongoing growth and success.	Organization Change Announcement sent to NL employees 15 Jun 2018. Reporting and responsibility changes are effective immediately	14-Nov-18
CC01505	Cleanroom	pass through window and install new, recondition floor, ceiling tiles, grills, gaskets, panel installation, epoxy paint, replace 3 laminar flow hoods.	Lab renovated as part of Itasca site expansion project	Renovation project and recertification took approximately 3 weeks.	30 Apr 2018, 08 May 2018 (equipment), 03 Jul 2018(QE)
CC01506	Testing Location	Location for the BI testing will move from room E228 to E229 to new location room E124 & 302P	Itasca renovation project, newly constructed area of facility.	No impact to operational process	23-Jul-18
CC01507	Business Critical	currently located in two places, Mastercontrol and LMS. Change is to maintain and approve in Mastercontrol using editable template	All sites need to have access to same MRR. Other sites do not have the LMS access.	No impact to operations	In-process
CC01508	Facility	Proposed change for the mixed beds arrangement	The change will affect the way we control the RW2 water resistivity	Approximately 1 hour downtime for RW2 water system. Will be completed without disruption to operations.	17 Aug 2018, Oct 2018
CC01509	Testing Location	Samples undergoing real time aging testing in RWV will be moved to off-site location at 3120 West California Ave, Suite F. Project plan 01-1712	Increase testing volume in chemistry requires additional lab space, the move of real time will accommodate expansion.	Move will be done in shifts with minimal interruption to samples.	17-Sep-18
CC01510	Equipment	Move oven E-1078 from M10 to M11, adjust counter space and relocate hood, install new laminar hood	Limited hood space, need to be able to perform Helmke and Gelbo test at same time usually ongoing every day.	Possibility of downtime during movement of oven, counter space and hood relocation	23-Oct-18

CC01511	Equipment	Replace 2 RO units in Redwood 1 purified water system. They are not like for like replacements	Older units need to be replaced	No downtime to operations. New units will be evaluated while water system remains in service.	In-process
CC01512	Engineering/Building	Room A132 remodel for future PEPB production in Bioburden	New MP65 sterilizer units to be installed requires dedicated power, purified water, drain, network access.	Unable to test approximately 1 day, overall change window 1.5 month	29-Nov-18
CC01513	Engineering/Building	Replace existing carbon steel feed water tank for RW4 steam boiler with stainless steel tank and sparge tube heater.	New feed water tank will provide improved temperature control of boiler feed water and increase equipment life span.	Main steam boiler will be turned off and isolated from steam system. The 2 backups will be placed in operation. Production reduced to 27% of current capacity. Impacted clients will be notified in advance as needed.	12-Apr-19
CC01514	Equipment	Relocate laminar flow hood E-2654 from room B119 to room B127.	Storage space needed in PCD lab to store PCD's built by subcontractor	No downtime for PCD production.	9-Oct-18
CC01515	Engineering/Building	Add a new port to the Redwood 1,2,3 compressed air system in room M06 (Protective Barriers)	Viral penetration and synthetic blood studies currently share testing equipment in room M06.	The current arrangement has resulted in conflicts and delays when we have work for both tests.	30-Nov-18
CC01516	Equipment	Propose new set points and range for E2921 incubator in room M08 Protective Barriers	Instead of purchasing another incubator, E2921 has space to incubate ISO22610 testing plates which uses same organism as BFE test.	No impact to BFE testing as range would still comply with standard and organism within range of ISO22610 testing. Downtime approximately 1 week for requal	14-Nov-18
CC01517	Equipment	The 3 plate readers in BET's room 202 will be moved to room 203. Model ELx808, E-4519, E-3204 & E-2155	Due to space constraints the office space in room 203 will be converted into testing lab space	No downtime. 1 plate reader at time will be moved and validated.	17-Apr-19
CC01518	Equipment	Pharm: Move biosafety hood (e-1297) from room 206 to room 209.	The hood is being moved to consolidate testing that is already being performed in 209.	Multiple resources available for testing while hood is down	11-Dec-18
CC01519	Cleanroom	Cleanroom maintenance 11 -14 Jan 2019	Improve testing environment and usability ensure cleanroom meets requirements.	Sponsor testing impacted by maintenance of cleanroom will be notified.	11 Jan 2019, PQ signed 13 Feb 2019