

NUMBER	CHANGE CATEGORY	2017- REQUESTED CHANGE	REASON FOR CHANGE	IMPACT	APPROXIMATE DATE IMPLEMENTED
CC01441	Equipment	Move an unused fridge #E-1694 from the warehouse to the HCR testing area for supply storage.	Additional space needed for supply storage	None. Supplies will be stored in current location until the additional fridge is added. Re-qual E071-7	14-Feb-17
CC01142	Cleanroom	Change how contamination recovery rates are being calculated for monitor type and apply a contamination recovery rate for each cleanroom and analyst.	Gives more accurate contamination recovery rate and allows for better trending.	No impact to testing analysts. Impact to excursion investigations only	24-May-17
CC01443	Business Critical	Integrate all North American sites (Ontario, Itasca, Mexico) previously Steripro Labs into the Nelson labs quality systems.	Needed to begin integration process	Impact to all major quality systems of the company and process owners	In process
CC01444	Engineering/Building	Add HEPA filters to air vents in the BF lab M04 (RWII)	Reduce contamination potential.	No impact, no change will occur related to EM alert and action levels.	20-Jan-17
CC01445	Final Product	Copy datapacks currently stored in Papervision to Docuware system. (years 2000-2007) Conversion and import will be conducted batch-by-batch with estimated completion approximately December 2017.	Moving datapacks to Docuware will have all of our datapacks in one location.	No downtime to operations. No impact to archives, just a move of location with different look-up function.	9-Jun-17
CC01446	Business Critical	Names of procedures will be updated to include a site identifier. Example: SOP0001 will become 800-SOP0001 to indicate global document. Additional site identifiers will be put in place for i.e., SLC, (801),Itasca (101), Mexico City (751).	To facilitate globalization of our document control system we need to add a site identifier to our procedures	No downtime to operations. (MasterControl)	20 Mar 2017 (Signed Closure Form)
CC01447	Major Software	Update Microsoft Office Suite from 2010 to 2013 on the MasterControl PDF publisher.	System update will assist with issues where equations do not publish accordingly and they are stuck in PDF publisher, manual operation to push through.	After hours, approximate 30 minutes downtime to software system.	12 May 2017 (signed closure form)

CC01448	Testing Location	Real Time Aging Testing in RDWIV room 204 will be moved to RDWV room 105.	Expansion of Specialized Reprocessing testing and office space needed in RDWIV.	Environmental verification will be conducted during move.	29-Mar-17
CC01449	Cleanroom	Change in active air sampling equipment used in cleanroom requires a change of air volume measure from 1.71 cubic meters to 1 cubic meter. Active air alert and action levels (SOP0121) will be updated to reflect guidance in EU/Annex 1. Active air monitoring plate media will change from Tryptic Soy Contact Agar (TSA) w. Lecithin, Tween 80, Histidine, Thiosulphate - Isolator Clean Room (LTHH-ICR) 55mm plates to TSA, 90 mm plate (non-contact plate).	Change to SAS samplers and action and alert level(s) aligns with USP <1116> and Annex 1. Change to active air monitoring plate media TSA is within the USP <1116> requirement.	Changes are procedural. (SOP0121 and WI0223). No downtime to operations.	24-May-17
CC01450	Engineering/Building	Replace the Log-in roll up door at the receiving dock with a new insulated, electronic roll up door	The new door will provide better insulation and a more consistent temperatures into the log-in area.	Regular log-in will proceed while the door is being replaced. The man door will be used in place of the dock door. No impact.	30-Mar-17
CC01451	Final Product	Bioburden Final Reports- Report the recovery efficiency at 100% instead of >99%. IRE calculations will be performed by averaging calculated counts and dividing by average titer, rather than calculating individual percentages then average.	Harmonize with other lab areas that are reporting 100% recoveries. IER calculation change to harmonize with the practice at other facilities to match SteriPro format.	No impact to previous testing.	17-Jul-17
CC01452	Final Product	Add "Testing Facility" to all final report templates. This meets ISO 17025 and GLP regulation.	Currently we list it on our letterhead, but now that we have multiple sited, it may not be clear to sponsors which facility did the testing.	No impact.	01 May 2017, SOP0085 effective 13 Jul 2017

CC01453	Equipment	Exchange Spectramax E-2032 (currently in Biocompatibility section) for E-3361 (currently in Specialized Healthcare Reprocessing section). The cuvette port in E-2032 is no longer functional but the plate reader is. SHR only has need of the plate reader and does not use the functional cuvette port in E-3361 for their testing.	In Biocompatibility, the cuvette port in E-2032 is no longer functional but the plate reader is. Both units are the same model (Spectramax Plus 384) and are used with the same software program and version. Both units are currently qualified for use and they will be used in the exact same locations in which they are currently used.	Downtime to lab area is approximate 4 hours to 1 working day. No impact to clients.	11-Apr-17
CC01454	Equipment	Liquid Particle Counter E-2211 located in Room 221 will be moved from bench top into hood E-2657.	Aligns with sampling practices outlined in USP 788 and 789 for particulate testing.	Additional LPC located in same room for testing while E-2211 change is completed.	2-May-17
CC01455-Cancelled	Other	Change > 90 day studies are tracked and evaluated by Management and QA. Current manual operation, change to CRM SQL report.	Increase visibility to lab and management.	No downtime to operations	Cancelled
CC01456	Equipment	For Packaging department to be located in single area, incubators will be relocated to specific area. Units 2865, 2866, 2867, 2868, 2869 (30-35C); 2803 (28-32); 2216 (20-25)	Packaging consolidation project	No downtime to operations. Re-qualification will occur live and details captured by validations	25-May-17
CC01457	Testing Location	Move the F2638 test equipment from RDW 4 room 206 to RDW 1 room A127. (F2638-E-3217), Dye Immersion (E-1638), Mass extraction leak tester (E-4446)	Packaging consolidation project	Downtime to operations approximately 5 days for each piece of equipment. Clients will be notified.	11-Apr-18
CC01458	Equipment	Implementation of new test method Mass Extraction for Container Closure Integrity.	New testing methodologies	Dye Migration, UvVis in operation while new method is brought online.	STP0140 effective 06 Dec 2017
CC01459-Cancelled	Final Product	800 FRT will differ from SOP0085, applicable WI, associated documents. Other NL NA sites will not have same system as does NL-UT system.	800 FRT's will require translation, will have to be manually maintained for the procedure numbers and revisions.	No impact, only associated with new 800 FRT	Cancelled- because at that time Itasca effectivity of FRT/SOP0085 had not taken place. See CC01473

CC01460	Equipment	Move incubator E-1363 located in A133 to A125. relocate E-1364 in A133 on south side of room. Move printer XP0397 to east side of counter in same room A133. Move either E-1235 or E-1192 refrigerator to A133.	Moving refrigerator upstairs will help team be more efficient. Relocating incubators will accommodate the space for the refrigerator.	No impact, incubator remain in use and monitored during move. Refrigerator will accommodate testing while other fridge is moved.	21-Jul-17
CC01461	Major Software	Media Prep: Use Silent Hawk system along with program that will automatically read sterilizer cycle tapes. Parameters will give pass/fail value.	Decrease the amount of time required to review cycle tapes by secondary reviewer.	Silent Hawk is already in place collecting data. This is addition of program after Silent Hawk pulls data. No downtime to operations.	14 Feb 2018, applicable forms updated Mar 2018, received closure 06 Jun 2018
CC01462	Business Critical	In Feb 2017 prefixes were added to the numbering of our procedures in the Document Number field in MasterControl, prefixes were also added to the Vault, Lifecycle, and Document InfoCard Type fields in MasterControl. It has become necessary to remove the prefixes from the Document Number field.	The addition of prefixes in the document number field has introduced some challenges in MasterControl	After hours, downtime of approximately 1 hour due to installing the script from MasterControl.	3-Aug-17
CC01463	Major Software	Move financial data from Microsoft Great Plains to Oracle JD Edwards E1 system.	Moving company to a one company models.	CRM and customer portal down after hours 30 Jun 2017 at 10PM to 01 Jul 8AM	2-Jul-17
CC01464	Equipment	Move Fridge E-3150 in room M23 to room M08.	E-3150 will replace fridge E-2832 in M08. E-2832 will be placed out of service	Bottleneck may occur pending MMO moving rolls of material mounted in room M08 to M11 before fridge can be moved to room M08.	20-Jul-17
CC01465	Equipment	Move Spectramax equipment #E-2032 from area B164 in RW1 to area 206 in RW4.	Consolidation of Specialized Reprocessing testing in same building on SLC campus. PRD 02-1609A	No impact. Duplicate instrument will already be installed in same room and validated prior to moving E-2032	5-Jan-18

CC01466	Engineering/Buildi	SteriPro-Itasca Renovation for offices 103, 104, 105, 125 and 126. Carpeting and finish flooring along North Wall of building	Improvement to facilities aesthetic appearance.	Change has no impact on structural or process change. Measures in place during change to limit impact to Micro testing in back of building	11-Aug-17
CC01467	Cleanroom	Adjust cleaning of the cleanroom by lowering the amount of sanitization requirements for select areas for 3 month trial.	Recent cleanroom renovations (walls, floors) have improved areas which allows for sanitization change to fit current needs for environment control.	Will continue to follow ISO 14644 practices for controlled environments	08 Mar 2018 (qt 4 environment trend report)
CC01468	Equipment	Replace existing fridge/freezers with True coolers in applicable areas.	Itasca Renovation . (Chemistry, Log-in, Micro, Sample prep)	None. Qualification of new equipment will take place.	Jun-Sep 2017
CC01469	Final Product	Adding a deviation summary to the final report templates (FRTs) and the automated reports in UNIFlow.	Clearer identification of a deviation to the sponsor within their final reports.	None. Change will be made gradually	2-Jan-18
CC01470	Organization	Move the Warehouse function and employees from Finance to the Operations team Log-In. Supervisor change.	Will align with handling of products, supplies, samples under one department.	IT, HR, Training, Finance, Warehouse, Log-in impacted by change. (Trading, org chart, system update, etc.)	30-Sep-17
CC01471	Final Product	Change the final report review process from paper copy to electronic. Additionally incorporating an electronic signature in compliance with 21 CFR Part 11.	Creation, collaboration, review and finalization of NL's final product to be completely electronic.	No downtime to operations. Electronic process will be implemented in conjunction with current process.	In process
CC01472	Final Product	Add the ilac-MRA Mark logo in the fully automated reports in Uniflow.	Support internationally accredited body	No downtime to operations. Logo can be implemented over time since ANAB logo is still accurate	19-Jan-18
CC01473	Final Product	Implementation of Nelson Final Report Template (FRT) in Itasca and Ontario.	Harmonize test offerings where applicable (currently: BET, Product Sterility, BI Sterility, EO Residual, Population Verification, Bioburden)	Upon a set deadline, the templates will be replaced. (one for the other)	9-Jul-18
CC01474	Business Critical	Nelson Labs acquisition of Toxikon Europe B.V.	Change of ownership for Toxikon Europe B.V. and will expand scope of responsibility for Nelson Labs	Nelson Labs operations will continue to run and operate as prior to this change.	Oct 2017, Aug 2018

CC01475	Engineering/Buildi	Remove water heater equipment E-3078 from for U48 Glassware washing room. Project plan 01-1710	Removing water heater will change cycle time of current installed washers approximately 10 minutes without the heater. Need to make room to accommodate new glassware washers.	Glassware/Media Prep downtime to operations is about 2 hours. Will coordinate with Glassware/Media Prep.	11-Dec-17
CC01476	Equipment	Replace Lancer washers with Miele washers. 6 in room U48 and 2 in room 206. New stainless steel pans to be added to platform for washers in room U48	Improved functionality that will increase production demands and have integrated process controls.	Room U48 approximate downtime for approximately 12 hours during pans added to platform. Washers will be switched out 1 at a time to continue operations.	Washer qualification Aug 2018, Documents, etc., Mar 2019
CC01477	Equipment	Move BSC (Hood) E-1569 from A-131 Radiation to Lab 227 Micro.	Micro performs most testing in a BSC. Confirmed with Radiation that the hood is not being used in current lab.	No downtime to operations.	14-Dec-17
CC01478	Other	Validate ProCare 10AO and the LaboClean FT qualified for use in new Miele washers.	ProCare 10AO and the LaboClean FT detergent use recommended by washer manufacturer.	No downtime to operations.	31 Aug 2018, procedures 08 Feb 2019
CC01479	Testing Location	Itasca- change location of sample preparation and sporing lab reprocesses in room 213 to room 130.	Itasca renovation.	No impact to operational process.	10-Nov-17
CC01480	Business Critical	Nelson Laboratories parent company change name from Sterigenics International LLC to Sotera Health, LLC	New parent company name combines integrated and holistic customer value as it combines offerings to better serve customers.	NL will continue to operate with no interruption of business	8-Nov-17
CC01481	Testing Location	Subcontract the Process Challenge Devices (PCD's) to Production Line, Inc. PCD's are currently produced at NL.	Ability to subcontract preparation of PCDs to 3rd party manufacturer will provide additional capacity to lab for testing services. In addition, Manage NL PCD's by the Itasca location and use of same subcontractor aligns with integration activities.	No downtime to operations. NL's SLC location will continue to prepare PCDs for clients until Production Line begins production. NL SLC will continue to be a back-up.	Obtained final closure 03 Oct 2018
CC01482	Other	Change environmental monitoring: Remove locations that are not critical to testing, change frequency of sampling to quarterly to less critical sites and annual to incubators.	Most of the rooms monitored are not classified and the need to conduct monthly monitoring is being proposed for change.	No downtime to operations. SOP0020 and applicable forms will need updated.	12-Apr-18

CC01483	Other	Implement a new lysate manufacturer as standard supply for North America Labs BET test. NL SLC uses Charles River, other sites use Lonza.	Change will allow other sites to align with NL SLC.	No impact. No expected downtime with reagent change.	9-Aug-18
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