

NUMBER	CHANGE CATEGORY	2019 REQUESTED CHANGE	REASON FOR CHANGE	IMPACT	APPROXIMATE DATE IMPLEMENTED
CC01520	Equipment	Upgrade the controls in the EO sterilizer E-3391	To improve the performance and reliability of the Joslyn 2038 EO sterilizer.	3-4 weeks; the sterilizer will be put out of service during installation and requalification of the unit.	In-process
CC01521	Equipment	To move the Inductively Coupled Plasm Mass Spec (ICP/MS) from current location in RW5 lab 104 to RW5 lab 108.	Move to new construction of a new Metal analysis lab to isolate the equipment and minimize environmental and cross contamination from other processes	During the move and requalification Metals testing will not be performed in house. The estimated duration of the down time will be 3-4 weeks. (Applicable clients will be notified if impacted)	19-Apr-19
CC01522	Equipment	Move the Milli-Q water Ultra Pure water system NLI# E-4068 from RW2 U19 to the newly constructed extraction lab in RW5 lab 105. Lab rooms indicated by AUX0004 r23.	The change will bring the type of water used in the Extractable/Leachable extraction to the point of use.	Anticipate the total down time to be 4 weeks for the move, reinstall, and re-qualification. A smaller water system that is already installed and qualified in RW5 will be used during the downtime.	30-Jul-19
CC01523	Equipment	Move the Analytical balance NLI E-4283 from RW5 104 to RW5 105.	Move is to get it out of the analysis lab and into the point of use or extraction lab to make it close to where it is needed.	Expected downtime will be 1 week. However, the section does have one other analytical balance that can be used for processing samples in RW2 lab room U17, NLI equipment #3336.	8-Mar-19
CC01524	Cleanroom	CANCELLED- Removal - patch of Cleanroom 7 floor that was installed Jan 2017. (1x2 in portion of top layer will be removed.	floor need examined by suppliers lab-advanced discoloration and wear occurred during last 2 years.	Downtime to room 7 is 1 day	CANCELLED

CC01525	Engineering/Build	Change associated with RW5 rooms 107 and 108. Room 107 has been repurposed from custodial room to a Glassware washing room for Chemistry processes. Room 108 has been repurposed from a break room to the Metals lab, housing ICP/MS instrumentation.	The change was part of the RW5 build out to complete the unfinished space and make it a full functioning laboratory for Extractable / Leachable testing.	Unable to use rooms under construction. Testing or glassware cleaning not impacted as conducted in assigned rooms prior to move.	12-Jul-19
CC01526	Equipment	Moving all of the Itasca and Ontario equipment under the Sterigenics system to NL's Uniflow system per SOP0067	Harmonization of calibrations and preventive maintenance programs.	Systems run simultaneously during transition	9-Jan-20
CC01527	Other	Remove the stamping set from Media QC testing found in SOP0155	Use of stamping set tests 18 additional organisms for several media types for qualitative growth. Test goes above and beyond expected for Media QC test of media. Removing stamps set would not adversely affect. (Reviewed applicable USP's, FDA guidance)	Once SOP updated and applicable recipes modified, this testing will be discontinued.	8-Oct-19
CC01528	Major Software	This request is to write and implement an enhanced Uniflow system for Media Prep. The enhanced version of Uniflow allows for additional flexibility for in-house and commercial media	This system enhancement is needed to allow for improved flexibility for in-house and commercially purchased media types. To prepare for other sites to begin use of Uniflow for testing purposes (such as Bioburden, BIs, and BET).	Will use current UNIFlow while enhancement is implemented	30 May 2020- Closure pwork received 02 Sep 2020

CC01529	Other	CSS harmonization- Itasca and Ontario will discontinue the Sterigenics system for Customer Specification Sheet (CSS) approval and adopt the Nelson Labs system for CSSs for the following testing areas: Bioburden, BI Sterility, Product Sterility, BET, Product Sporing, and Residual Analysis. This will not change the content contained with a CSS	The content within a CSS will not differ, this change will not impact testing as the numbering, process and approval route will only allow for a more efficient system for both customers and lab personnel.	No downtime to operations.	In-process
CC01530	Other	Harmonize the Test Pack (TP), PCD, and BI request processes at the Mexico, Ontario, Itasca and Salt Lake City facilities. This will include harmonizing the process for ordering/billing, labeling, quality process controls and procedures/ forms.	To create a harmonized system for the sponsors to provide a consistent experience that meets their expectations.	No downtime to operations.	In-process
CC01531	Engineering/Build	Expand Redwood 5 lease to include office and sample storage location space on first floor. (will not be used for lab testing).	Additional space needed.	No impact. Additional space needed for study directors and sample storage.	16 Aug 2019, AUX0004 updated 08 Nov 2019
CC01532	Equipment	Move applicable refrigerators, hoods, shakers from Bioburden lab A118 to A132. Move applicable equipment in same room to different location in same room.	To accommodate workflow through Bioburden with new Systec MediaPrep 60 sterilizers change will be made. Testing to occur in A118 and setup, prep, etc., in room A132	No impact. Fridge will be monitored during move, other equipment work will be shifted to remaining hoods in service.	29-Jul-19

CC01533	Business Critical	Replacing Nelson Labs disaster recovery (DR) location from St. George, Utah with a Verizon-owned data center/facility located in Downers Grove, IL.	Have Nelson Labs DR location the same as the Sotera Health data warehouse center; however, the Verizon facility will be Nelson's DR location. The Verizon facility will not be the original data warehouse center for Nelson, as that will remain in SLC.	Users at the Nelson SLC facilities will not notice any disruptions to their normal work day	3-Jul-19
CC01534	Equipment	Itasca location- New Gas Chromatogram (GC) method created for analyzing EO residuals (EO, ECH, and EG). This new method will run on Itasca's Agilent 7890 GCs. The change will a transition of Itasca's current processes (Sterigenics Work Instructions G-WI-LB-CHM-006;G-WI-LB-CHM-007; and G-WI-LB-CHM-008) to STP0016.	Harmonization of EO residual testing between the two lab locations (SLC and Itasca), allowing Itasca to implement the same test procedure that is run in Salt Lake City	The method validation was completed on each GC instrument (Equipment Number E-5020 and E-5021) at different times	23-Oct-19
CC01535	Cleanroom	Cleanroom maintenance- replace light fixtures in corridor, floor/biological safety cabinets , hood maintenance. Install new phone, reinstall previous hood camera.	Improve test environment and usability	Cleanroom will not be used for sterility testing on 12 Jul 2019. Media prep will not be able to have media sterilized into the cleanroom until the night of 14 Jul 2019.	12-Jul-19
CC01536	Equipment	Install a backup 125kW Diesel Generator with a 400 Amp Transfer Switch for the RW5 facility to provide power for equipment during a power outage.	To provide emergency power to key items in the lab, including Fume Hoods, Freezers, Refrigerators, Incubators, and our Computer systems in case of a power outage	4 hours on a Saturday during installation	29 Aug 2019 (SOP update)
CC01537	Equipment	Replace the Elga water conditioning system integrated into equipment ID E-3140; accelerated aging chamber with the Aries Filterworks system	The Elga system is no longer adequate to supply our requirements.	No impact. Switch over will not interfere with operations	30-Dec-19

CC01538	Equipment	Double door fridge E-4088 in room #RW4-201 will be swapped with single door fridge E-2028 in room M06	Specialized Reprocessing is wanting to make more room for scope cabinets and Protective Barriers is wanting the extra fridge space for media.	profiling of both fridges once moved which should take 24 hours.	27-Aug-19
CC01539	Equipment	Delta P- test equipment EN 14683 and ASTM F2100 are now harmonized to require this upgraded for different pressure testing the STP0004	This improved apparatus was implemented in the two standards that require this method (EN 14683 in March 2019 and ASTM F2100 in August 2019).	This has already been validated and incorporated into the STP	30-Aug-19
CC01540	Final Product	The final report template (FRT) for simulated use, cleaning and disinfection validations will be updated to remove the Procedure section from the final report and instead the procedure will be included as an appendix and referenced in the summary section	Change will reduce time to write report, reduce opportunity for error, increase focus, better product for sponsor.	We will follow our current process until this new process is in place.	In-process
CC01541	Other	Remove the reference and resource section in documents which will be stored on the info card/attachments as link to procedure	References will be under attachments on infocard, easier to update and access, fewer minor updates.	No impact, change affects document management process, no change to MasterControl system	In-process
CC01542	Other	The cell culture transfer log book will change from a paper system to a Uniflow system. This is a new UNIFlow application.	Electronic data recording of our cell culture passages will be more efficient	The paper logbook process will be used until the Uniflow system is validated	17-Jan-20
CC01543	Equipment	Replace the flow meter component of the batch controller system ID# E-3847.	Our actual flow rate at the batch controller is near the bottom of the accurate range of the current flow meter.	Associated steam kettle will be filled by the alternate Media Prep flow meter.	17-Oct-19

CC01544	Major software	Update the Rees system from version 2.0.1017 to patch 2.0.1020	The current version of Rees has known security vulnerabilities that are fixed with this patch	Estimated down time is 2 hours while the update runs	3-Dec-19
CC01545	Safety	The proposed change is to replace the Sulfuric Acid/No Chromix Cleaning procedure WI0154 with the Miele Automatic Glassware Washer procedure WI0322 as the primary method to wash the analytical glassware. This includes analytical testing that requires low level organics and that has utilized acid washed glassware (Gravimetric, Hydrocarbon Oil Index (HOI) and Total Organic Carbon (TOC). WI0154 -Sulfuric Acid/No Chromix procedure is a manual operation (washing station)	The reason for this change is due to the safety risk to employees. WI0154 directs the use of high volumes of acid exposure and presents a serious risk to employee safety.	Process will transition to WI0322. No downtime	In-process
CC01546	Equipment	Move laminal flow hood in current BET lab building 4 from current location to new location in adjacent room.	Part of Mexico City lab renovation project.	No downtime to operations.	25-Oct-19
CC01547	Test Location	Move testing location of STP0175 Growth Promotion from Product Sterility to Micro	Aligns with additional testing Micro conducts.	No downtime to operations.	Received closure form 10 Apr 2020

CC01548	Equipment	Lab equipment for testing will be moved from building one (1) to building four (4). Equipment that supports Media Prep, BI Testing, and Bioburden will be moved and placed in operation according to established procedures and protocols. BET and Test Pack move from building 4 1st floor to 2nd	Mexico City Lab renovation project. Consolidation of all Mexico City Lab operations into building four for the purpose of preparing lab operations as a recognized, certified, stand alone operation for Cofepris certification.	The move will be made during a plant shutdown while no customers are processing in the EO facility. Systems will be qualified and brought on line during this shutdown period	received closure form 12 Aug 2020
CC01549	Equipment	Itasca location- HVAC system for Chemistry (RTU #12) to be replaced with same functioning unit	Replacing RTU #12 as maintenance change	Area will be evacuated for about 1 hour during the movement of the unit onto the roof with a crane. Lab may not be operational 0 -2 days depending on the outside weather and how cold it is inside the Chem Lab	15-Dec-19
CC01550	Equipment	Purchase epMotion 5075C fluid handling system in order to automate pipetting required to set up the LAL assay. Project # PO1-1911	Automation will increase consistence of results, reduce error, and increase analyst safety	Testing will take place according to current procedures outlined is STP0046 until IQOQPQ of epMotion can be complete.	14 Aug 2020 Equipment, TRO finalized 16 Oct 2020
CC01551	Other	Relocate applicable person/teams i.e., DLO's, Subcontracting, Sr. Scientists, Purchasing, Consulting, OpEx.	Identified closer collaboration is needed amongst teams for business development, integration activity, etc.	No impact to operations	6-Feb-20
CC01552	Equipment	Replace the current control system (Trinity control version 1.4) in the Primus sterilizer E-3021 with a new control system (PSS11).	The current control system is malfunctioning. The manufacturer cannot repair, and they have recommended the control system upgrade.	Downtime 16 Dec through 29 Feb 2020	2/24/2020, course 21 Apr 2020

CC01553	Cleanroom	Cleanroom operations will be interrupted from 14 Feb 2020 thru 28 Feb 2020. During this shutdown, cleanroom floors will be resurfaced, light fixtures will be replaced in the cleanroom corridor, media storage, and gowning room. In addition, the camera in the media storage will be fixed	The floor has been identified as needing to be resurfaced in order to maintain the integrity and classification of the cleanroom. The other repairs will improve the testing environment	Downtime for Sterility testing and sterility media production 14-28 Feb 2019	24-Feb-20
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