

NUMBER	CHANGE CATEGORY	2020 REQUESTED CHANGE	REASON FOR CHANGE	IMPACT	APPROXIMATE DATE IMPLEMENTED
CC01554	Major Software	Work with the Software development team to scope, current state/future state, wireframe, plan, develop, test, and deploy a SSF online form as a solution.	Make the form more user-friendly and multipurpose. For NL, dramatically help with eliminating many of the quote conversion issues, etc.	Improve our ability to forecast, more real-time ability to understand what is coming in and plan accordingly (resources and etc.). Reduce quality issues.	12 Jul 2020 implemented. 01 Jan 2021 ended user adoption
CC01555	Engineering/Building	Next stage of the RW5 expansion project for the Chemistry Department. Two currently vacant rooms on the second floor of RW5 need to be outfitted with the cabinetry, countertops, plumbing and HVAC to prepare for their future usage.	The change is part of the RW5 expansion plan to complete the unfinished spaces and make them outfitted to support E&L testing and routine chemistry work, including Total Organic Carbon, Wet Oxidation Method (TOC) and Hydrocarbon Oil Index (HOI)	The building updates are to a currently vacant room where no laboratory tests are performed.	27-Feb-20
CC01556	Other	Packaging is currently using reusable funnels, but would like to have the option to be able to use the disposable funnel in the F1608 membrane filtration portion of the study.	Packaging supply of reusable funnels sometimes do not rotate quickly enough through Media/Glassware when the volume of incoming studies is high	None-Either disposable or reusable funnels would be used.	20-Aug-20
CC01557	Engineering/Building	During the cleanroom shutdown, scheduled for the 14th Feb 2020 thru 28th Feb 2020, the Media Prep floors in rooms U44-U47 will be resurfaced from the 16th Feb 2020 thru 23rd Feb 2020	The floor has been identified as needing to be resurfaced.	All media production will be stopped from the 16th Feb 2020 thru 23rd Feb 2020. Cleanroom only media production will be down from the 14 Feb 2020 to 28 Feb 2020	24-Apr-20
CC01558	Engineering/Building	Bacterial endotoxin-Test methods, routine monitoring and alternatives to batch testing AAMI ST72:2011/(R)2016 previously listed the typical temperature range for "room temperature" as 18-25°C. Propose room temperature now be considered 20-25°C.	AAMI ST72:2019 now describes room temperature as 20-25°C.	No downtime to operations.	18-Mar-20

CC01559	Equipment	A new UV/Vis spectrophotometer, E-5428, has been installed in Packaging and we are ready to begin use. Note: Other UV/Vis spectrophotometer, E-1638 will remain in service	New spectrophotometer purchased to increase Dye Immersion testing capacity. Instrument is updated version of the one currently used. Hardware, software, graph displays, reporting format different than current UV/Vis	No downtime to operations.	19-Jun-20
CC01560	Equipment	Lab equipment to support BET testing move from 1st Floor lab room number 106 to the 2nd Floor room number 203. Change also include operation range of incubator E-5265 in room 111 and requalify as freezer.	Equipment (3 pieces) being relocated to support BET operations as well as incubator operation range to support needs of facility	No downtime to operations.	23-Jun-20
CC01561	Other	Chemistry Discontinue Salt Spray Fog test conducted in B155 RWD I. Test code SCT100, SCT105.	Space needed for Media QC assessment done to determine move to Chemistry area, etc., time, cost and low revenue test would not be worth the revenue.	Test will end mid March 2020	18-Sep-20
CC01562	Major Software	Implementation of UNIFlow for Media Production (EO Sterility media only), QC (EO Sterility media only), EO Sterility testing, and BET testing	UNIFlow will reduce paperwork, improve overall quality, and improve turn-times.	No downtime to operations.	30-Oct-20
CC01563	Other	Allow Study Directors to access LMS studies via Virtual Private Network (VPN) – Pulse Secure for data and final report review and approval	Change will, in the short and potentially long term, allow us to flexibly use our study director resources on and off premise. To summarize, we are creating the ability to view hard copy documents offsite in order to review and approve data and final reports for automated testing remotely. This is not a procedure change	No Impact or procedure change (applicable procedures)	23-Mar-20
CC01564	Major Software	Uniflow will be used for data recording for Sterility testing in the Cleanroom and the Isolator.	UNIFlow will improve overall quality, reduce paperwork, and mitigate risk of transcription during the reporting process	Downtime less than a day while computers installed.	18-Nov-20

CC01565	Other	<p>STP0005, FRT0005 update to New change: Only perform one one-minute control count before and after the test article and one one-minute count with the test article in the test system. New change: An equilibrate is performed for 30-60 seconds without recording particle counts, clearing the system of any residual particles, and establishing a state of stable equilibrium</p>	<p>Due to shortages and unavailability of PPE in the healthcare setting, especially face masks, the need to perform the Latex Particle Challenge testing quickly and efficiently and to comply with the Nelson Labs quality systems</p>	<p>No downtime to operations.</p>	<p>16 Sep 2020 Addendum</p>
CC01566	Organization	<p>Operational Excellence To align with our strategic priority of driving operational excellence we are resourcing the team. John Bolinder, VP Operations - North America and Jessica Olson, Director OpEx will have new team members assigned to support their key initiatives</p>	<p>Consolidating several lab sections in Salt Lake City (SLC) and appointing leaders to some significant new and expanded positions to support our focus on operational excellence.</p>	<p>No downtime to operations.</p>	<p>12-Aug-20</p>
CC01567	Other	<p>The proposed change would allow for a cell culture media lot numbers to be larger than 1 L. Remove the requirement to measure and adjust the pH using HCl from the recipes 1XMEM5C (MR-702) and 1XMEM5SFC (MR-1132).</p>	<p>The unflow recipes would simply need to be updated to allow for larger lot sizes. Allowing for larger lot sizes will increase efficiency and reduce direct material costs because the media will be made in the original manufacture bottle.</p>	<p>No downtime to operations. The ratio of the primary ingredients used for the production of 1XMEM5C or 1XMEM5SFC would not change and performance will not be impacted</p>	<p>5-Jun-20</p>
CC01568	Major Software	<p>The current control board for the Primus steam sterilizer in RW1 (E-2565) is not functional. A new control board (PSS11) has been received to replace it.</p>	<p>The current control board cannot be repaired and Primus has recommended that the control board be updated.</p>	<p>Sterilizer is currently not operational . It is anticipated that after this change, the sterilizer will be functional again.</p>	<p>09 Oct 2020, TRO effective 27 Oct 2020</p>

CC01569	Major Software	Introduce and implement the DocuSign application in Salt Lake City for signing documents by Quality Personnel. In a later stage, the usage of the tool may be extended to other types of documents and personnel	Supporting quality documents that are used outside of existing platforms with electronic signatures are in need of an option for electronic signatures which is 21 CFR Part 11 compliant.	DocuSign application will provide an electronic signature platform in SLC for the Quality Personnel working remotely to sign documents electronically.	14-Dec-20
CC01570	Customer Service	The proposed change is to discontinue receiving, sterility testing and releasing biological indicators (BIs) on Sunday's	Discontinuing testing of BIs on Sunday will further align our operations across all of our locations and to better serve our customers during regular business hours. In addition, it will remove the operational constraints of staffing for that day in both, EO Sterilization and login including working 6-day shifts or split-hours shifts	TAT impact will be for those sponsors that submit samples with shortened incubation periods (i.e. self-contained BIs or studies with reduced incubation times)	27-Oct-20
CC01571	Cleanroom	The cleanroom will have maintenance performed to repair caulking in the sterilizer and incubator hallways, and to reapply paint to painted surfaces. Cleanroom computers will be installed in the five testing rooms and in the cleanroom corridor	The maintenance will prolong the lifespan of the cleanroom suite. The computers will provide access for using Uniflow for data entry in the cleanroom	The cleanroom will not be used for testing on 24 Jul 2020 (Friday). Media Prep will not be able to have media sterilized into the cleanroom until the night of 26 Jul 2020 (Sunday)	27 Aug 2020, closure info provided 21 Oct 2020
CC01572	Equipment	Boiler system (Hurst 40 HP boiler) for building to be replaced with same functioning unit (Williams and Davis 40 HP boiler) as currently supports building;	Itasca has one boiler unit that was installed at the time of facility start up in 2001. This boiler unit is currently experiencing reoccurring down-time and struggles to maintain daily function	HCR- one client impacted by approximately 1-3 weeks downtime	18-Dec-20
CC01573	Equipment	E-4060 Hydraulic tester will be replaced with E-5921 Pneumatic Burst tester. The method is going from Hydraulic (oil based) to Pneumatic (air based). Instead of following ISO13938-1 we will be following ISO13938-2.	Based on technical issues with the hydraulic tester and the lack of technical support from the manufacturer, this tester will be replaced with the James Heal Pneumatic tester manufactured in England.	No downtime as current tester will be used until replaced tester/test validated	2-Nov-20

CC01574	Test location	The ISO18562 VOC testing location and air source will change from clean house air in M10 to pure Nitrogen in U61	Pure Nitrogen provides a much cleaner background and Chemistry has approved the use of counter space and Nitrogen air source in U61.	No downtime as current location will be used till moved.	2-Nov-20
CC01575	Equipment	Automatic Sphereflash E-5189 Colony Counter will move from M08 Redwood 2, First Floor to M24 Redwood 2 First Floor.	A third BFE testing apparatus is being built in M08 where more space is needed for testing. Moving the Sphereflash will free up about 6 feet of counter space to allow for a third apparatus and much needed space.	Approximately 7 days downtime for moving the Sphereflash and re-calibrating. Hand colony counters will be used while Sphereflash is down.	28-Aug-20
CC01576	Equipment	Double door fridge E-2221 in the warehouse quarantine area will move to room M24 Redwood 2 First Floor	Using E-2221 for overflow BFEA plates needed for BFE testing. Inconvenient for fridge to be located in quarantine which is inaccessible after hours and on the weekends. M24 lab has an outlet and wall large enough for the fridge to be re-locate	Profiling of the fridge once moved should take 24 hours.	17-Sep-20
CC01577	Equipment	Replacing an old Agilent 5890 GC (E-5019) with an Agilent 8860 GC (E-6048)	PC that controlled the 5890 GC stopped working, Chemstation software installed on the PC was no longer supported by Agilent, so replacing the PC was not an option.	No impact. Additional equipment available for use.	16-Jun-21
CC01578	Testing Location	Expand the Login area to include the applicable rooms in Redwood I. No lab equipment moving, office computers and workstations. EO batch release samples and PCD storage will move to Rooms B108 and B147.	Login expansion is needed to better manage sample volumes, discrepancies and deliveries.	Minimal impact to EO dept; moving sample preparation from Redwood I, Room B132 to B108.	12-Oct-20

CC01579	Organization	Leadership changes: Jeffrey Nelson will move from the role of President of Nelson Labs to the role of Chairman of Nelson Labs. Joe Shrawder will move to role of President of Nelson Labs.	Jeff Nelson's Chairman role will lead efforts to grow our Expert Advisory Services, help lead M&A efforts, focus on incremental growth for the company.. Joe Shrawder's role as President will support new strategic priority of Driving Operational Excellence	No impact	19 Oct 2020, closure 17 Nov 2020
CC01580	Engineer/Building	RWI-2nd Floor-Room B130: Wall to be install from B131 across B130 to east wall and around north side of roof access ladder. Door installation on west side of wall for access between rooms	Allow double door separation of sample receiving area for processing. Allow better temperature and pest control of laboratory receiving area	minimal downtime as work will be done during weekend and slower times	12-Apr-21
CC01581	Engineer/Building	For Log-In RWI-Second Floor-Room B136: Expand Room encompassing open area of locker and wash station.	Expansion of Room B136 to allow more space for Login duties, and delivering sample	downtime will be minimal as work will be done on weekend	2-Mar-21
CC01582	Method	10% Phenol Recipe Modification for STP0204 Glutaraldehyde Analysis by UV/VIS, , M337-1 Phenol in Methanol_Glutaraldehyde Analysis	Modified recipe of the 10% phenol solution was validated which produces a homogenous solution and thus a slightly smaller variability.	N/A- Adding methanol to phenol solution serves only as an aid to completely dissolving the phenol. The actual working principles of the test method are exactly the same.	03 Feb 2021
CC01583	Facilities	Cleanroom shutdown for maintenance and semi-annual requalification	Maintenance and requalification	No sponsor notification, minimal disruption to sponsor testing, No product sterility testing available between Thursday 14- Monday 18 Jan 2021	22-Apr-21
CC01584	Method	Discontinue Dissolve Oxygen Test STP0084	No demand, No testing since 2016	Testing discontinuation, no testing since 2016. Equipment no longer in service.	3-Mar-21
CC01585	Method	Discontinue Residual Powder Glove Test STP0070	1 recent test, other than that no testing since 2016	Testing discontinuation (2 sponsors impacted)	26-Apr-21
CC01586	Equipment	Fridge (E-2221) and Hood (E-5215) location move	Making room for new TSI testers	N/A	12-Mar-21