

NUMBER	2016 CHANGE CATEGORY	REQUESTED CHANGE	REASON FOR CHANGE	IMPACT	APPROXIMATE DATE IMPLEMENTED
CC01398	Major Software	BET Uniflow system enhancement to allow batch data collection for Prep device, prep liquid, make dilutions and additional prep.	Enhancement will increase speed and accuracy of data collection during sample preparation.	No downtime to operations. Installation to take place during non-business hours.	14-Mar-16
CC01399	Testing location	Remove Packaging Dye Migration testing (STP0076) from Redwood 4 location.	Additional space is needed for HCR scope testing	No impact. Redwood 1 Packaging department currently has lab area for dye migration to be performed.	20-Jan-16
CC01400	Engineering/Build	Redwood 4 (2nd floor) build out is needed for HCR work. Includes addition of walls, electrical/network/vacuum etc.	New space frees up area for an exclusive area for HCR.	HCS and Packaging may experience short downtime to operations while working on electrical/vacuum, etc., where areas have concluded with some strategic scheduling, they will be able to work around interruptions.	25-Jan-17
CC01401	Equipment	Replace non working components in the EO disposer E-1417. (Components are not like for like) Replace with new Allen- Bradley PLC platform controllers.	Needs to be placed back in service.	The disposer has been out of service for some time. MMO, QC validations, QA involved with change. (requalification)	26-Mar-16
CC01402	Engineering/Build	Install connection to the house vacuum system in RDW2 room M04	Connection needed, BF lab is moving to room M04	No downtime to operations during installation.	1-Mar-16
CC01403	Equipment	Move fridge E-2826 currently in A132 to room M04	Moving fridge is associated with B/F location in room M04	Items currently in fridge will need relocated during move-requalification	17-Feb-16
CC01404	Major Software	Upgrade MasterControl 11.3 version to 11.4 for improved functionality	Version 11.4 will include certain functions that were not effective or included in version 11.3	Approximate downtime of 4 hours during off hours.	6-May-16

CC01405	Other	Extraction time of device immersions (BET) changed from 40-60 minutes to > 60 minutes	Change with extraction time brings harmony between NLI procedure and applicable compendia documents	Training on new extraction parameters, validation.	8-Sep-15
CC01406	Business critical	Datapacks stored in file system accessed by CRM will be imported into Docuware.	Datapacks are being imported to Docuware to have a central lookup locations. Will not include datapacks stored in PaperVision.	Datapacks will be accessible from CRM while importing to Docuware.	1-Apr-16
CC01407	Other	BI Sterility, Product Sterility and Isolator areas procedure/process to coincide with ISO 14644-1 and ISO 14644-2 update	ISO 14644-1 and ISO 14644-2 updated. Applicable areas need to coincide.	No impact. Procedures/protocols to be updated	Change Control Cancelled
CC01408	Business critical	Change of ownership. Acquisition of NLI by Sterigenics.	Change of ownership	NLI will continue with no interruption of business.	4-Apr-16
CC01409	Equipment	Move incubator 1629 from BSL3 lab to room 226. Change temperature range from 25-30 degree C to 35-37 degree C.	Incubator needed for clinical scope project in Micro. Change temperature range that is close to human body temperature.	No downtime to operations.	21-Apr-16
CC01410	Testing location	Clinical scope testing will be moved from HCR to Micro.	Distribute workload and consolidate expertise of scope testing. (Micro has been performing membrane filtration portion)	No impact. In interim of training Micro, POD analysts have been performing extraction portion.	9-May-16
CC01411	Engineering/Build	Add compressed air and vacuum ports to east wall in RDW3 room 221 Particulates lab	New study requires compressed air/vacuum connections.	No downtime to operations	2-Jun-16
CC01412	Other	KC HealthCare is now Halyard. Packaging design will change. Clients will need to be notified since KC wraps are referenced in PDS/Reports	PDS/Final reports outline KC wraps. Customers have type of wrap in their IFU	No impact. Change associated with customer notification of KC-Halyard package design change.	7-Dec-16
CC01413	Equipment	Relocate hood E2658 from Biocomp to Bioburden room A132. Purchase balance, and install computer for Bioburden testing.	Bioburden needs additional testing space for biohazard product types. Biocomp is purchasing a different hood so E2658 became available for Bioburden use.	Hood will be transferred to Bioburden once Biocomp has replacement hood. No downtime to operations.	27-Jun-16

CC01414	Organization	Split HCR into 2 sections. One for cleaning and disinfection and one for scopes, reprocessing studies, repeats and thermal testing. Add additional section leader to be over cleaning and disinfection.	HCR experience significant demands across all areas of testing.	None. Teams focused in specialized expertise.	20-Jun-16
CC01415	Final Product	NAMSA is discontinuing large BI strip (6mmx30mm) PN STN-06 effective 15 May 2016.	NLI will not be able to make PCD's which use PN STN-06.	NLI PCD's made with PN STP-06 will no longer be offered to clients	4-Jan-17
CC01416	Cleanroom	Repairs to cleanroom 8.	Repairs needed to ensure integrity of the cleanroom	Cleanroom 8 will be down for approximately 10 days. Entire cleanroom will be shut down for 3 days.	23-May-16
CC01417	Business critical	Nelson Laboratories, Inc. name change to Nelson Laboratories LLC with Sterigenics International LLC acquisition.	Ownership change by Sterigenics our company name is officially changing.	None Change associated with company name change.	17-Jun-16
CC01418	Equipment	Replace water reservoir temp switch on Primus Sterilizer E-3141. Change will only affect vacuum capabilities of the sterilizer.	Change should enable Primus sterilizer to produce deeper vacuum drying level.	Component replacement will take about 10 minutes. Functionality verification will be completed.	8-Jun-16
CC01419	Equipment	Swap location of refrigerator E-3311 currently in U50 and E-2348 currently in room B-163.	Better utilization of the equipment where more fridge space is needed. (1 fridge is a double door)	Monitor the units through out the move.	23-Jun-16
CC01420	Other	Merge SDS, PDS, Protocol and other testing instructions into one system (testing instructions)	Current system is no longer adequate to our needs.	Current system will roll into new system. Client notification is needed.	16-Dec-16
CC01421	Organization	Biocompatibility and Subcontracting sections will report to Director of Lab Operations (DLO) Tina May. HCR Specialized Reprocessing (Scopes) and HCS will report to DLO D.Floyd.	Aligns sections overseeing chemical characterization testing under one DLO	None. Organizational change.	7-Jul-16

CC01422	Cleanroom	Cleanroom, installation of new pass through glass doors and minor construction repairs.	New pass through doors will help improve the process by allowing teams inside and out of the cleanroom to view if items are in the pass through.	Cleanroom testing will be stopped for install, repairs and qualification. 3 days during weekend. No client notification needed.	9-Jul-16
CC01423	Equipment	Move gram stainer E-3067 from room M30 to M31. Internal ID's work is being moved to M31.	Better work flow and location more user friendly.	In the interim, Media QC will coordinate with IDs section to use there gram stain	27-Jul-16
CC01424	Cleanroom	Modify 2 of the cleanrooms racks that store quarantine media in the sterilizer hallway.	Adding panels to cover back of 2 quarantine racks will provide a visual difference from other racks in the cleanroom.	None	6-Jan-17
CC01425	Final Product	Change final report templates(FRT) acceptance criteria to test method acceptance criteria. Include GMP compliance statement to GLP QA compliance statement.	Separates acceptance criteria for test method from sponsor performance/standard. GMP compliance statement was not listed in the GLP QA compliance statement.	FRT updated and will continue to updated as available. (Automated report templates in UNIFlow and Reporting updating those not included in automated system.)	31-Jul-16
CC01426	Equipment	Validation performed to show that Hood Warm-up Time is no longer needed. (E240-1)	Remove signs posted on each hood with "Hood Warm-up Time". Validation shows warm-up time is not needed.	None	In-process
CC01427	Equipment	Move TOC analyzer 1010 (E-1640) from room U59 to room U61	Free up space for study director and analyst workspace.	TOC testing capacity may be cut in half during requalification. Have another analyzer to run samples. Duration for downtime is 4 weeks. Sponsor studies will be managed through Service Center, sales team and study director.	17-Oct-16
CC01428	Other	Allow use of washed or unwashed vinyl caps for PDC preparation. (QC000218) MFG part # 647936)	Usage of washed caps in place of unwashed caps to minimize variation of silicone present on surface of caps.	No impact, washed caps are considered "like for like".	In-process

CC01429	Equipment	Move FTIR spectrometer from RDW2 to RDW5. Move microscope #3018, #3365 and the air filter system #1994 and #3037 from Room U61 RDW2 to Room 103 RDW5.	Will alleviate work space in RDW2 and maximize work space in RDW5	Downtime to operations possibly 7 days	25-Oct-16
CC01430	Other	Millipore change tubing and modified assembly solvent mixture for canister sets TZHAPC210, THASY210, TZHVS210 Steritest.	Supplier Notification of Change	None. The evaluation performed by manufacture (Millipore) evaluated all potential use of supply. No additional internal testing is needed. (Reviewed by B. Kammerman)	N/A
CC01431	Testing location	Transfer hemoglobin testing (test codes: PAB110, PAB115 and HCX610) from the Healthcare Reprocessing (HCR) group to Specialized Reprocessing (SPR). The transfer includes transfer of 2 analysts and the current spectrophotometer. An additional spectrophotometer will also be purchased and validated.	Transfer is part of the separation of responsibilities with the creation of the new SPR section. Allow for management and supervision of testing to be in one section. Will create laboratory/office space for HCR.	No impact. New spectrophotometer will be purchased first so there is redundancy before the old one is moved.	In process
CC01432	Testing location	Change location and section ownership of Carbohydrate testing (STP0088) currently managed by Chemistry and transfer work and management to Specialized Reprocessing (SPR).	Vast majority of carbs testing currently performed is for validation work in HCR and SPR. (In-house transfer system) consolidation of the assays would benefit where sections are most often used.	No impact. Training will be completed prior to moving the location of the testing. Spectrophotometer that is used will not change as it is used shared with other areas.	15-Sep-17
CC01433	Equipment	Move freezer E-4231 in room U07 to Room U50	Freezer is owned by QC Validations but shared with HCR. Moving it in the room U50 allows for an efficiency gain to the lab and more control of HCR testing materials.	Materials will be moved to another freezer during move. (about 1 day)	15-Nov-16

CC01434	Equipment	Move Differential Scanning Calorimeter (DSC) E-2701 from U19 in RW2 to 104 in RW5.	Provide additional bench space in RW2 Chemistry area and alleviate working space constraints. This move will also help continue the migration of Chemistry to RW5.	Downtime to operations expected approximately 1 week	12/8/2018 (Qualification approval form signed)
CC01435	Engineering/Build	Add branch to RW2 compressed air system in basement B01 with new port connection near roll up door. Install a check valve also to prevent potential backflow.	New air branch to be used by warehouse for general purposes such as inflating tires.	No downtime to lab users	3-Jan-17
CC01436	Cleanroom	Floors in cleanroom, gown, incubator hallway and U38 will be resurfaced. Cleaning closet renovated with new sink and fiberglass reinforcement plastic panels installed on walls.	testing facilities improvement.	estimated duration is 30 Dec 2016-13 Jan 2017	Final Report approval signed by QA 29 Mar 2017
CC01437	Major Software	Enhance UNIFlow to support additional testing types and will also allow for automated reports to be electronically signed and uploaded to secure site. (Project Request Plan # 02-1408	To allow for additional testing types and automated/electronic signed reports	None. Will continue to use current UNIFlow until validation implemented.	10-Dec-16
CC01438	Other	Change the amount of datapacks audited by Document Imaging per month before they are shred. Currently audit 1,000 a month. Want to sample-audit under ISO2859 approximately 200 datapacks per month.	Positive trends in current process with certain percent of error free datapacks. ISO2859 sampling will be under recommended practices.	None	20-Dec-16
CC01439	Testing location	CANCELLED- RE-ISSUED UNDER CC01448 Time Aging Testing in RDW4 room 204 will be moved to RDW4 warehouse.	CANCELLED - Expansion of Specialized Reprocessing testing and office space.	CANCELLED - Environmental verification will be conducted during move and temperature mapping.	CANCELLED

CC01440	Testing location	Move Bioburden tissue testing to Microbiology Section	PRD 01-1610. Allows Bioburden additional testing capacity and Micro opportunity to utilize equipment and staff.	Testing will continue to Bioburden as needed during transfer.	4-Jan-17
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