CASE STUDY



Temperature-Mapping for Compliance and Consistency

Compliant Temperature-Mapping Kits provide major benefits to facilities including user-friendly software and instantly generated reports.

About Nelson Laboratories, LLC

Nelson Laboratories, LLC is a leading global provider of laboratory testing and expert advisory services with 13 global lab sites and headquarters based in Salt Lake City, Utah. As a Sotera Health company, Nelson Laboratories performs various microbiological and analytical laboratory tests across the medical device, pharmaceutical, protective. barriers. and tissue industries. Nelson Laboratories has over 35 years of experience helping clients mitigate risk, be the first to market, and in the end help them succeed with their customers.



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Rich Floyd, B.A.S. Critical Environments Supervisor Nelson Laboratories, LLC.

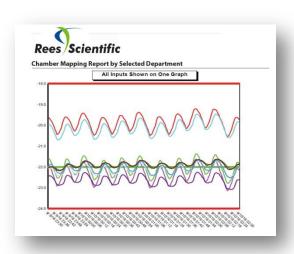
Mapping Regulations & Reporting

Temperature-mapping is the process of testing a temperature-controlled storage unit or room by placing sensors uniformly throughout the space to determine if it can maintain the temperature within defined limits. This is performed in units such as refrigerators, freezers, incubators, rooms, and other chambers. A report of the data is created to identify hot spots or internal temperature changes and to manage the storage of product within the unit.

To demonstrate continuing compliance of temperature-controlled storage areas, temperature-mapping of each unit before the installation and on a periodic basis is a requirement from the World Health Organization (WHO). WHO also requires that "all mapping exercises should be fully documented in order to demonstrate compliance to management, clients and the regulatory authorities."¹

According to Rich Floyd, Critical Environments Supervisor for Nelson Laboratories, LLC, "We need to be able to perform the annual chamber mapping and provide the report of the data." Nelson Laboratories was already using a data logger with thermocouples to perform annual temperature-mapping of all incubators, refrigerators, freezers, and other chambers within their facilities. They decided to look into other options that would provide faster reporting while helping them remain in compliance with regulatory authorizes.

¹https://www.who.int/biologicals/expert_committee/Supplement-8-TS-mapping-storage-areas-ECSPP-ECBS.pdf



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The Solution

After using Rees Scientific's compliant temperature monitoring solutions for over 10 years on 400+ units, Nelson Laboratories decided to test 5 of the Instant Chamber Mapping Kits in 2017. "I really like the ease of use," explained Rich Floyd, "it is a big plus that the reports that the Mapping software provides are generated by the system and we do not have to do all of the data compilations manually."

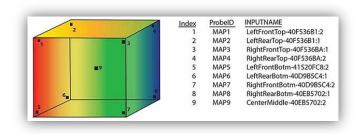
Following the initial testing of the 5 Instant Chamber Mapping Kits, Nelson Laboratories found that they were more user-friendly than what they were previously using. The Mapping Kits also instantly generated multiple reports of the data which was something they had to manually prepare before. They decided to add more Mapping Kits so that they could perform temperature-mapping on multiple units at once. "We currently have 10 Chamber Mapping kits," he said, "nine have 10 RTD modules and the other one has 10 high accuracy TEMP/RH modules."



Additional Benefits

"One of the added things that make it a major improvement for us is that we use the Teamviewer software and I can check on the status from anywhere at any time and be able to have full functionality remotely" explained Rich Floyd. "We have lab sites in California, Utah, Illinois, Montana, New Jersey, and one in Mexico currently and I can send the Mapping Kit to any of these facilities and have the staff onsite load the Mapping Kit into a chamber," he added, "I can still be here in Utah and be able to perform the mapping of the chambers without having to travel to each site to get it done." Being able to perform mapping from anywhere in the world with the help of local employees is a major benefit for the facility and its multiple sites.

Throughout the year, Nelson Laboratories also has Rees Scientific re-calibrate each of its Instant Chamber Mapping Kits in stages. 10 mapping kits gives Nelson Laboratories the confidence that temperature-mapping services will not be paused while kits are being recalibrated. Re-calibration of the Mapping Kits allows them to remain compliant and keeps the sensors and modules validated while in proper working order.



The Conclusion

Nelson Laboratories quickly learned that the Rees Scientific Instant Chamber Mapping Kits were user-friendly, provided consistent and automated reports and overall were more effective for their facility and its 13 sites compared to a standard data logger and thermocouples. Temperature-mapping was made easier by the Mapping Kits while still helping them remain in compliance with their regulatory authorities.

Prepared by Kristie Naulty & Gagan Kaur with special thanks to Michael Hanssens, Ricardo Padilla & Rich Floyd.