Guide to an efficient and secure lab environment:

Management that minimises the risks to lab managers

A course of events worth considering

When the temperature of the refrigerator is read on Monday morning, it is discovered that the temperature threshold has been exceeded since the reading taken on Friday morning. What do you do now? According to the instructions, you need to discard the entire content of the refrigerator, i.e. all the valuable reagents and samples that have been stored in the refrigerator need to be thrown away. DISASTER!

The problem is, it is not just about the financial value of what needs to be discarded and then bought again: the work done by staff on the Monday (perhaps even the whole week's work) will be affected and will need to be replanned. What do you do about the patients waiting in a queue? Is the refrigerator broken, and does it need to be replaced?

This raises many questions – above all, the matter of whether the disaster could have been averted if other procedures had been in place.

Current situation

Manual readings and checks have been performed since the beginning; this is what has always been done in laboratories. Every working day, in the morning, someone goes around taking readings and writing down the temperatures in the refrigerators and freezers. The actual equipment used to measure the temperature has perhaps evolved from simple mercury thermometers to digital maximum/minimum thermometers that monitor the highest and lowest temperatures recorded since the last time they were reset. However, there are a number of problems associated with taking temperature readings manually.

Time taken

The time used for taking temperature readings detracts from other work tasks. Temperatures are often taken first thing in the morning, when someone goes round taking the temperature readings. It may only take a minute or so for someone to write down the temperature reading and current date and time and then sign for each reading. However, there are usually a number of refrigerators and freezers where readings need to be taken.

Here is a brief and simplified calculation as an example:
Suppose there are ten refrigerators or freezers and that it takes one minute to document the current temperature. This steals ten minutes from each day. This amounts to just over one working hour per week, so that over a year almost one and a half working weeks have been spent taking temperature readings.

The actual time taken certainly does not end there; further work time must be spent on the administration of the documentation – for example, dealing with all the paperwork on which the temperature readings are written, which is then perhaps placed in binders that in turn have to be stored away in some secure way or another.

Documentation

This is in paper format, usually handwritten and placed in marked binders. Over time, this amounts to a very large number of binders to store. Monitoring any deviations can prove difficult when using a paper and binder-based system, as it is difficult to gain a proper overview of the quality of the cold storage over time.
Allow us to describe an example: one year's logging from a laboratory room is perhaps stored in three or four different binders and spread over several hundred handwritten pages.

Traceability

When there is an internal quality audit or an external audit from a controlling authority (for example, the Swedish Medical Products Agency) and staff are asked to demonstrate a so-called audit trail, they need to be good at finding things in binders. Even though all the temperature logs are written down on paper and saved in the binders, it can be difficult to pinpoint individual events or periods etc.

Continuity

When you "only" take a temperature reading once a day, the reality is that you know nothing about how the temperature fluctuates during the day. As we said above, most people take temperature readings first thing in the morning. The temperature is then usually "good" as the refrigerator door has been closed all night.
But what is the temperature like in the middle of the day once the door has been opened and closed a number of times?

A maximum/minimum thermometer will, of course, show the highest and lowest temperatures recorded during the reading interval, BUT it tells you nothing about how long the temperature remained at the maximum value. Was it just for a minute or so? Or was the temperature at the maximum value for several hours? Information like this may be of vital importance and form a critical basis for deciding whether to discard or use samples from your cold storage.

Finally, there is one other thing to factor into your assurance and safety calculation: the human factor. What happens if someone who was meant to take the temperature readings is taken ill? Taking temperature readings is not normally the main job of an employee: it may well slip down the list of priorities when conditions at work are stressful or perhaps even be forgotten on some days.

In summary, we can say that the "current situation" of manual temperature readings leads to control problems, which in turn lead to inefficiency. However, above all it leads to fairly major risks – risks to which the operation presumably cannot afford to be exposed.

Vision of the future

Nowadays, however, there are automatic systems that help with quality assurance and logging of temperatures in laboratories. Let us return to the disaster scenario depicted at the start of this document. This time, however, the course of events is played out in a lab that has automatic and continuous temperature logging:

To begin with, the temperature in the refrigerator is logged once every half hour instead of just once a day. When the temperature threshold is exceeded, an alarm is sent immediately via SMS to the on-duty staff and via e-mail to the staff responsible in the lab. It is then possible to log into the system immediately using a smartphone or PC and take a look at what has happened. It is seen that the temperature is too high, and when the staff enter the lab, they discover that the refrigerator door has been left slightly ajar, probably triggering the alarm. Once the door has been closed, the alarm is acknowledged and signed off and the deviation stored in the system database.

However, for the purpose of a good story, let us suppose that the laboratory manager does not see the e-mail about the alarm until Monday morning By logging into the system, it is possible to look at the temperature graph of the refrigerator in question and to see how the temperature has changed over the past week – in particular for how long the temperature was above the alarm thresholds. It can be seen that the temperature alarm lasted only for a short while and that, two loggings later, the temperature inside the refrigerator had returned to within the limits. It can also be seen who acknowledged the alarm, when it was acknowledged and what action was taken to rectify the fault.

In other words, as there is valid documentation showing that the incorrect temperature (the air temperature in the refrigerator) was only over the limit for just over an hour, we can safely make the decision that it is not necessary to discard the samples stored in the refrigerator. It is even possible to add and save a comment on the system about the decision made, and of course, all deviations and changes made to the system have to be signed for so that actions taken are fully traceable in the future.

For most laboratories – and, indeed, for anyone whose job involves cold storage of any kind – traceability is absolutely everything. With an automatic system of continuous logging, all measurement data in the database are stored with proper timestamps, which allows the history to be used at any time to create reports or generate graphs of various time periods – for example, what the measurements looked like over the past month or past six months. For complete traceability, it is important to be able to verify every step. It is vital to know what measurement data come from what sensor, and it is also important for all changes made to the system to be stored in the database. Of course, it is important to ensure that the equipment is measuring the values correctly. For this reason, it should be possible to calibrate an automatic system used for continuous logging. To preserve traceability, the calibrations must also be stored in the database.

Valuable work time can clearly be saved by procuring an automatic system for continuous logging; at the same time, you can feel reassured and secure in the knowledge that you will receive an alarm in the event of any deviations. The actual documentation takes care of itself, as all loggings, events, alarms and other activities are stored in the database, and

at any given time it is possible to create a report from the system that will provide an overview of the level of quality being maintained.

A modern system also offers a high level of flexibility; there are often many different types of sensor to log – for example, temperature, relative humidity, CO2, differential pressure, etc. It is normally also possible to connect very large systems of measurement points together – for example, from different storeys and different buildings, or even from laboratories in different geographical locations (different towns or countries). In short, the modern lab can gain copious benefits by using automatic systems of continuous logging.

Summary and recommendations

There are a great number of questions that those considering a temperature logging system should ask themselves, and a great number of requirements to consider. If you are interested in taking a closer look at the requirements that you should have for a temperature logging system, I recommend that you read our document: “Requirements for laboratory control systems”.

My name is Per Hammargren and I am the Sales and Marketing Manager at ICU Scandinavia and the author of this document. I am one of the founders of ICU Scandinavia and I have an IT background. Since the start back in 1992, we at ICU Scandinavia have helped thousands of laboratories, hospitals, private clinics, pharmaceutical companies, logistics companies, fertility clinics, etc., worldwide by providing automatic temperature monitoring systems.

ICU Scandinavia AB *is a leader in automatic systems for monitoring, log and quality assurance in laboratories and for food safety. Our systems, Boomerang and Coolguard, meet the regulatory requirements for logging and documentation for laboratories, cold storage facilities and food safety. In 1998 we were pioneers in automatic temperature monitoring and log. Today our experience within the field is unbeatable and we work together with world leading customers and partners, in order to assure quality and security in laboratories and restaurants all over the world. ICU Scandinavia holds offices in three countries: Poland, Switzerland and in Sweden where our headquarters is located.* [*www.icuscandinavia.com*](http://www.icuscandinavia.com)