Investigation into the Neo freezer malfunction

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Contents

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Abbreviations

DUC	Data Under Central
FA	Facilities Office
GVS	Professional Services (formerly University Administration)
KI	Karolinska Institutet
PLC	Programmable Logic Controller
SCADA	Supervisory Control And Data Acquisition

Introduction

Outline

The supply of liquid nitrogen to the cryo freezers was interrupted on 22 December 2023 on account of the bulk tank valve being shut off. This happened because an oxygen-level alarm was triggered during a service operation.

The investigation into the malfunction has shown that it did not occur due to any single event or source of error, but was the result of multiple issues, such as organisational flaws including a lack of clarity in terms of job description, authorisation, communication and information sharing. This mainly applies to procurement and the transfer of completed projects to the operational units and during technical maintenance. There are also shortcomings in assuring the necessary knowledge and skills for guaranteeing the function of critical systems.

Under the remit of this assignment, the investigation identifies areas of improvement and proposes measures that should be investigated further in order to minimise the risk of anything similar happening again. The investigation recommends that the improvement work commences without delay and with clearly defined tasks and authorisations within the KI organisation.

Background

During the 2023 Christmas break, a freezer malfunction occurred – herein under referred to as the malfunction – at the Neo building on KI's Flemingsberg campus, which organisationally operates under the KI South departmental group. The malfunction occurred when the automatic refilling of liquid nitrogen into the cryo freezers (category Isothermal) was interrupted, upon which the temperature in 16 out of the 19 freezers rose, destroying a large amount of biological research material.

The KI management (President, Vice-President and University Director) appointed an investigative team [1] to

- investigate technical or other causes of the interruption to the supply of liquid nitrogen
- find technical and organisational reasons why the alarm failed and was not conveyed or acted upon.

KI's Chief Security Officer (CSO) convened a steering group with representatives of the affected departments, the service team at Neo, other service teams at KI (ANA Futura and Biomedicum), the Facilities Office (FA) (part of GVS) and the Dean of KI South. The group was supplemented with support from the Legal Office (part of GVS) and Communication Tools and Support.

In addition, an external review group was appointed to conduct an independent audit and verification of information [2]. It was also said that representatives of Region Stockholm could be called in of necessary.

The internal investigation was carried out with the assistance of a consultant who was installed at FA. The steering group held weekly meetings at which the different members supported the investigation with factual and historical knowledge. They also were able to co-opt additional competence to the investigation.

This report describes the events surrounding the malfunction, its scale, consequences and underlying causes, and makes recommendations for measures that can be taken to minimise the risk of anything similar occurring again.

The incident

Events of potential importance to the investigation were gathered from the affected departments before and during the technical investigation and through interviews. These events are listed below.

2023–11–10 A review of the remaining points of the guarantee inspection of the alarm system, which is conducted five years after the final inspection in accordance with the procurement [3] [4]. During the inspection the alarm system was found to be operational.

2023-11-20 15:43 Service team personnel send an error report to the supplier stating that for 6 hours an alarm had been active that should have sent text message notifications from the 2G modem. It is suspected, however, that no such texts had been sent during this time [5].

2023-11-22 The supplier troubleshoots on site and finds that the modem is unstable and should be updated to a 4G modem, but that the text messaging service should be fully operational [6].

2023-12-22 A planned service of the O_2 sensor is carried out on site by external technicians in the morning (undocumented, reported orally to the Neo service team).

2023-12-22 12:36 The control computer for liquid nitrogen transmits an alarm via text to the service team [7] [8] [9].

2023-12-22 External technicians tell the service team that the work has been carried out (undocumented, reported orally to the Neo service team).

2023-12-22 17:39 Members of a research group (Neo) enter the freezer hotel to leave samples. Verified by the access system log.

2023-12-22 21:33 Alarm triggered by an unsuccessful refilling of liquid nitrogen. SCADA sends out alarms via email (a “source alarm”, see Technical Investigation) and text message to registered users as the alarm for each freezer is triggered [7] [8] [9].

2023-12-23 11:08 Members of a research group (Neo) visit the freezer hotel after having read the alarm email. They check their freezer, note that an alarm has been triggered and inform their group leader. The group leader

sends notification of the alarm to the Neo service team by sending an email to the electronic error reporting system (Nilex) [10].

2023-12-24 10:46 Members of another research group (Neo) visit the freezer hotel after having read the alarm email. They check their freezer, note that an alarm has been triggered and inform their group leader.

2023-12-27 15:03 Members of a research group (Neo) go to fetch cells and note that most of the cryo freezers are transmitting an alarm. They find that their freezer has a temperature of around -130 °C and contact their group leader.

2023-12-27 16:34 The group leader sends information about the malfunction via email to the facility manger, the Neo service team, the members of his/her group and to the Neo steering group[11]. The KI management is informed at the same time. The research group leader also informs Neo's service team on the phone. The temperature in all cryo freezers is checked.

2023-12-27 17:40 The Neo service team clears and resets the alarm in the control computer for nitrogen supply, upon which the refilling of liquid nitrogen is initiated. The alarm resets itself, which is also confirmed by SCADA through email and text messages [7] [8] [9]. The Neo service team carry out an ocular inspection of the system without finding any obvious error (oral information).

2023-12-28 A thorough troubleshoot of the entire system is conducted and it is found that 16 of the 19 cryo freezers have elevated temperatures.

2023-12-28 The supplier checks the liquid nitrogen and tests the refilling operation without finding any anomalies (oral information).

2023-12-28 The facility proprietor checks that supply of compressed air to Neo for 18–29/12 2023 without finding any anomalies (oral information).

2023-12-28 The supplier checks the cryo freezers without finding any anomalies (oral information).

2023-12-28 The supplier checks the bulk tank (outdoors) and finds minor faults: 12 bar excess pressure, a small leak at a joint, a partly tightened tap, serious icing on a coupling/valve and on the façade outflow (oral information).

2023-12-29 The supplier troubleshoots the alarm system without finding any anomalies (oral information).

2024-01-03 The Neo service team compiles a malfunction timeline [12].

2024-01-09 The accident commission is appointed by the KI management [1].

2024-01-24 Start-up meeting held for the technical investigation.

Measures

Immediately following notification of the malfunction, the following measures were taken:

- Meeting to build an overview of the incident, and to share and gather information at both a local and central level.
- The affected suppliers conducted a troubleshooting of their products/services with the Neo service team, finding that the liquid nitrogen supply system was operational (see The Incident).
- The investigation was launched [1].
- Access and alarm system logs were gathered by the Security Office.
- KI's CSO issued extra duties for the KI South guards involving two visual and auditory checks of the Neo freezer hotel every 24 hours (oral information).

Technical Investigation

Participants

The participants co-opted to and present at the technical investigation are listed in a separate annex [13].

Method

The investigation was conducted by a consultant installed at FA with the assistance of external investigators. The suppliers also took part and contributed system knowledge vital to the technical investigation. Representatives appointed by the departments attended the site visits.

The suppliers and external investigators conducted their own on-site inspections at different times to make an initial assessment and evaluation of the incident and to secure data (system backups). Each supplier presented its own inspection report. A KI representative (either from FA or the CSO) attended each on-site inspection.

On-site technical analysis

Those involved in the technical investigation were summoned on 8 February 2024 to carry out a joint on-site technical analysis. The day began with a presentation of the participants and information in order to give the investigators the optimal platform from which to investigate the malfunction. Each participant was asked to write a report on this occasion, too. Tests were conducted on 12 and 13 February to verify the different possible scenarios that had arisen from the meeting of 8 February. A register was taken of all present at these two meetings [13].

Technical description of Neo's liquid nitrogen supply system

The system for the automatic refilling of liquid nitrogen at Neo is divided into four units (see Figure 1):

- Bulk tank of liquid nitrogen
- Feed system (pipes, valves and phase separators)
- Control system for automatic refilling
- Cryo freezers ("Isothermals")

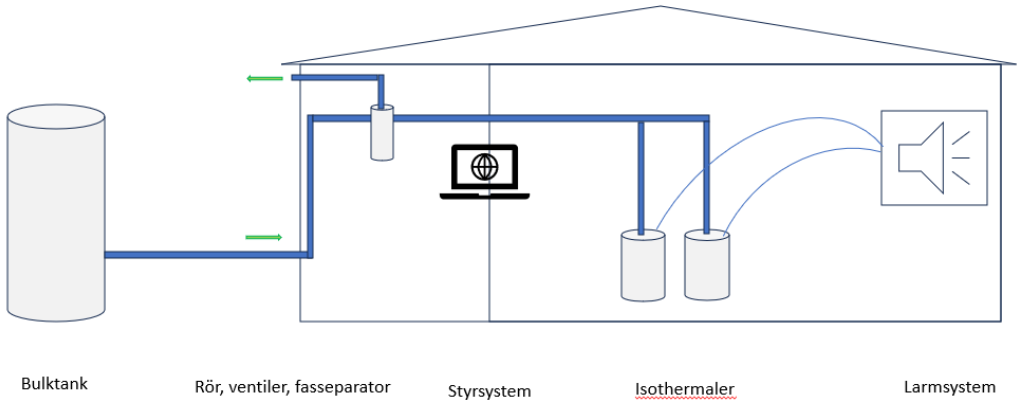

Figure 1: Automatic refilling of liquid nitrogen.

The cryo freezers are supplied automatically with liquid nitrogen [14]. A cryo freezer can signal that it needs refilling with liquid nitrogen either when it reaches the minimum level set for liquid nitrogen or via a timer, which is always overridden when the minimum level is reached.

The control system makes sure that the piping system is always filled with liquid nitrogen. The valves that open and close the feed pipes require compressed air. The piping system with phase separator leads away gaseous nitrogen to ensure that only liquid nitrogen is distributed to the freezers. The bulk tank of liquid nitrogen is monitored and refilled by the gas supplier. The system also includes three security functions that interrupt the supply of liquid nitrogen from the bulk tank independently of each other in the event of:

- a low O_2 level in one of the four O_2 sensors
- high pressure in the phase separator
- the activation of the emergency shut-off

Technical description of the freezer hotel alarm at Neo
The overall monitoring system, SCADA (Supervisory Control And Data Acquisition), handles alarm administration. For example, the definition of alarm thresholds and contacts (email addresses and/or phone numbers) to be informed when an alarm for a connected object is triggered. Each object/system fitted with an alarm is linked up to SCADA via the PLC (Programmable Logic Controller), which receives analogue and digital signals. These signals are interpreted by SCADA to determine whether or not an alarm has been activated.

There are five alarm parameters in SCADA that are set up for each cryo freezer (see Table 1). The *Internal alarm 1* (e.g. the "source alarm" for each cryo freezer) is a sum-alarm A from the cryo freezers that requires action by the alarm recipients. The source alarm needs resetting after activation in order for successive alarms to reach the registered recipients. All other sum-alarms from the cryo freezer resume without physical resetting. *Internal alarm 2* is a sum-alarm A from the cryo freezers (which requires action by the alarm recipients); the alarm point is only activated when external PT100 sensors are installed.

Three of the alarm parameters are different types of *Temperature sensor alarm*. Neo's cryo freezers lack independent external temperature sensors (PT100 sensors), without which no *Temperature sensor alarm* is activated.

☐	NEO_3318_KRYO12_SL1	Internal alarm 1 - Alarm	A
☐	NEO_3318_KRYO12_HT2	High high temperature - Temperature sensor	A
☐	NEO_3318_KRYO12_HT1	High temperature - Temperature sensor	A
☐	NEO_3318_KRYO12_GFL	Sensor error - Temperature sensor	A
☐	NEO_3318_KRYO12_SL2	Internal alarm 2 - Alarm	A

Table 1: Parameters that can trigger a cryo freezer alarm.

There are two alarm parameters that can be generated from the control computer for the liquid nitrogen system (see Table 2). The two alarms can by activated by O_2 sensors, emergency shut-off, high pressure in the phase separator and a timeout from the gas relief valves. These two alarms were programmed to be transmitted from SCADA (via text message) to the Neo service team.

	Larmsignal	Beskrivning	Larmklass
☐	NEO_3318_AS201_LQ	Low oxygenlevel - Degassing and pressurisation system	A
☐	NEO_3318_AS201_SL	Main alarm - Degassing and pressurisation system	A

Table 2: Low oxygen level and Main alarm can be generated from O_2 sensors, emergency shut-off, high pressure in the phase separator and timeout from the relief valves.

There are two types of alarm parameter that are not transmitted via the control computer for the liquid nitrogen system but that are connected direct to the PLC. These two alarm types (see Table 3) were never activated in connection with the malfunction as they are related to a loss of power.

☐	NEO_AL031_FS101_FS00	Tripped circuit breaker - Circuit breaker	A
☐	NEO_AL031_UPS_SL	Alarm - UPS	A

Table 3: Two types of alarm that are not transmitted via the control computer for the liquid nitrogen system but that are connected direct to the PLC.

Causes of the malfunction

The technical investigation conducted on 8 February found that the bulk tank's shut-off valve had been closed on the morning of 22 December. It turned out to require further testing to find out if it was the O_2 alarm or the high-pressure alarm that caused this to happen. It could, however, be ruled out that the emergency shut-off had been activated.

The technical investigation could also rule out sabotage or antagonism.

Additional testing showed that it was not the high-pressure alarm that had caused the bulk tank valve to close. The investigation showed that the malfunction had been initiated when one of the O_2 sensors was serviced on 22 December. The service triggered the O_2 alarm, which caused the valve to close. The service was conducted because the O_2 sensor had drifted within its measurement range and could no longer be calibrated. The supplier recommended that the sensor be replaced (according to oral information). The replacement of the O_2 sensor was carried out by an external technician in consultation with the Neo service team. Once this had been done, the external technician informed the Neo service team by phone that the work was completed and that all alarms could be cleared and reset in the liquid nitrogen control computer. After such work has been completed, alarms are to be reset manually in order for the system to work properly again. The technician then left Neo (according to oral information). The service team did not reset the alarm and the valve remained closed. The suppliers' reports are appended to this report [15] [16] [17].

According to oral information, the service team had decided to reduce the minimum level of nitrogen in the tank on all freezers from the factory setting of 26 cm to 10 cm. For safety reasons, filling was to be done at night. According to oral information, three cryo freezers managed to stay cold at

the time of the malfunction because their liquid nitrogen tanks were larger, and one of them had a fault that led to it being overfilled on refilling.

The alarm chain triggered by the malfunction

Texts and emails informing recipients of the alarm were sent to the telephone numbers and email addresses supplied by the affected research groups [7] [9]. It was not possible to ascertain afterwards if the texts had been received. Members of the Neo service team gave oral confirmation that the texts had been received by the group, but since a service was underway at the time, the alarm was not acted upon.

No texts stating that the alarm had been reset were sent to the service team since no resetting had been done in the control computer. If the alarm had been cleared in the control computer, the nitrogen valve from the bulk tank would have been opened and liquid nitrogen would have been fed into the cryo freezers [17].

Organisational investigation

Design stage of the Neo project

The KI management signed a construction contract with a building contractor with the purpose of constructing Neo according to KI's wishes. KI would then lease Neo for a 20-year period as it may not own its buildings. The KI management assigned the project to the FA's facility manager [18].

The FA's facility manager appointed an internal project manager. The project was to produce new, modern research premises, and Neo became one of the two projects that made up the "Future Lab" concept. The project was initiated in 2015 and transferred to Neo in 2018. Procurement of the construction project, including fixtures and fittings, complied with the Public Procurement Act (2016:1145), to which public authorities are subject.

While FA operated a documentation and registration process for the construction project [19], procedures were not followed. According to the scant information that remains, a room-function programme was produced with Neo's future operations and an architect's office, including system and programme documents and a construction programme. FA appointed a joint

Future Lab reference group comprising all departments and heads of departments [18] [20]. Regular meetings were held with Neo's tenants during the detail design stage concerning the needs, functional requirements and adaptations, such as refilling stations and lift transportation (according to oral information).

Transfer

The project also included plans for the transfer and training for the activity-specific systems. There is no documentation, however, to verify the extent to which this was done. Regular risk assessments for the nitrogen activities were apparently conducted at user-group meetings between FA and Neo's tenants, but they were not documented. Likewise, there is no documentation of risk assessments concerning the colocation of electrical and nitrogen-cooled freezers and the non-delivery of nitrogen. The extent of the transfer from FA to Neo's steering group is unknown, as it was not documented.

The boundaries between Neo's tenants, FA and the building proprietor were specified in a leasing contract [21], and while those between the proprietor and FA as regards investments were specifically listed [22], there was no such list for the transfer of the project to Neo's tenants.

Commissioning

After the transfer, the issues of faults in the freezer hotel and its partial completion were raised in Neo's facility group. For example, the inspection window had been placed to high, there was no oxygen indicator outside the room, the emergency shut-off lacked a casing and the signage was inadequate [23] [24] [25]. One person in the group was tasked with passing these opinions onto the Neo steering group, but there is no confirmation of this happening in any steering group minutes.

Several problems remained ahead of the commissioning of the freezer hotel concerning alarms and completion of the facility. An independent body conducted a final inspection and a guarantee inspection of SCADA and approved the commissioning of the facility [3]. Initially, the suppler had to make several weekend visits to ensure that the alarm worked properly and to manage incidents (according to oral information). Both FA and the

operations in Neo felt that there were surprisingly many problems with the alarm. FA discussed remedial measures with the supplier (oral information).

Administration

Neo's low-temperature activities were not called a freezer facility (which is standard for other freezer units at KI) but a freezer hotel, meaning that all those who used it were responsible for their own material and equipment, and that no common records were kept. The research groups that used the freezer hotel had responsibility for their cryo freezers as regards their purchase and installation, the administration of alarm points (oral information) and the registration of alarm recipients in the research group. A degree of practical assistance for the registration was provided by the Neo service team (oral information).

The Neo service team and the research groups were said to share administration of the freezer hotel along with FA, but the investigation has not been able to find any documentation to confirm this, so if such an agreement was in place it must have been oral. The investigation has found evidence of several shortcomings in the running of the freezer hotel. There were no procedures for the annual check of the alarm chain and no service plan and evacuation tanks to enable such a service. There were no external temperature indicators on the freezers or any protective equipment in the event of an incident involving liquid nitrogen. Apart from the odd exception (see Interviews), such problems were not formally raised at the Neo steering group meetings. Nor were there any procedures in place for the writing of reports to the relevant heads of department. Since the transfer, FA has had meetings with the tenants, and apart from guarantee inspections, the notes from these meetings make no mention of problems related to the freezer hotel [26].

Legal requirement regarding the storage of biobank samples

Legal requirements

The Biobank Act regulates how human biological material is to be gathered and stored in biobanks for, amongst other purposes, research [27]. The Act provides that such samples must be stored safely. No further regulations about how biobank material is to be stored are given. According to section 8 of the Biobank Ordinance, the National Board of Health and Welfare is able to issue instructions concerning the storage and coding of samples in biobanks [28]. The drafting of new instructions began in the spring of 2023, but no new directions have yet been announced [29]. Chapter 5 section 3 of the now revoked directions stated that tissue samples had to be stored in a manner that safeguarded quality, traceability and safety [30].

Principal's responsibilities

Chapter 1 section 2 defines a biobank is one or more collections of samples held by one and the same principal [27]. According to chapter 2 section 3, a biobank principal is responsible for ensuring that adequate resources are available for maintaining and operating the biobank in accordance with the legal requirements [27].

Page 91 of the drafting history of the Biobank Act states that the principal's responsibilities include making sure that sufficient resources and organisation are in place for enabling compliance with the Act, and that all those working with biobanks – especially the biobank manager – are given sufficient authority and properly followed up [31].

The principal is to appoint a biobank manager, a requirement that KI has fulfilled since December 2023 [32]. The biobank samples affected by the malfunction were, however, said to derive from biobanks with principals other than KI. The collections that have been destroyed are estimated to comprise 34,400 biobank samples, 3,800 samples from animal models, 2,600 samples from cell lines and 6,300 samples from manipulated/edited cell lines. Many sample collections came to KI from Stockholm's Medical

Biobank and are still considered its property. Stockholm's Medical Biobank has been informed of the incident.

The Biobank Act now in effect has removed the system of primary and secondary biobanks [27]. This is expressed in chapter 5 section 6 paragraph 2, which provides that a released sample ceases to be part of the biobank from which it was released [27], and a sample which is stored after having been released must be included in a new or existing biobank in the premises of the recipient [27]. Many of the samples destroyed by the malfunction of the cryo freezers had, however, been released to Karolinska Institutet under the terms of the former Biobank Act regarding, for example, the use for ethically approved research purposes in healthcare [33]. A certain amount of documentation on transferred samples exists at KI in application forms drawn up for accessing sample collections.

Scope of samples destroyed

Different kinds of biological material need to be stored and handled depending on their nature to avoid destruction. To comply with the legal requirements in the regard, page 221 therefore requires the registration of information concerning the kind of biological material a sample comprises [31].

Damages

Chater 8 section 2 of the Biobank Act provides that a biobank principal shall compensate the sample donor for the harm and violation of personal integrity that the process has caused them if a sample is handled in violation with the law [27].

Supervision

The Biobank Act states that the supervisory authority for biobanks is the Health and Social Care Inspectorate (IVO). IVO has opened a supervisory case on account of the malfunction [34].

Interviews

Participants

Interviews have been mainly conducted with individuals who were either present in the freezer hotel during the malfunction or subsequently involved. Interviews have also been conducted with people linked to Neo's freezer activities and the construction of the Neo building. The interviewees' names have been withheld in the interest of their privacy and safety.

Method

The questions asked during each interview are listed in a separate annex [35]. Since the interviews were carried out by different FA staff, there are possible variations in how they are worded, but in general all interviewees were asked to give their version of the malfunction, its causes and what KI must do to minimise the risk of any similar recurrence. The interviews are not presented in full with respect to the privacy and safety of the interviewees. Instead, their answers have been compiled under subheadings.

Compiled interview material

It is clear from the interviews that there have been numerous underlying organisational flaws that eventually gave rise to individual events that cause the malfunction to happen. Some of them had been partially flagged earlier but left unremedied. There is an experienced lack of clarity concerning responsibilities and authorisations and a failure of communication and information-sharing.

Inventory and risk-assessment of Neo's activities

There is no comprehensive list of Neo's freezer activities or register of all biobank material stored in its freezer hotel, although local registers were possibly compiled by each research group. An estimation of the number of destroyed samples is listed under the Legal Investigation section regarding biobank samples.

There is no documented risk assessment from either FA's construction project or Neo's tenants concerning, for example, liquid nitrogen activities and the colocation of electrical freezers and nitrogen freezers.

Risk assessment documentation was requested during the interviews. Risks, problems and needs are said to have been addressed at the steering group meetings, but only in exceptional cases do the minutes of such meetings confirm this. When risks and problems appear in the steering group meeting minutes, it is only briefly and without mention of remedial plans [36]. Similar issues are said to have been raised in the tenants' (user group) meetings with FA, but there are no confirmatory documents here, either.

There is a central decision on KI's risk analyses for 2024, in which the KI management established a low risk of research material being destroyed by, for example, the malfunction (or inadequacy) of the emergency power supply to the biobanks or a lack of security surrounding research material. Since the risk was considered low, it was to be covered/handled locally. According to information gleaned from the interviews, the risk assessment was not anchored locally at Neo.

Requirements specification

In connection with the procurement and installation of the freezer hotel at Neo, there was no internal technical standard for the system and no external independent temperature monitoring of most of the Neo freezer hotel freezers. There were no specified requirements concerning the age and condition of the freezers and no protective life-saving equipment (e.g. OXY boxes and breathing equipment) in the event of accidents.

Documentation and traceability

It emerged from the interviews that the registration of documentation from the Neo building project was considered inadequate, despite the fact that at the time of the project there was an internal FA guideline describing the registration requirements. It also emerged that at the time of the construction project there was no clear place for archiving documentation. Staff talked of documents being saved on private storage spaces and presumably being lost when FA staff left their employment. Information was not classified, labelled or handled in accordance with KI's information security management system or processed in compliance with the information security requirements imposed on KI as a public authority.

Going by the interviews, it is clear that there is a serious lack of documentation and follow-up in the KI organisation as a whole.

Transfer and reception

When Neo (building, technical installations, surveillance systems, etc.) was transferred from FA to the relevant departments the limits of each party's responsibilities were not made clear. Some FA staff said that the transfer went well and was clear, while others claimed that the transfer did not provide Neo's tenants with the right conditions for taking over the building and that they were not in agreement with the assignment taken over from FA. At the time of transfer, the PT100 sensors that had been planned according to interviews with operations were, for reasons unknown, never installed. Information also seems to have been given orally at the time of transfer, which explains the lack of certainty as to whether all relevant tenants were actually informed of the requirements placed upon them.

FA's project manager, who according to the relevant department was in charge of the relocation of freezers, installation of PT100 gauges and alarm points, left his/her employment in the middle of the move from the old premises to Neo. The project manager was not replaced, which was seen as one reason why problems were not followed up.

It emerged from the interviews that selected personnel at Neo underwent training in the freezer hotel at the time of the transfer. However, the training was considered so poor that it took a follow-up meeting to give them an understanding of how the SCADA alarm system and freezer hotel worked.

System owner

No system owner was appointed for the activity-specific computerised systems (SCADA, PLC, DUC), and neither was it felt that the heads of department had delegated the administration clearly. The service team lacked planning and order management systems for dealing with long-term maintenance and service plans. Many of the interviewees felt there were deficiencies in traceability and follow up.

Standby function

Neo's research groups felt it was unclear who would handle any emergency situations that arose. Compared with conventional freezer facilities, the size

of the service team gave limited opportunities at Neo for a round-the-clock standby function for technical systems. New personnel were not hired when members of Neo's service team left their employment and there were no written procedures to follow in the event of a crisis, such as a malfunction. Moreover, not all cryo freezers were labelled with contact details and there was no regular check of the alarm chain. Even though the service team lacked contingency plans for alarms during regular working hours, they were the ones who received the alarm from the nitrogen control system.

Lack of clarity in delegation and authorisation

The demarcation of roles and responsibilities between FA, the service team, the control group and the research groups was felt to be unclear. Before the relocation to Neo, each department was in charge of its own freezers and there was a clear chain of responsibility. After the relocation, many research groups felt that problems were not remedied and that unofficial responsibility was placed on individual research groups for the daily running of the SCADA system (programming, testing, activation and management of freezer alarms) and other such tasks. At the same time, certain tasks fell to Neo's steering group or the service team. However, written task descriptions and delegations of responsibility were lacking.

During the interviews, it emerged that research groups claimed to have often raised problems to the Neo steering group, which omitted to act on them; however, this could not be verified by the steering group minutes. Many mentioned that clearer boundaries between Neo and FA would create a shared understanding of task-sharing and ensure that people who were delegated various tasks had the competence to perform them.

Training and skills

Personnel who were to use the freezer hotel were to have received a basic training at the time of transfer, but many interviewees said that the required training was never provided or was inadequate.

There were no procedures in place to record who had been trained in the use of the freezer hotel and when new personnel and researchers arrived, it was not clear whether anyone made sure that they received basic training

in, for example, the handling of cryo freezers and alarms. Similarly, it was felt that the requirement to provide refresher courses was not met.

It is unclear how and on what grounds the Neo service team was formed. It emerged from interviews that the service team had not received any more advanced training to be able to support the research groups in such circumstances as the activation of an alarm or minor faults.

Comparisons were made with existing freezer facilities in Biomedicum and ANA Futura, which make sure that the administration of ULT freezers (-80 °C, -150 °C, cryo freezers) is only done by the respective service team's personnel with SCADA competence. This was not the case at Neo.

Previous incidents

While it emerged from the interviews that many people felt that they had raised problems with the freezer hotel, only a few of these problems are mentioned in the minutes from the Neo steering group meetings. For example, it was discussed that unscreened cables had been used on the installation of the alarm system and were to be replaced [38]. It emerged from the interviews that several different alarms had come from the cryo freezers and that a culture had arisen at Neo in which "false alarms" were not taken seriously, which some of the interviewees argued could have been linked especially to two incidents that occurred in 2021 and 2022.

At the Neo steering group meeting of 2021-10-21, the steering group was informed of an incident in which several freezers of the type that maintains a temperature of -80 °C transmitted an alarm that was probably related to an interruption to the power supply [39]. The incident was reported in KI's incident reporting system [40]. The steering group decided that Neo needed better procedures for meeting the Legal, Financial and Administrative Services Agency's requirements for insuring freezers. It also found that individual research groups had responsibility for making changes to the alarm system when freezers were changed. One person was tasked with updating the procedures in the freezer hotel and to report back at the next meeting. This decision was not followed up on and the measures were not taken.

The oxygen level alarm was tested on 2022-02-23 by the Neo service team. On 2022-02-24 researchers reported to the Neo service team by email that all cryo freezers in the freezer hotel were transmitting a source alarm. It turned out that the test of the oxygen level alarm had interrupted the nitrogen supply to the cryo freezers – the same series of events that occasioned the malfunction during the 2023 Christmas break. The liquid nitrogen system was restored on 2022-02-24. The Neo & BioNut Work Environment & Lab Safety Coordinator found that the alarm – besides the email notification – was only visible on logging on to the control computer and that the alarm system settings needed adjustment [41]. The incident was never discussed by the Neo steering group.

Judging by the interviews, Neo's tenants felt that the problems with the freezer hotel were flagged but that no one acted upon them. Within FA it was felt that Neo's tenants did not take the problems seriously. There was a lack of clarity in mandates and escalation paths in the event of problems.

Recommended measures

In a fully functional organisation, there should be solutions and redundancy that allow occasional errors to occur without them having serious consequences, especially when it comes to activity-critical infrastructure. The measures presented here are designed to create a safe and robust freezer infrastructure at KI with clear mandates both internally and vis-à-vis external parties and suppliers. The measures should be further assessed before they are decided upon and implemented.

The investigation proposes that the freezer activities in Neo be made a freezer facility like the rest of KI's freezer activities rather than remain as a freezer hotel. Henceforth it will therefore be referred to as the freezer facility.

Freezer facility contents

There should be a comprehensive register of the biobank material stored in KI's freezer facilities showing the nature of the material, how long it is to be stored for and what research project it belongs to. Such a regularly updated register ensures compliance with KI's document management plan [42]. The

information such a register is to contain should be made clear, and the registration of material should be implemented equally throughout KI.

Analysis of the university's activities and associated risks

According to the regulatory requirements, KI is to conduct a risk analysis to identify the risk of damage or loss that exists at the university. Such risks are to be evaluated and the resulting costs that KI has or might incur are to be calculated. KI shall also, according to section 3 of the ordinance on public authorities' risk management, take appropriate measure to limit risk and prevent damage or loss [43].

KI's overall risk analysis should be well-anchored locally. Similarly, more serious locally identified risks should be raised at a central level to ensure that the overall risk analysis covers the entire university.

Over and above KI's general risk analysis, local risk analyses should be conducted on the construction, extension or renovation of buildings and the relocation of operational units that clearly state who is to perform what actions. These risk analyses should then form the basis of continuity plans for each operational unit.

Requirements specification

Each technical system (e.g. cryo freezers) should have accompanying documentation with information on technical standards, legal requirements, insurance requirements, regulatory requirements and the university's own requirements. Such documentation also facilitates the preparation of requirement specifications for future technology-intensive projects. Options for service contracts should also be included on the procurement of technical systems. Service contracts should, if possible, be coordinated for activity-critical systems and KI should appoint someone to take charge of such contracts.

KI has insurance by agreement with the Legal, Financial and Administrative Services Agency, which pays damages for property that has been lost in a freezer or other low-temperature environment only if said environment is equipped with a working temperature alarm connected to an alarm receiver

designed to limit possible damage. PT100 sensors should always be installed on all freezers.

Common requirements should be in place for all freezer facilities (e.g. the condition, age and quality of freezers and tanks) and protective equipment at KI.

Documentation and traceability

Project documentation, risk assessment and transfer plans shall always be clearly included in ordinary operation. Templates might be necessary. It must be clear what documentation should be collected and registered during a project to provide adequate traceability. This should be done in compliance with KI's document management plan [42]. KI's work with data security should be strengthened and implemented without delay centrally and locally.

Transfer and reception

When a completed product is delivered by a project manager to a recipient unit, the allocation of responsibilities and demarcation of responsibility for specific measures (e.g. the relevant training of personnel, ensuring compliance with service plans, regular maintenance and upkeep of effective continuity plans) should be made clear.

The project manager should ensure that the recipient is able to properly handle the object before it is delivered. This can be done, for example, by involving the recipient in good time, providing adequate system and safety training and providing opportunities for joint inspections of the object. Such inspection tours in which information is given orally should, however, be seen as a complement to a written transfer rather than as a replacement.

A clear implementation plan must be in place in which the recipient should guarantee that it has the resources to receive the object. Decisions should also be taken on where responsibility for activity-critical systems is to lie and on service contracts for, above all, technical activity-critical systems.

System owner

For the administration of activity-critical computerised systems (e.g. SCADA, PLC and DUC for freezer facilities) there should be a system owner with responsibility for monitoring system versions, technical lifespans and the safety and overall function of these systems. The system owner should also make sure that his/her co-workers have sufficient competence for handling the systems. The system owner should also be tasked with homogenising the settings for activity-critical systems of the same type (e.g. for alarms).

Systems for maintenance, checks and follow-ups

There should be a common KI system for the planning and follow-up of maintenance, which will make the activity less vulnerable to staff absence. Systematic maintenance enhances reliability and lengthens the probable lifespan of technical systems. A common maintenance system is also expected to facilitate financial planning when it comes, for instance, to the replacement and upgrading of systems and technologies. If the maintenance system is used to register errors and faults, it also makes matters relating to guarantee measures and inspections easier.

Standby function

To achieve a robust operation with redundant protection effectively, a central, common set of operational procedures needs to be applied to activity-critical systems such as freezer facilities. There should be a dedicated, round-the-clock standby function able to remedy and report errors and faults in emergency situations. The investigation suggests that an organisation for a KI-wide service team be located centrally (see Delegation and Authorisation) and the team should be assigned an emergency standby function. Its contact details should also be clearly provided.

Crisis organisation and management

KI should ensure that there is a well-established crisis organisation at both a central and local level. Continuity plans for critical systems should be drawn up. The investigation suggests that an officer on call or the equivalent be

installed at KI to initiate and coordinate the initial discovery, verification, alarm and information work in the event of a crisis.

Delegation and authorisation

FA's mission and the limits of responsibility for the entire project and continued administration should be clarified vis-à-vis the departments.

A steering group for department-wide premises should have a clear mandate to take financial decisions that not only concern these premises but also the facility manager and service organisation. Such a steering group should always include the heads of the relevant departments and its meetings should always be minuted and transparent.

There should be a central service team at KI with strong local acceptance. It should be large enough and have the capacity to handle several freezer facilities at the same time, while also having local knowledge about the different places.

The role and authorisations of the service team should be clear. Having a central service team creates robustness and eliminates many vulnerabilities. It ensures broad and consistent competence and quality assurance in the service team and makes it easier for internal controls regarding external requirements (legal, insurance, etc.) to be followed up.

The facility manager and service team are delegated a task for installation, programming, testing, activation, alarm management and troubleshooting. This therefore also entails setting common requirements for equipment and work methods in the freezer facility regardless of location on the KI campus. The task also includes responsibility for compulsory training for anyone wishing to access the freezer facilities.

Training and skills

A staff member's line manager should make sure that he or she has adequate training and skills before being given access to freezer facilities.

Incident reporting

Heads of department should stress to their staff that near accidents, accidents and incidents should be reported along the formal channels. They should also ensure that appropriate action is taken and followed up.

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