

Human factors that lead to non-compliance with standard operating procedures

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Human factors that lead to non-compliance with standard operating procedures

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The Advisory Committee on Dangerous Pathogens categorises biological agents into Hazard Groups 1 (negligible hazard) to 4 (highly pathogenic) according to their potential to cause human infection, the likelihood that infection could spread in the community, and the availability of effective treatment. For laboratories where biological agents are handled, controls proportionate to these hazards are specified and laboratories are designated Containment Levels 1 to 4. These controls are a combination of structural requirements and working procedures. To protect the health of workers, especially with more pathogenic biological agents, it is important that these controls are applied stringently.

This report presents results from the Health and Safety Laboratory's study on the Human Factors that lead to non-compliance with Standard Operating Procedures (SOPs) in Containment Level 3 (CL3) laboratories. The research stemmed from recognition by HSE intervention managers that RIDDOR investigations in CL3 laboratories were often identifying non-compliance with SOPs and organisational learning deficiencies as contributory factors.

Understanding the human factors influences on CL3 laboratory workers that could lead to non-compliance with SOPs will inform HSE HID-SI intervention strategy, thereby helping to drive up safety performance standards in the CL3 laboratory sector.

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KEY MESSAGES

- The reasons for cutting corners and the situations where cutting corners could be more likely were mainly found to be due to situational and organisational factors. For example, time pressure, workload, staffing levels, training, supervision, and availability of resources.
- Controls to address situational and organisational issues, and promote compliance with SOPs, were found to be wide ranging. For example, predicting peaks in demand, planning a realistically achievable workload, and engendering an organisational culture where staff feel able to challenge management pressure
- Participants reported a particular ‘type’ of person, described as being conscientious, patient, willing to comply, and confident but not overconfident, as being best suited to CL3 laboratory work.
- The SOP systems and documents were reported to be generally usable and fit for purpose. Participants reported a number of features of their SOPs that reflect the literature on accepted good practice, for example, inclusion of visual aids.
- Participant laboratories all reported having internal systems for capturing information from near misses and incidents and the capacity to learn from those experiences. Some laboratories had a more comprehensive system for sharing information with other laboratories than others.
- Whilst some differences were apparent in the findings from the various classifications of CL3 laboratories involved in this research (research laboratories, diagnostic laboratories, human pathogens, animal pathogens, genetic engineering), no significant differences in the main issues emerged.

EXECUTIVE SUMMARY

Introduction

The Advisory Committee on Dangerous Pathogens categorises biological agents into Hazard Groups 1 (negligible hazard) to 4 (highly pathogenic) according to their potential to cause human infection, the likelihood that infection could spread in the community, and the availability of effective treatment. For laboratories where biological agents are handled, controls proportionate to these hazards are specified and laboratories are designated Containment Levels 1 to 4. These controls are a combination of structural requirements and working procedures. To protect the health of workers, especially with more pathogenic biological agents, it is important that these controls are applied stringently.

This report presents results from the Health and Safety Laboratory's study on the Human Factors that lead to non-compliance with Standard Operating Procedures (SOPs) in Containment Level 3 (CL3) laboratories. The research stemmed from recognition by HSE intervention managers that RIDDOR investigations in CL3 laboratories were often identifying non-compliance with SOPs and organisational learning deficiencies as contributory factors.

Understanding the human factors influences on CL3 laboratory workers that could lead to non-compliance with SOPs will inform HSE HID-SI intervention strategy, thereby helping to drive up safety performance standards in the CL3 laboratory sector.

Method

Six focus groups were carried out across a range of laboratories that reflect the variety of contexts of the CL3 laboratory sector. Data gathered in the focus groups was subject to a rigorous thematic analysis and findings were compared to the literature on accepted good practice for the human factors that relate to non-compliance with SOPs.

Main findings

The SOPs were reported to be, in the main, usable and fit for purpose. Procedures were said to be up-to-date, contained the right level of detail, and reflected how the tasks were performed. Staff also said they were involved in the development of procedures to ensure they were aligned with the practicalities of carrying out the work.

In terms of compliance, a number of reasons and situations were highlighted where corners could be cut. These were primarily situational in nature, relating to organisational factors within the scope of management to influence, for example, time pressure, workload, staffing levels, training, supervision, and availability of facilities were common themes across the six focus groups. On an individual level, the findings suggest that a particular 'type' of person could be best suited to CL3 laboratory working. Such an individual was described as being conscientious, patient, willing to comply, and confident but not overconfident. Optimising violations were not apparent in the data, which indicates that CL3 laboratory workers are not cutting corners as a result of a need for excitement in their jobs.

Controls to address situational and organisational issues include workload and time management, booking timeslots on CL3 facilities, and challenging the pressure from

management. Predicting peaks in demand and planning a realistically achievable workload was reported as likely to have a positive impact on compliance with SOPs. An organisational culture where staff feel able to challenge management pressure was reported to be an important factor in compliance with SOPs. A progressive management approach should recognise this and be mindful that short-term productivity gains could compromise health and safety and set the tone within the work environment where non-compliance with SOPs may become the accepted way of working in order to get the work done in the time available.

Whilst some differences were apparent in the findings from the various classifications of CL3 laboratories involved in this research, no significant differences in the main issues emerged. Indeed, the reported 'reasons for cutting corners' and 'situations where cutting corners may be more likely' were familiar from research in other industry sectors. This suggests that CL3 laboratories experience similar challenges to other sectors where compliance with safety critical procedures is a common feature of the work. This is a view supported by the research literature.

Laboratories that took part in this research all have internal systems for capturing information from near misses and incidents, and learning from those experiences. Whilst this is an accepted approach for development, and is supported by the literature, there is potential benefit in the wider communication of information with other laboratories.

Future directions

In order to maintain and progress compliance with SOPs, CL3 laboratories should continue with the controls they already have in place but with a particular focus on controls relating to situational violations, as this was the most common area of non-compliance. As situational controls are correlated with organisational factors, it is likely that management will have more influence than laboratory workers. Efforts should therefore be made by management in CL3 laboratories, with support from the regulator, towards engendering a management approach that builds on existing good practice and focuses on the various situational and organisational factors described in this research (for example, workload planning, realistic time scheduling, and availability of resources) in order to maintain compliance with SOPs and, therefore, maintain health and safety standards across the industry.

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1. INTRODUCTION

The Advisory Committee on Dangerous Pathogens (ACDP) is an expert body comprising of representatives from HSE, other Government agencies and academic scientists. Its purpose is to recognise and advise on measures to control the risks of human infection in the workplace and wider impacts on public health. ACDP categorises biological agents into Hazard Groups 1 (negligible hazard) to 4 (highly pathogenic) according to their potential to cause human infection and the likely consequences were an infection to occur. For laboratories where biological agents are handled, controls proportionate to these hazards are specified and laboratories are designated Containment Levels 1 to 4. These controls are a combination of structural requirements and working procedures. These are described in detail in the ACDP publication ‘The management, design and operation of microbiological containment laboratories’¹. This guidance explains the legal requirements set out in the biological agents provisions of COSHH (Control of Substances Hazardous to Health Regulations 2002 (as amended)⁸), with particular attention to how these requirements influence the design, construction and operation of laboratories. To protect the health of workers and others, especially with more pathogenic biological agents, it is important that these controls are applied stringently.

In reviewing RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations) investigations, as well as other types of failures in the Biological Agents sector that result from the failure of a dutyholder to comply, HSE intervention managers had noticed that problems often appear to arise from a failure to follow Standard Operating Procedures (SOPs), or else dutyholders do not appear to be learning from the causes of events and applying lessons to other parts of the organisation that are within the dutyholders’ purview. This sort of failure falls into the scope of ‘human factors’.

HSL Human Sciences Unit had recently conducted research into risk taking behaviour in Containment Level 4 Laboratories¹¹, but specific peer reviewed analysis of non-compliant behaviour was not within the scope of this work. Therefore to build upon the knowledge of this area HSE commissioned HSL to determine the human factors that lead to non-compliance with SOPs incidents at Containment Level 3 (CL3) laboratories in Great Britain. The findings from this research will be used to inform future HID-SI (Hazardous Installations Directorate – Specialised Industries) intervention strategy, thereby helping to reduce the number of future incidents.

1.1 HUMAN FACTORS

HSE has published key guidance documents on the topics of human factors and human failures, for example, HSG48 – Reducing error and influencing behaviour³. From this guidance, HSE offer a definition of human factors:

Human factors refer to environmental, organisational and job factors, and human and individual characteristics which influence behaviour at work in a way which can affect health and safety.

1.2 PROCEDURES

HSG48 covers a number of broad topics relating to human factors in the workplace with a view to assisting organisations to drive up health and safety performance by controlling the impact of human factors. One such topic is (Standard Operating) Procedures, and HSG48 states:

Procedures, especially operating and maintenance procedures, are important for the prevention of accidents and ill health. Written procedures are vital in maintaining consistency and in ensuring that everyone has the same basic level of information. They are a key element of a safety management system and an important training tool. However, poor procedures can be a reason for people not following recommended actions.

Procedures ideally need to:

- *Be accurate and complete;*
- *Be clear and concise with an appropriate level of detail;*
- *Be current and up to date;*
- *Be supported by training;*
- *Identify any hazards;*
- *State necessary precautions for hazards;*
- *Use familiar language;*
- *Use consistent terminology;*
- *Reflect how tasks are actually carried out;*
- *Promote ownership by users;*
- *Be in a suitable format; and*
- *Be accessible.*

It is widely accepted that procedures play a vital role within organisations, for example, in relation to maintaining quality, health and safety, and consistency of outcomes. There is however a body of evidence that indicates that the root cause of accidents can often be traced back to procedures not having been followed. Examples of major accidents where non-compliance with Procedures was a contributory factor include Chernobyl (1986), Piper Alpha (1988), and Clapham Junction (1988). In human factors terms, when a worker acts in a way not consistent with SOPs, and the action was intentional, then this non-compliance is referred to as a 'violation'. This does not mean that the action was malicious in nature, rather that the individual believed that the action was, for some reason, justified.

1.3 VIOLATIONS

HSE recognises that the underlying causes of procedural violations are not wholly the responsibility of the frontline worker, and that management have a key role to play in ensuring work is carried out in accordance with SOPs.

*Violations are highly susceptible to management influence, as most underlying causes of violations are created by management, accepted by management or condoned as normal working practice by management neglect.*⁴

Further to this, HSE offers a useful definition of violations as being:

*Any deliberate deviations from the rules, procedures, instructions and regulations drawn up for the safe or efficient operation and maintenance of plant or equipment.*⁵

Within the human factors literature, violations are often categorised as routine violations, situational violations, exceptional violations and optimising violations. These categories are outlined in the following sections.

1.3.1 Routine violations

*A routine violation is a behaviour in opposition to the rule, procedure or instruction that has become the normal way of behaving within the person's peer/work group. The violating behaviour is normally automatic and unconscious. The violation is recognised as such by the individual, if questioned.*⁴

1.3.2 Situational violations

*A situational violation occurs because of factors dictated by the employee's immediate workspace or environment.*⁴

These include:

- *Design of the work area;*
- *Condition of the work area;*
- *Time pressure;*
- *Staffing levels;*
- *Supervision;*
- *Equipment availability;*
- *Equipment design;*
- *Other factors outside the organisation's control are also included here, for example, weather and time of day.*

1.3.3 Exceptional violations

Exceptional violations are rare and happen only in particular circumstances, often when something goes wrong. They occur to a large extent when an individual is attempting to solve problems in unusual situations. The individual, in attempting to solve new problems, violates a

rule to achieve the desired goal. These violations are commonly associated with high risk, often because the consequences of the action are not fully understood or because the violation is known to be dangerous but seems inescapable.⁴

1.3.4 Optimising violations

Optimising violations are created by a motive to optimise a work situation. These violations are usually caused through a need for excitement in jobs which are considered repetitive, unchallenging or boring, a desire to explore the boundaries of a system which are thought to be too restrictive, or pure inquisitiveness.⁴

1.4 ERRORS

To complete the picture, a further category of human failures exists that may result in a work outcome inconsistent with that which the SOPs guide towards. This type of human failure is termed 'human error'. Human errors are actions or decisions that deviate from an accepted standard and result in an undesirable outcome. Human errors are unintentional and categorised into skill-based errors (slips and lapses) and mistakes (rule-based and knowledge-based).

The focus of this work is on non-compliance with SOPs, which is a violation issue rather than an error issue. This brief description of error has been included to complete the picture in terms of the generally accepted model of human failure.

1.5 AIMS

The aims of this research were to:

- Identify the key human factors that influence the non-compliant behaviour of staff working in CL3 laboratories (specifically why they fail to follow the SOPs).
- Determine the control measures/barriers that can be applied to reduce such behaviours.

1.6 OBJECTIVES

The objectives of this research were to:

- Review RIDDOR and Accident Investigation reports to inform the content of vignettes (short stories or scenarios) for use in focus groups (semi-structured group discussions) with CL3 laboratory staff.
- Conduct focus groups and interviews to collect data to address the aims.
- Analyse data collected to determine the types of human factors that underlie non-compliant behaviour at CL3 laboratories.
- Conduct a small literature review to establish the sorts of control measures that may be utilised to reduce the likelihood of such incidents in the future.

2. IMPLICATIONS

- The reasons for, and situations where, corners could be cut were primarily found to be situational in nature and related to organisational factors within the commonly accepted framework of human factors. This being the case, CL3 laboratory management are more likely to be able to influence these factors, for example, time pressure, workload, staffing levels, training, supervision, and availability of resources, than CL3 laboratory staff. With respect to these issues, the challenges faced by CL3 laboratories are similar to other sectors where compliance with SOPs is a common feature of the work, and is a view supported by the literature.
- Controls to address situational and organisational issues include workload and time management, booking timeslots on CL3 facilities, and challenging the pressure from management. Predicting peaks in demand and planning a realistically achievable workload was reported as likely to have a positive impact on compliance with SOPs. CL3 laboratory management should aim to effectively manage resources such that they create the optimal conditions for SOPs to be adhered to.
- An organisational culture where staff feel able to challenge management pressure was reported to be an important factor in compliance with SOPs. Management should be mindful that short-term productivity gains could compromise health and safety. Local leadership could set the tone within the work environment where non-compliance with SOPs may become the accepted way of working. CL3 laboratory management should strive to ensure this does not happen.
- On an individual level, participants reported a particular ‘type’ of person, described as being conscientious, patient, willing to comply, and confident but not overconfident, as being best suited to CL3 laboratory work. This could inform a targeted approach to recruitment and selection.
- The SOPs themselves were reported to be, in the main, usable and fit for purpose. A usable index structure and inclusion of visual aids were said to make it easier to work with SOPs. Overly lengthy SOPs containing perceived unnecessary detail and electronic SOP systems that were perceived as impractical and slow were said to make it more difficult to work with SOPs. These findings correlate with the literature on accepted good practice. Those writing the SOPs should refer to good practice guidance on writing procedures in order to maintain a usable SOP system and promote compliance.
- Participant CL3 laboratories all had internal systems for capturing information from near misses and incidents and the capacity to learn from those experiences. Potential gains could accrue from the wider communication of near miss and incident information with other laboratories, with a view to driving up standards across the sector by learning from others’ experiences and control approaches. The information-sharing model implemented by the HPA appears to be a useful template for such a strategy. HSE may also be able to facilitate sharing of information.
- Care should be taken with extrapolation of the findings of this research to the wider population of CL3 laboratories due to the nature of qualitative research and the possibility that the current sample may not be representative of the population of CL3 laboratories in Great Britain. However, as the findings are broadly in line with findings from research into the underlying causes of procedural violations in other industry

sectors, it could be hypothesised that the reasons and situations put forward by participants in this research regarding why and when they may not follow SOPs could also be evident in other CL3 laboratories.

3. METHODOLOGY

3.1 STUDY DESIGN

This study aimed to draw upon the contextual insights of staff working in CL3 laboratories. Therefore, a qualitative research methodology was deemed appropriate to gather and analyse the views of subject matter experts by conducting a series of focus groups. This methodology was chosen because the objectives of the study required a detailed exploration of the views and experiences of participants. Vignettes (hypothetical short stories or scenarios) were used in the focus groups to allow participants to talk openly about the salient issues without needing to refer directly to their own actions.

In addition to the focus groups, a brief literature review was conducted to determine control measures that may help address non-compliance with SOPs.

3.2 SAMPLING STRATEGY AND RECRUITMENT

A purposive sample of six CL3 laboratories was selected from the 759 CL3 laboratories in Great Britain, to include the five key areas of operation as outlined in Table 1.

Table 1: The five key areas of CL3 laboratory operations in the research sample

Research laboratories	Diagnostic laboratories
Human pathogens	Human pathogens
Animal pathogens	Animal pathogens
Genetic engineering	

HSE colleagues supplied contact details of potential participant laboratories, drawing on established industry contacts (specifically BSOs (Biological Safety Officers)) from a range of organisations operating CL3 laboratories. HSL staff undertook the recruitment of participant laboratories using the prepared recruitment script (see Annex 1). Following a verbal description of the research, the BSOs from the potential participant laboratories were sent additional information in the form of a covering letter (see Annex 2), an information document (see Annex 3), and consent form for the focus group participants (see Annex 4).

3.3 PREPARATION OF VIGNETTES

Vignettes have been described as “short stories about hypothetical characters in specified circumstances, to whose situation the interviewee is invited to respond”². Vignettes were chosen for use at the focus groups because they facilitate swift participant understanding of the

topic of interest and allow information to be elicited without participants having to admit that they have not followed the SOPs themselves.

A review of RIDDOR reports and Accident Investigation reports informed the development of the vignettes. The two sources of information on incidents were explored to identify related themes that were then used to inform the content of the vignettes.

The vignettes were subject to an iterative review process during their development. Reviewers included internal HSL microbiology specialists and external Biological Safety Officers (BSOs). This process ensured that the final versions of the vignettes were valid and contained appropriate content that would elicit relevant and informative data. A total of ten vignettes were developed and up to three were selected for each focus group session, based on relevance to the organisation. The vignettes can be found at Annex 5.

3.4 QUALITATIVE DATA COLLECTION

Two HSL researchers facilitated the six focus groups. All focus groups were audio recorded, with the consent of all participants. Participants were given assurances of the confidentiality and anonymity of the information being collected. The lead researcher facilitated the focus group sessions, guiding the discussion through the topics as set out in the topic guide (see Annex 6) and accommodating relevant departures from the prepared questions where appropriate. The second researcher took written notes to back-up the audio recordings.

The audio recordings from the six focus groups were transcribed verbatim by an external contractor, and checked by the lead researcher. Any notes from the focus groups were used to supplement the verbatim transcripts.

Table 2: Focus group details

Date	Laboratory type category	Number of participants
19/5/11	Research laboratory – Human pathogens	6
24/5/11	Diagnostic laboratory – Human pathogens	7
25/5/11	Diagnostic laboratory – Human pathogens	4
27/5/11	Research laboratory – Animal pathogens	5
7/7/11	Diagnostic laboratory – Animal pathogens	5
28/7/11	Research laboratory – Genetic engineering	8

3.5 DATA ANALYSIS

Data collected in the focus groups was analysed using a systematic approach as advocated by the National Centre for Social Research¹⁴. This approach develops, refines and modifies an analytic (or thematic) framework, into which every piece of data is then systematically and consistently analysed. The analytical framework was initially informed by the research objectives, research topics in the focus group topic guide, and by the key issues that emerged from the data. The framework was grounded in the data and not imposed by the researcher. A matrix of themes and sub-themes was derived from the data, which was then used to explore, and to compare and contrast, the patterns of responses in the data. The data analysis resulted in the identification of a number of key issues concerning the human factors that lead to non-compliance with SOPs in CL3 laboratories.

3.6 LITERATURE SEARCH

Following analysis of the focus group data and having established the types of human factors that result in non-compliance with SOPs in CL3 laboratories, a brief targeted literature search was carried out. This was to identify the control measures that may be effectively employed to reduce the likelihood of such non-compliances in the future (for example, barriers that have been tried and tested by other organisations from various industries and those that are recognised by HSE as good practice). The literature search used the terms Biohazard, CL3 laboratory, human factors, standard operating procedures, non-compliance, violations, and cutting corners. English language articles from the last ten years were sought from the following databases: OSH-ROM, Biosis Previews, CAB Abstracts, Ei Compendex, and EMBASE.

4. FINDINGS

4.1 INTRODUCTION

Findings from the six focus groups are reported in this section. The findings have been structured according to the focus group question schedule (Annex 6) and the key human factors that lead to non-compliance with SOPs.

4.2 VIGNETTES

The vignettes worked well as a vehicle to aid discussion of the issues during the focus groups. Participants said the vignettes were valid and that they could relate to the content and context of each one presented. The discussions that followed each vignette were rich in detail and participants readily described reasons why the scenario could have occurred and potential controls to prevent reoccurrence. It can therefore be said that the strategy of using vignettes at the start of the focus group sessions was successful in terms of both breaking the ice, and engaging participants in discussions of a relatively sensitive nature without their needing to refer to their own specific behaviours.

The discussions relating to each vignette, whilst relevant to the topics in question and analysed in their entirety along with the main body of the focus group discussions, are not presented in full as a stand-alone section. Rather, the themes arising from the vignettes are used, where appropriate, to supplement the themes arising from analysis of the main topics of discussion.

4.3 MAIN RISKS

The focus groups reported a consensus opinion that the main risk when working in the CL3 environment was infecting oneself. Other risks included infecting others (colleagues, family, wider society), cross-contamination between samples leading to false results, and the risk posed by unauthorised access to Hazard Group 3 (HG3) pathogens.

4.4 STANDARD OPERATING PROCEDURES

4.4.1 How useful are the SOPs?

All focus group participants reported that SOPs are useful. SOPs were reported to be used as a reference, a reminder, and to justify the approach taken. Participants said that SOPs were essential in the CL3 environment, for example, to maintain ISO9001 compliance, as a guide during training sessions, and to help engender a consistent approach to routine procedures across all staff. SOPs were also said to be helpful during audits and in discussions with customers. A comment from participants engaged in research activity suggested a difficulty with adherence to SOPs during exploratory research. During such activity the research method and therefore the SOP is often developed as part of the work.

4.4.2 How practical are the SOPs?

Focus group participants offered a range of views on the practicality of SOPs. Some participants felt that the SOPs generally contained the right level of detail, were practical, and reflected how the specific tasks were performed. Participants said that the majority of SOPs were easy to use, and whilst some specific SOPs were complex, this reflected the nature of the task.

Some participants suggested that in some cases the SOPs did not match the practicalities of the work, contained unnecessary detail, and could be out of date if lab techniques had changed. It should be noted that SOPs in regular use were reported to be updated regularly, whilst those SOPs that were used less frequently may receive less frequent updates. This links to a related issue suggested by some participants; laboratory methods change frequently, resulting in management needing to update SOPs and communicate the changes to staff.

The communication of changes to SOPs was said to be an issue, with informal methods such as post-it notes and ad hoc chats having to be relied upon in the absence of sufficient formal communication via staff meetings. Specific issues include all staff not being present on one day to be informed of changes to SOPs in a consistent way, lack of resources to update the SOPs leading to out-of-date SOPs, and software systems precluding the use of post-it notes to keep up with frequent changes.

Some participants suggested that some SOPs were written in a language that could be open to interpretation. In such instances staff would write their own bench notes from the SOP and worked from those notes instead. Some SOPs were also said to have been written by individuals who had not worked in CL3 for some time, and therefore may not be fully abreast of current working practices. The level of language adopted in the SOPs and the prior knowledge that the SOPs assume was said to be challenging for some of the lower grades of CL3 laboratory worker.

Comments arose from participants alluding to a need to balance the amount of technically detailed information within the SOP with the practicality of the SOP. Efforts to reduce the amount of reading that CL3 laboratory staff were required to undertake were said to have been made, as some participants suggested that the time required to read the SOPs was an issue.

4.4.3 Involvement in developing SOPs

All focus group participants said that they (and all other CL3 laboratory staff) were able to feed into the SOP development process. Some participants said that the senior staff grades were more likely to be responsible for writing and reviewing the SOPs whilst the junior grades would feedback on the SOPs once they were active in the laboratory. Participants described a variety of formal arrangements in place in their respective organisations that enable SOP development, for example monthly safety meetings to discuss any current SOP related issues and yearly safety audits to more fully review all SOPs. The SOP systems in place were said to be formally document controlled to manage any changes centrally, with the documents being presented in a standard format to promote consistency and usability. Participants reported that all CL3 staff were required to sign to confirm their having read the latest versions of the SOPs.

4.5 PERCEPTIONS OF RISK CONTROLS AND SAFETY MANAGEMENT SYSTEMS

For the purposes of this section the findings are presented with reference to the HSE framework of human factors violations. Themes emerging from the focus groups in response to questions regarding participants' perceptions of risk controls and safety management systems (Annex 6, question 3) have been categorised and reported in terms of routine, situational, and exceptional violations. Themes that could be considered to fall within the category of optimising violations were not apparent during the analysis, and therefore this category of violations is not included.

4.5.1 Main reasons for CL3 laboratory workers to cut corners

4.5.1.1 *Routine violations*

The main reasons for cutting corners that fall within the routine violations subcategory relate to workers' **personality**, **attitude** and **complacency**. These were described as key contributors to corner cutting, but also as being fundamental to success at CL3, including compliance with SOPs. Personality is considered to be relatively stable in most individuals, and a significant discipline has developed that attempts to describe and measure personality in order to inform, for example, the recruitment and selection process. Attitudes could be considered as the manifestations of personality, with one example relevant to CL3 working being the tendency for complacency.

4.5.1.2 *Situational violations*

Focus group participants offered a wide range of reasons for CL3 workers to cut corners that fall into the situational violations subcategory. This type of corner cutting often occurs because it is perceived that the rules are too difficult to be kept to. Participants offered more reasons for corner cutting that fell into this category than any other.

Possibly the most strongly reported group of situational factors that were given by participants as reasons for cutting corners are related to **time pressure**, **workload**, and **staffing levels**. All focus groups described at length the various commercial pressures, service level agreements, and turnaround time expectations that CL3 staff were under in order to deliver their work. There was a consensus view that these sorts of pressures lead to corner cutting. Further to this, participants also stated that perceived **unrealistic workload allocations** and insufficient staffing levels exacerbated the situation.

Participants also gave a consensus view that **insufficient training** and **supervision** of CL3 staff could lead to corner cutting. On a related note, lack of a general understanding of the SOPs, perceived inaccessibility of SOPs, and a lack of understanding of the technical underpinnings of SOPs could also lead to cutting corners. Participants suggested that such issues could be addressed by increased training and supervision, however it was also mentioned that the recruitment process could have a part to play in selecting staff with appropriate competencies and experience.

Insufficient facilities (workspace, equipment, consumables) were also offered as a reason for corner cutting, along with **poor standards of housekeeping**, and **insufficient pre-work**

preparation. These sorts of factors, relating to the workspace and its pre and post work action requirements, were suggested to have deteriorated over time and could be addressed by allowing more time for the work. One focus group also raised the concern that an increase in staff numbers in one particular laboratory had had the effect of reducing community awareness, with staff not leaving microbiological safety cabinets in an appropriate condition for the next user.

4.5.1.3 Exceptional violations

Participants reported relatively few reasons for the occurrence of exceptional violations. Some participants suggested that they may not follow a small number of the SOPs in every detail as they perceived there to be **simpler methods** that were still safe. Further to this, some participants offered the view that historical control methods were perceived by staff with longer tenure as **sufficiently effective** in controlling the risks. Both these views suggest that staff may not fully accept changes to SOPs as they develop over time, particularly if the changes introduce perceived unnecessary additional efforts by CL3 staff. A final reason offered by participants for cutting corners that relates to the exceptional violations subcategory is that of impractical SOPs. Some participants said that **some SOPs were impractical**, however it must be noted that this view was against the majority view across all the focus groups where SOPs were generally considered to be practical.

4.5.2 Situations where CL3 laboratory workers could cut corners

4.5.2.1 Routine

Corner cutting situations relating to the routine violations subcategory are linked to CL3 workers' **personality**. Whilst an individual's personality may not be interpreted as a 'situation' per se, focus group participants felt that the pervading nature of personality meant that it was a factor worthy of consideration in all situations where corner cutting was evident.

4.5.2.2 Situational

Participants offered a wide range of situations where CL3 workers could be more likely to cut corners that fall into the situational violations subcategory. As in section 4.5.1.2, this type of violation subcategory featured strongly in the discussions and yielded the largest number of comments and suggestions. Participants said that situations where the **workload was high** and they were **under pressure** in terms of time were the sorts of situations where corners may be cut. Participants also said that other pressures such as **external pressures**, for example, meetings, and commercial pressures, for example sample **turnaround times defined in service level agreements** could also influence CL3 workers to work in a way not consistent with SOPs.

Other situations that may lead to corner cutting that featured less strongly in the discussions were concerned with **insufficient staffing levels** and **insufficient facilities** (workspace, equipment, consumables). Participants offered the view that insufficient staffing could lead directly to cutting corners, or indirectly via increasing the stress levels of CL3 workers who may then cut corners as a way of coping with the situation. Either way, working in accordance with

SOPs could be compromised. The topic of insufficient facilities was raised at laboratories that dealt with human pathogens and was not raised at laboratories that dealt with animal pathogens.

4.5.2.3 Exceptional

Factors that fall into the exceptional violations subcategory were relatively fewer in number. Some participants in some of the focus groups said that situations could arise where an individual CL3 worker may perceive there to be a **legacy control method** for a particular laboratory process that was sufficiently effective. Whilst this was said to be relatively uncommon, it is worthy of note as management should be aware of the influence of employees with longer tenure on those relatively early in their careers. Participants also suggested that CL3 **workers' health** could be an issue in some circumstances and that staff should not work in CL3 if they did not feel well and able.

4.5.3 Controls in place to avoid cutting corners

Following the discussions in the focus groups that yielded the findings presented in sections 4.5.1 'reasons for cutting corners' and 4.5.2 'situations where corners may be cut', participants were guided to consider potential controls that could address the points they had raised. The suggestions for controls are again presented according to the subcategories of violations.

4.5.3.1 Routine

The main controls that fall within the routine violations subcategory relate to addressing corner cutting that has become the accepted way of working. Participants reported a consensus view that a primary control to address corner cutting is **increased supervision and monitoring**. Various types of supervision were described by participants, for example, peer-to-peer, grade based, closed circuit television (CCTV), and external audits. All focus groups recommended the various types of monitoring as a tried and tested mechanism for addressing non-compliance with SOPs.

Related to the peer-to-peer and grade based internal supervisor practises referred to above, participants from some of the laboratories dealing with human pathogens praised the benefits of an **open culture**, where colleagues felt able to keep an eye on each other and comment on each others' working methods without fear of misinterpretation and reprisal. Those laboratories that referred to peer-to-peer supervision felt that it stemmed from an open culture driven from management. Some participants from the laboratories that dealt with animal pathogens were aware of the benefits of a no-blame culture, however they felt that in some instances the principles of such a culture were not strictly adhered to.

Participants suggested one of the key controls to mitigate corner cutting in a wide range of CL3 circumstances is **communication**. All focus groups readily grasped the significance of communication in relation to compliance with SOPs and articulated a variety of communication methods and channels that enable CL3 workers to maintain compliance. Some examples include memos, emails, team meetings, safety briefings, formal training, and performance appraisals. In addition to the formal methods of communication, all participants expressed the view that informal communication between colleagues was a key feature in the sharing of good practice and the maintenance of standards.

Participants from laboratories dealing with human pathogens in a diagnostic capacity also suggested the **recruitment and selection process** as a key control to address issues with corner cutting in CL3 staff. Candidates for CL3 jobs were said to be assessed during interview with a view to understanding their motivations and confidence, along with technical credentials, as a particular ‘type’ of individual that was ‘suited’ to the CL3 environment was sought. Participants in all focus groups referred to their observations of a particular type of personality that is well suited to CL3 work, and described facets of personality, for example, conscientiousness as being relevant.

4.5.3.2 *Situational*

Suggested controls that sit within the situational subcategory of violations were again the primary area of participants’ focus during the discussions and yielded the greater number of suggestions. Participants from all focus groups felt strongly that staff **training and competency assurance** measures were primary controls to maintain compliance with SOPs. All groups also mentioned **experience** of the CL3 workplace as a key control measure to maintain standards across the range of CL3 activities.

Beyond the more general control measures of training and competence, participants focused on one of the primary topics that regularly featured in the focus group discussions, that of **workload and time management**. There was a consensus view across all focus groups that a key contributor to the control of non-compliance with SOPs is allocation of an **appropriate workload** for each individual, which is **realistically achievable** within a given timeframe. Related to this, participants from laboratories dealing with human pathogens felt that **booking timeslots** on CL3 facilities helped staff maintain standards, knowing that they have a certain amount of time to complete their work that is pre-agreed for each type of process they undertake. These participants also said that efforts to **predict workload and plan the usage of CL3 facilities** within contracted service level agreements helped to avoid situations where staff felt overloaded and under time pressure.

Participants from laboratories dealing with human pathogens also suggested that **rota systems** could contribute to managing the usage of CL3 facilities and thus help to maintain compliance with SOPs, with an essential part of such an approach being team flexibility. Participants from laboratories dealing with animal pathogens said that **challenging pressure from management** was sometimes required in order to carry out work in full accordance with SOPs.

4.5.3.3 *Exceptional*

A control measure suggested in some of the focus groups that falls within the exceptional violations subcategory is **formal disciplinary action**. Whilst this was alluded to by other focus groups in the context of an outcome from the performance appraisal system, participants in one focus group suggested that formal disciplinary action could be a useful control to minimise corner cutting in CL3 work.

4.6 HUMAN FACTORS (NON)-COMPLIANCE WITH SOPS

Focus group participants were asked about compliance with SOPs from a slightly different perspective to ensure a comprehensive analysis of the topic. They were asked to identify the factors that made it more difficult to comply with SOPs and the factors that made it easier. Similar topics were raised to those raised during earlier discussions about the main reasons and situations where CL3 laboratory workers may cut corners. Sections 4.5.1 (reasons for cutting corners) and 4.5.2 (situations where cutting corners may be more likely) categorised participants' comments according to the different types of human factors violations. In this section, participants' comments have been categorised and presented with reference to the three main Human Factors categories detailed in HSG48. These Human Factors categories are termed 'Individual', 'Job' and 'Organisational' factors. The majority of factors reported by participants fell into the job and organisational categories, with relatively few in the individual category.

4.6.1 Individual factors

4.6.1.1 *Factors that make it more difficult to follow Standard Operating Procedures*

Participants reported a small number of factors that fall into the individual factors subcategory of the overarching human factors framework. **Personality** facets such as not being conscientious, impatience, complacency, unwillingness to comply, and generally poor 'common sense' were said to make it more difficult to follow SOPs, should they feature heavily in an individuals' nature.

Other individual factors that make it more difficult to follow SOPs include a **lack of experience**, a lack of competency in terms of **time management and planning**, and **English not being the first language** of the individual.

4.6.1.2 *Factors that make it easier to follow Standard Operating Procedures*

In terms of factors that make it easier to follow SOPs, participants said that **prior CL3 laboratory experience** and **personal copies of the procedures** with individuals' own notes on them are helpful. It could also be inferred that the factors reported in section 4.6.1.1 that participants said would make it more difficult to follow SOPs would, if inverted, make it easier, for example, a personality where conscientiousness, patience, complacency, willingness to comply, and general 'common sense' featured strongly in an individuals' nature.

4.6.2 Job factors

4.6.2.1 *Factors that make it more difficult to follow Standard Operating Procedures*

Factors that make it more difficult to follow SOPs that fell into the job factors category included a number of comments focused on the SOP system itself, for example, **unnecessary detail** in SOPs, perceived **overly lengthy** or **overwhelming** SOPs, **locating the correct section within SOPs**, **cross-referencing between SOPs**, the SOPs **numbering system** not reflecting the

content, and the **electronic SOPs system being impractical and slow**. Whilst all these points were raised at least once across the six focus groups, it should be noted that none of these comments were consensus views and were often related to a specific SOP or individual perspective.

Participants also said that a **lack of equipment** and a **lack of PPE** could make it more difficult to follow SOPs. Laboratories involved in CL3 work in a research capacity also said that the **nature of research work** meant that sometimes they were developing the procedures as the work progressed.

4.6.2.2 Factors that make it easier to follow Standard Operating Procedures

In terms of making it easier to follow SOPs, participants reported a number of factors that fall into the job factors category of the overarching human factors framework. A **usable index system** for SOPs, **access to hard copies** of SOPs, **tick sheets** to aid tracking progress through SOPs, and **visual aids** in SOPs were all suggested by participants as ways to make following procedures more easy. Participants also reported that having SOPs **written by individuals who do the work** is helpful, as they would be familiar with the relevant details of the job and practical constraints of CL3 laboratory work. **Adequate supervision** of new starters was also put forward as a means of making it easier for SOPs to be followed.

4.6.3 Organisational factors

4.6.3.1 Factors that make it more difficult to follow Standard Operating Procedures

Factors that make it more difficult to follow SOPs that fell into the organisational factors category were similar in nature to those reported in sections 4.5.1 (reasons for cutting corners) and 4.5.2 (situations where cutting corners may be more likely). This suggests that the main issues that result in corners being cut are often organisational factors, and could be influenced more by management than workers. Participants reported a number of organisational factors that make it more difficult to follow SOPs, including a **culture to deliver results quickly** (related to perceived unrealistic service level agreements), **general time pressure**, **excessive workload**, **poor communication**, and **poor quality training**.

Some participants at some of the focus groups also said that the policy of **lone working** in their CL3 laboratories could make it more difficult to follow procedures, although this was not the case for all laboratories included in the study. A further additional point mentioned by a small number of participants related to **inconsistent practices** in the use of PPE across the various areas within the laboratory, for example, 2 pairs of gloves being required in some areas, and only one pair of gloves being required in other areas.

4.6.3.2 Factors that make it easier to follow Standard Operating Procedures

In terms of making it easier to follow SOPs, participants reported a variety of factors that fall into the organisational factors category of the overarching human factors framework. Participants reported that they had an organisational **culture that does not allow new starters to be pushed through training too quickly**, **sufficient resources and training**, and **external**

audits. These were said to help CL3 laboratory workers to follow procedures. Participants at one of the focus groups also said that **planning periods of high demand** was a good way of managing workload and helped with procedural compliance.

Participants also said that the **consistency of enforcement** of SOPs helped, along with the **consistency of staff** following the procedures. One focus group suggested that their local **out of hours working policy** helped maintain adherence with the procedures as it reduced the time pressure on staff between the normal 9-5 working hours. One final point made in one focus group was that **working in pairs** helped with procedural compliance. In this arrangement, one of the pair would be doing the work in the cabinet whilst the other one of the pair would be reading from the SOP.

4.7 ORGANISATIONAL LEARNING AND COMMUNICATION

This research also considered the topics of organisational learning and communication. Whilst these topics are not fundamental to non-compliance with SOPs *per se*, it was felt that the research would benefit from the inclusion of some additional understanding of CL3 laboratories' approach to gathering, analysing, and sharing information related to incidents and near misses, and communication and learning within the sector. This stemmed from the analysis of RIDDOR data that led to the commissioning of this research, where it was felt that CL3 laboratories could benefit from applying learning from analysis of the causes of incidents and near misses.

4.7.1 Likely near misses in CL3 work

Participants reported a number of likely near misses that could occur in the CL3 laboratory environment. These included equipment failures, poor equipment quality and maintenance, insufficient laboratory space or poor organisation of equipment within the laboratory, samples being processed without relevant information, lack of understanding of SOPs by staff, complacency in staff, and trips and spillages.

4.7.2 Reporting and communication of near misses

Participants described a variety of formal systems in place in their respective organisations to facilitate the reporting and communication of information relating to near misses, and recognised that near miss reporting can lead to learning opportunities. In the first instance, all participants said that their organisations had a policy in place for near miss reporting and analysis and that all CL3 laboratory staff were encouraged to report. Staff were said to be able to report near misses using incident forms found in the laboratories and by using internal and, in some cases, external IT systems. Where laboratories had implemented IT systems to capture information, participants thought accessibility and usability issues were a barrier to near miss reporting.

Near misses that were reported were regularly analysed with a view to improving policies, SOPs, and health and safety in general. Participants reported that information from the analysis of near misses was communicated to staff in a number of ways, for example, during weekly staff meetings.

4.7.3 How information from incidents and near misses is analysed

All participants said that their respective organisations had formal systems in place, supported by organisational policies, which analyse information from incidents and near misses. Information was gathered by designated health and safety advisors, subjected to trend analysis, and fed into Biological Safety Committee and General Safety Committee meetings. Those participants from laboratories who were part of the Health Protection Agency (HPA) also said that incidents and near misses were reported to the HPA via an IT system, alongside the internal laboratory system.

4.7.4 Changes made in light of analysis of incidents and near misses

All participants reported their organisations had made changes in light of analysis of incidents and near misses, for example, modifying equipment, introducing additional training, withdrawing Bunsen Burners, and selecting PPE with enhanced specifications.

4.7.5 Communication of information from analysis of accidents and near misses

All participants reported receiving information regarding accidents and near misses at staff meetings, however some participants alluded to the potential need for improvement in the cascade of information. Whilst the communication of significant safety critical information was consistently fed back in team briefings, for example, regarding a change in protocol, less significant information was inconsistently fed back and varied across laboratory team leaders. Participants suggested that multiple channels of communication would help improve feedback, for example, using notice boards as well as verbal briefings and emails, because some staff did not have time to access email. In addition, some laboratories have implemented a seven-day rota pattern and it was suggested this had led to some staff missing information in team meetings because they were held on days when they were not at work.

Participants said that information was communicated well in staff meetings and that they had access to health and safety meeting agendas and minutes, however they would welcome more feedback to the individuals who raised the near miss report. All participants said that upward channels of communication, in their respective organisations, were of a good standard.

4.7.6 Communication of lessons learned to and from other organisations

Participants said that information about lessons learned was shared between organisations via both formal and informal networks. A number of organisations were described that facilitate the sharing of health and safety information within the CL3 laboratory sector, for example the Medical Research Council (MRC) and the Health Protection Agency (HPA). These organisations were said to gather pertinent health and safety information from their various member laboratories and distribute the information with the aim of sharing good practice and driving up standards. In addition to these networks, participants also said that information is

communicated to other organisations by means of a forum for Biological Safety Advisors, attended by representatives from a variety of CL3 laboratories.

An example of inter-laboratory communication was given that related to planned changes; participants said that managers had consulted other laboratories that had implemented a similar change in order to ascertain any relevant issues that may impact on success. In terms of informal networks, participants said that, like many specialist vocations, there was a community of CL3 laboratory staff and that relationships are forged and maintained as individuals progress through their careers.

4.8 FINDINGS FROM THE REVIEW OF TARGETTED LITERATURE

There are four key HSE guidance documents that outline the type of control measures that could be employed to reduce the likelihood of non-compliance to SOPs in the workplace:

- HSE Books (1999) HSG48 - Reducing error and influencing behaviour (second edition). ISBN 07176 2452 8.³
- HSE Books (1999) Improving compliance with safety procedures – Reducing industrial violations. ISBN: 0 7176 0970 7.⁴
- HSE (2004) Inspectors' toolkit: Reliability and usability of procedures. Free information sheet. Available on HSE's website.⁶
- HSE (2004) Revitalising Procedures. Free information sheet. Available on HSE's website.⁷

The guidance documents (in particular the HSE briefing note on reliability and usability of procedures) describe how to develop procedures that are appropriate, reliable, useful, up-to-date, fit for purpose and owned by the workforce. For example when ensuring that the procedures are clear and facilitate accurate assimilation of information the SOP steps should be numbered, with only one action for each procedural step, using short and simple sentences. Having clear procedures, together with other action (e.g. worker involvement in the development of the procedures) should help to ensure compliance.

The HSE information sheet on revitalising procedures details the type of action that can be taken to encourage compliance with procedures:

- Design the job or task so that the correct procedure is hard to avoid
- Base the procedure on how the task is actually performed
- Identify incentives to take short cuts (such as work pressures) and address these directly
- Adopt a control and review process to keep procedures relevant and up-to-date.

HSG48 (reducing error and influencing behaviour) outlines specifically the action that can be taken by managers to reduce the likelihood of the different types of violation (i.e. intentional non-compliance with procedures).

To reduce routine violations managers could:

- Take steps to increase the chances of violations being detected (e.g. by routine monitoring);
- Think about whether there are any unnecessary rules;
- Make rules and procedures relevant and practical;
- Explain the reasons behind certain rules or procedures and their relevance;
- Improve design factors that affect the likelihood of corner cutting (e.g. difficult-to-use or uncomfortable personal protective equipment);
- Involve the workforce in drawing up rules to try to increase acceptance.

To reduce situational violations managers should consider:

- Improving the working environment;
- Providing appropriate supervision;
- Improving job design and planning;
- Establishing a positive health and safety culture.

To minimise exceptional violations managers could:

- Provide more training for abnormal and emergency situations;
- During risk assessments think about the possibility of violations;
- Try to reduce the time pressure on staff to act quickly in novel situations.

The report on improving compliance with safety procedures and reducing industrial violations was developed by the Human Factors in Reliability Group as a practical guide to reducing the potential for violations. Organisations can identify their specific violation problems and the corresponding solution/s having administered and analysed the results of a workforce questionnaire. There are 13 potential solutions:

- Rules and procedures (design) e.g. SOPs need to be practical with a clear and acceptable aim;
- Rules and procedures (application) e.g. SOPs need to be applicable to the setting for which they are intended, up-to-date and easy to understand;
- Training (rules and procedures) e.g. a systematic approach to determining refresher training needs should be in place and measures for testing understanding of the learning outcomes need to be developed and applied;
- Training (hazards and risks) e.g. having assessed the workforce's understanding of hazards and their perception of the risk and benefits of failing to follow SOPs, management should develop the workforce's awareness of hazards and risks through appropriate training;

- Safety commitment (workforce) e.g. the attitudes of workers towards safety in the workplace have been successfully influenced by, for instance involving the workforce in safety campaigns and drafting the SOPs;
- Safety commitment (management) e.g. managers need to convey to the workforce their commitment to safety through their actions, for instance by providing an effective near miss reporting procedure;
- Supervision (monitoring and detection) e.g. through active monitoring (such as unannounced inspections) and reactive monitoring (e.g. incident investigation to identify violations, underlying causes and lessons learnt);
- Supervision (style) e.g. supervisors should be ‘attacking’ the unsafe practice and not the individual when addressing violations;
- Plant and equipment design and modification e.g. in order to minimise the likelihood of non-compliance designers should design systems that facilitate safe use, give clear warnings when operated unsafely and provide sufficient opportunity to recover from any error;
- Job design e.g. if the nature of the work is too constrained and mundane, safety standards can slip as operatives experiment with alternative working practices. To prevent this behaviour, job design improvements can be made, for instance flexible working groups can be set up where responsibility for production and quality is shared;
- Working conditions e.g. important factors that can lead to error and violations and therefore need to be optimised to facilitate safe compliant behaviour are noise, lighting, thermal environment and personal protective equipment;
- Logistic support e.g. appropriate resources need to be freely available because lack of logistic support can often lead to non-compliance with SOPs;
- Organisation e.g. this includes improvements in the senior management style, attitudes, policies and safety culture (i.e. avoidance of a ‘blame’ culture), for instance discipline to enforce compliance should be fair and consistent.

Incidents in the United States of America (e.g. failure to report a Brucella infection at a Texas University) left microbiologists looking for the type of Government action that could be taken to ensure safety and build public trust. The two ideas reported by Kaiser (2007)⁹ are:

- Setting up an anonymous national accident reporting system that would enable different organisations to learn from the mistakes of others (noting that the incidents reported would need to be well defined and include analysis of the underlying causes of the incident as well as the facts surrounding it)
- USA biosafety laboratories 3 and 4 to be licensed by the federal government, and as such would be regulated, inspected and expected to follow the same SOPs.

In Great Britain the Reporting of Injuries, Diseases and Dangerous Occurrences Regulation (RIDDOR) was set up in 1995. Safety alerts are produced by HSE to alert employers to the action that they should take following an incident. Great Britain CL3 and CL4 laboratories are regulated under the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as

amended)⁸ which outlines the approved code of practice (ACOP) and supporting guidance. Regulation 8 (use of control measures etc) ACOP places duties on the employer to ‘establish procedures to ensure that control measures.... are properly used or applied’ and duties are placed on the employee to ‘use the control measures in the way they are intended to be used and as instructed’. However there is no guidance to accompany this ACOP illustrating good practice and helping employers and employees comply with regulation 8.

4.8.1 Learning organisations

Wilday et al (2011) discussed learning organisation principles and information flows in relation to the Competent Authority’s (HSE, Environment Agency and Scottish Environment Protection Agency) introduction of the COMAH (Control of Major Accident Hazards) remodelling project (including a new intelligence system and the sharing of information by the Competent Authority to help industry learn lessons)¹⁵. A learning organisation is viewed as having both strong leadership and a culture of learning. The experience of COMAH remodelling is used as a case study to examine the practical steps to becoming a learning organisation for major hazards, with communication initiatives (e.g. training) being critical to addressing the challenges faced.

Lekka (2010) has reviewed the characteristics of high reliability organisations (HROs)¹⁰. These high hazard organisations are able to maintain virtually error-free performance over a long period of time. HROs were identified as having developed and maintained a virtually error-free performance over a long period of time by:

- Continuous training to improve technical competence
- Rewards for near miss reporting
- Open discussion of errors to identify causes
- Analysis of near misses and past incidents to identify accident trends and develop appropriate control measures.

4.9 LIMITATIONS

The findings from the focus groups provide rich insights into the perceptions and beliefs of only a small sample of CL3 laboratory workers. These individuals were selected as they had both the knowledge to comment on the human factors that lead to non-compliance with SOPs in CL3 laboratories, and were willing to participate in the research. The findings are therefore not intended to be representative of the views of the full range of CL3 laboratory workers.

There is a likelihood of social desirability bias being present throughout the focus group discussions; with the probability that participants, at least in some degree, provided responses that they felt would satisfy the researchers (or the HSE, who commissioned this research). Nevertheless, the research has produced both positive and less favourable comments suggesting that participants have expressed a balanced view regarding the human factors that lead to non-compliance with SOPs in CL3 laboratories.

It must also be noted that whilst the researchers requested focus group participants be drawn from the pool of CL3 laboratory staff within the participant organisations, some organisations provided staff with supervisory and management responsibilities along with the CL3 laboratory

workers. This could have influenced some participants' responses, and could be a further source of bias.

5. CONCLUSIONS

Overall, this research has identified generally good standards in respect of compliance with SOPs in the participant CL3 laboratories, but there is room for improvement in some areas. Generally, the SOPs themselves are thought to be acceptable, usable, practical, and fit with good practice from the literature. Most participants said they have input into the development of procedures. Whilst some differences were apparent in the findings from the various classifications of CL3 laboratories involved in this research (Table 1) no significant differences in the major issues discussed in the focus groups were apparent. Indeed, the human factors issues that participants raised in the focus group sessions as ‘reasons for cutting corners’ and ‘situations where cutting corners may be more likely’ were familiar. This suggests that the CL3 laboratory sector experiences similar challenges to other industry sectors where compliance with procedures is a common feature. This view is supported by the literature.

5.1 CUTTING CORNERS – REASONS AND SITUATIONS

The main reasons for cutting corners put forward by participants, with respect to the various categories of violations detailed in section 1.3, were primarily situational violations. These factors are more likely to be influenced by management than workers. For example, time pressure, workload, staffing levels, insufficient training and supervision, and insufficient facilities were common themes across the six focus groups. Whilst management may not be able to remedy all (or any) of these issues immediately they are at least more within the remit of management to address. That said, management may also feel that some of these issues are not directly under their control and that decisions may need to be escalated.

Other reasons suggested by participants for cutting corners fall into the routine (for example, personality) and exceptional (for example, impractical SOPs) violation categories. Personality is relatively stable in most individuals and is unlikely to change significantly in response to traditional training techniques. It could therefore be a consideration during recruitment and selection of CL3 laboratory workers. There was a consistent message across the six focus groups that a particular ‘type’ of person was best suited to CL3 laboratory working. When prompted further, participants described the personality attributes of such an individual as conscientious, patient, willing to comply, and confident but not overconfident. In respect of the exceptional violations, some participants suggested that a small number of SOPs were impractical. This should be balanced against the majority view that in the main, SOPs are practical and fit for purpose. One potential explanation for this could be the point raised in one focus group that SOPs that are in regular use are familiar and receive regular updates, whereas those SOPs that are used infrequently may become unfamiliar and the methods contained within could be superseded.

The main situations where cutting corners could be more likely, again with respect to the categories of violations detailed in section 1.3, were primarily situational violations. Time pressure, external pressures, inflexible service level agreements, insufficient staffing levels and insufficient facilities were all put forward in the majority of focus group sessions as situations where the likelihood for corner cutting could increase. Once again, these issues fit more readily within the scope of management influence than that of the CL3 laboratory workers themselves. Other situations where participants felt corner cutting could be more likely fall into the routine (for example, personality) and exceptional (for example, workers’ health) violation categories.

5.2 FOLLOWING PROCEDURES – EASE AND DIFFICULTY

From a different perspective, participants offered their views on what made it easier or more difficult to follow SOPs, and the findings yielded a pattern similar to the one described above. In this instance, the focus group discussions were analysed and categorised into the overarching human factors framework of organisational, job, and individual factors, as opposed to the framework of violations used to categorise the data obtained relating to reasons and situations for cutting corners. Findings were predominately organisational and job factors as opposed to individual factors, and are therefore considered to be more within the scope of management to influence.

5.2.1 Organisational factors

In terms of organisational factors, those that make it easier to follow SOPs were wide ranging and include culture, sufficient resources and training, external audits, planning periods of high demand, consistency of enforcement, and consistency of staff. Conversely, the organisational factors that make it more difficult to follow SOPs include a culture to deliver results quickly (related to perceived unrealistic service level agreements), general time pressure, excessive workload, poor communication, and poor quality training. Common themes are clear in these findings, and are also reflected in the previous paragraphs covering reasons and situations for corner cutting.

5.2.2 Job factors

Considering job factors, those that make it easier to follow SOPs were in the main focused on the SOPs themselves, for example, having a usable index system for SOPs, tick sheets to aid tracking progress through SOPs, including visual aids in SOPs, having access to hard copies of SOPs, and arranging for the SOPs to be written by individuals who do the work. Job factors reported to make it more difficult to follow SOPs include unnecessary detail in SOPs, overly lengthy or overwhelming SOPs, locating the correct section within SOPs, cross-referencing between SOPs, the SOPs numbering system not reflecting the content, and the electronic SOPs system being impractical and slow. There are a number of useful points contained in these findings relevant to any organisation seeking to design usable SOPs for staff, and drawing on the review of targeted literature concerning what makes for a good procedure (section 4.8), there are some clear correlations between participants views and accepted good practice.

Other job factors that make it more difficult to follow SOPs include a lack of equipment, lack of PPE, and the exploratory nature of research work. Taking the first two of these (and the final job factor that makes it easier to follow SOPs – supervision), it can be seen that parallels can be drawn with the previously discussed situational violations. Thus a pattern is emerging that broadly describes situational violations as being highly correlated with organisational and job factors categories of the general human factors framework. As situational violations are the most prevalent and significant in the findings of this research, it could be suggested that the reasons for these violations are more related to the influence of management (in terms of their influence on organisational and job factors) than that of the laboratory workers (individual factors). This view is consistent with the selected literature regarding violations (section 1.3).

5.2.3 Individual factors

With reference to individual factors, prior lab experience makes following SOPs easier, as procedures and safety are already well established in an individuals' approach to CL3 work. Individual factors that make it more difficult to follow SOPs include a lack of experience, lack of competencies relating to time management and planning, and personality. These factors are about individual characteristics, and whilst experience and competence could be addressed by time on the job and training, personality is relatively stable for most individuals. With this in mind, CL3 laboratory managers may consider a selection process that is designed to assess personality such that the desired characteristics, for example, conscientiousness and patience, are recognised, measured, and fed into the recruitment decisions. It should be noted that there are also parallels between these individual factors from the human factors framework and the routine violations from the violations framework as described earlier.

There are therefore some useful findings emergent from this research that could guide the focus of management in CL3 laboratories as they look to drive up compliance with Standard Operating Systems. The following sections provide further insight into improving compliance.

5.3 WHAT CAN BE DONE TO IMPROVE COMPLIANCE WITH SOPS?

The CL3 laboratories that participated in the research had controls in place to minimise the likelihood of non-compliance with SOPs, and those controls are in line with accepted good practice as evidenced by the review of targeted literature (section 4.8).

Controls to address situational violations include workload and time management, booking timeslots on CL3 facilities, and challenging the pressure from management. Predicting peaks in demand and planning a realistically achievable workload was said to make a significant difference to the time pressure staff felt when carrying out their work, so any efforts made in these areas are likely to have a positive impact on compliance with SOPs. Related to this, staff should feel able to challenge management pressure to deliver more work in a specified time frame if they are concerned that safety could be compromised. An open organisational culture is a key prerequisite for staff to feel able to challenge management. A progressive management approach should recognise this and be mindful that short-term productivity gains could compromise health and safety and set the tone within the work environment where non-compliance with SOPs may become the accepted way of working in order to get the work done in the time available.

Examples of the controls in place to address routine violations include supervision and training, an open culture, communication, and the recruitment and selection process. These are common control methods found in a wide range of organisations across many industrial sectors where compliance with procedures is a key aspect of the work. In terms of exceptional violations, the only control that emerged from the focus groups was that of formal disciplinary action. Whilst this is a valid control, it could be considered an option to be used only for the most serious transgressions and after other staff management techniques have been exhausted.

5.4 ORGANISATIONAL LEARNING AND COMMUNICATION

Organisations looking to drive up standards of compliance with SOPs often benefit from analysis of underlying causes related to incidents that they experience themselves or that other comparable organisations experience. The findings suggest that the laboratories that took part

in this research all have good internal systems including formal policies and procedures designed to capture near miss and incident data, analyse it, and share the learning within the organisation. Learning and making changes in light of that learning should help reduce the potential for similar events in the future. Further improvements could be gained from sharing such information with other laboratories. Other industry sectors, for example the offshore sector, have arrangements to share health and safety related information between companies with a view to driving up standards and bringing more consistency in approaches across the whole sector, with some success. Whilst some CL3 laboratories are members of a wider network, for example the diagnostic laboratories that deal with human pathogens were members of the HPA, not all participant laboratories were involved in such networks. This could be due to some of the participant laboratories not having as readily definable peer group as those laboratories involved with the HPA, however this should not be seen as a barrier to further efforts in this area as learning from others' experiences could bring significant advantages.

5.5 FUTURE DIRECTIONS

In order to maintain and progress compliance with SOPs, CL3 laboratories should continue with the controls they already have in place but with a particular focus on the controls relating to situational violations, as this was the most common area where non-compliance could occur. As the situational controls are correlated with the organisational factors from the human factors framework, the likelihood is that they will mostly be able to be influenced by management rather than laboratory workers. Efforts should therefore be made towards engendering a management approach in CL3 laboratories that builds on existing good practice and focuses on the various situational and organisational factors described in this research (for example, workload planning, realistic time scheduling, and availability of resources) in order to maintain compliance with SOPs and, therefore, maintain health and safety standards across the industry.

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7. ANNEXES

7.1 ANNEX 1 – RECRUITMENT SCRIPT FOR POTENTIAL PARTICIPANT CL3 LABORATORIES

These are some notes to help recruit six organisations with CL3 facilities to take part in this research. The primary contact at each organisation is likely to be the BSO (Biological Safety officer) or equivalent role. Two researchers will be visiting the premises to conduct the focus groups.

Good morning/afternoon, my name is.....

I am calling from the Health and Safety Laboratory. We are carrying out research on behalf of the Health and Safety Executive about the Human Factors that lead to non-compliance with Standard Operating Procedures in Containment Level 3 (CL3) laboratories.

The reason I am contacting you is to ask if your organisation would be willing to take part in this research. The Health and Safety Executive want to gain a better understanding of the key human factors that influence the non-compliant behaviour of laboratory technicians at CL3 laboratories (specifically why they fail to follow the SOPs) so that they can determine the control measures/barriers that can be applied to reduce such behaviours. To do that we need to carry out focus groups with CL3 laboratory technicians so that we can give accurate feedback to HSE. We plan to carry out six focus groups, each with between 8 and 10 participants, in six different CL3 labs across Great Britain.

The focus group will take about two hours. The researchers will ask participants on the day if the focus group can be recorded, but it is just for the purposes of the research and the recording will not be available to anyone outside the research team at HSL.

Any data gathered in this study will be treated as commercial in confidence, and findings will only be published without identifying which individuals or organisations participated. A written report on findings will be available from the HSE. All participating organisations will also receive a copy of the final report produced towards the end of this year.

Send out copy of the confirmation letter, information sheet and consent. The consent form can be returned by post or email (if we can scan it) whichever is most convenient to the duty holder (or we can do this during the visit).

7.2 ANNEX 2 – COVERING LETTER FOR BIOLOGICAL SAFETY OFFICERS

Harpur Hill, Buxton
Derbyshire, SK17 9JN
Telephone: +44 (0)1298 218000
Facsimile: +44 (0)1298 218590



Date 2011

Dear

Following on from our recent telephone conversation, I am writing to thank you for agreeing to take part in our research project on the Human Factors that lead to non-compliance with Standard Operating procedures in Containment Level 3 (CL3) laboratories. This letter is to confirm that two of our researchers will visit you at your premises ondate..... 2011 attime.....

The focus group will last around two hours.

I enclose further information on the project for you. Please feel free to contact me at any point with any further questions that you may have or if you no longer wish to participate in the research or should you need to change the date and/or time of the upcoming focus group.

Thank you again for helping us to identify the key human factors that influence the non-compliant behaviour of laboratory technicians at CL3 laboratories.

Yours sincerely

Simon Bates CPsychol
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Buxton
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Direct fax: +44 (0)1298 218394
Email: simon.bates@hsl.gov.uk

Enc

Study title: Human Factors that lead to non-compliance with Standard Operating Procedures

Who is conducting this research?

The Health and Safety Executive (HSE) commissioned Health and Safety Laboratory (HSL) Work Psychologists to undertake this research. HSL undertakes research on behalf of HSE.

What is the purpose of this research?

This research was commissioned by the HSE's Biological Agents Unit in response to analysis of investigation records that indicate that issues often appear to arise from a failure to follow Standard Operating Procedures (SOPs) in CL3 laboratories. It is intended to conduct focus groups at 6 dutyholders' premises to gather information about the key human factors that influence non-compliant behaviour of laboratory technicians at CL3 laboratories.

What does the research involve if I agree to take part?

HSL would like to invite you to hold a focus group (with between 8 and 10 of your laboratory technicians as participants) at your premises with two of our researchers to discuss the human factors that influence non-compliance with SOPs. Vignettes (hypothetical short stories or scenarios) will be used in the focus group to allow participants to talk openly about the salient issues without needing to refer directly to their own actions. The information your organisation provides will feed into a report to inform future HSE intervention strategy, thereby helping to reduce the number of future incidents. If you are happy for us to do so, we would like to audio record the focus group so that we have an accurate record.

Do I have to take part?

Taking part in this research is entirely voluntary. If you do decide to take part, please complete the attached consent form agreeing that HSL hold the information you provide for research purposes only. You may withdraw from the research at any time without giving a reason. Also, feel free to ask the research team any questions if anything is unclear.

Will the information I provide be treated in confidence?

Under no circumstances will personally identifiable information be reported in research reports/articles, and you can be assured that participants' anonymity will be upheld. HSL's data management systems abide by the requirements of the Data Protection Act. Information shared with us will be held at HSL on a secure network or in a locked cabinet and will be only used by researchers involved in the project for the purposes of this research. All data collected (electronic and hard copy) will be stored under an alias rather than the company name (e.g. Company 1, etc.). At no stage in the data analysis or report writing will companies be identified by anything other than the alias. All data will be destroyed ten years after the research is completed in line with the Data Protection Act.

What do I do next?

If you are happy to take part in this research please read through the **consent form** and return either as an attachment via email or by post to the address below. If you are returning via email please indicate your consent by typing your name on the signature line. If you have any other questions or would like any further clarification, please contact:

Mr. Simon Bates CPsychol
Health and Safety Laboratory
Harpur Hill
Buxton, Derbyshire
SK17 9JN.

Tel: 01298 218565 (simon.bates@hsl.gov.uk)

7.3 ANNEX 3 – INFORMATION DOCUMENT FOR FOCUS GROUP PARTICIPANTS

Study title: Human Factors that lead to non-compliance with Standard Operating Procedures

Who is conducting this research?

The Health and Safety Laboratory (HSL), a research agency of the Health and Safety Executive (HSE) in the UK, is carrying out this research.

Why is this research carried out?

The main purpose of this study is to identify the key human factors that influence behaviour of laboratory workers when working with high-hazard pathogens in Containment Level 3 (CL3) laboratories in the UK.

Who will participate in this research?

This study aims to draw upon the contextual insight of staff working in CL3 laboratories.

What does the research involve if I agree to take part?

Researchers from HSL will interview a group of staff through a focus group to discuss the human factors that could lead to non-compliance with standard operating procedures within CL3 laboratories. Vignettes (hypothetical short stories or scenarios) will be used in the focus group to allow participants to talk openly about the salient issues without needing to refer directly to their own actions. The questions will cover the following topics:

- Why CL3 laboratory staff may not follow SOPs.
- What type of human factors influence non-compliance with SOPs.
- What type of human factors influence compliance with SOPs.

In addition, if you are happy for us to do so, we would also like to audio record the discussions so that we gather accurate and complete data.

Do I have to take part?

Taking part in this research is entirely voluntary. You may withdraw from the research at any time without giving a reason. Also, feel free to ask researchers any questions if something is unclear.

Will the information I provide be treated in confidence?

The information that you and other staff members provide will be made anonymous. A report of results will be available in September 2011 and you can receive a copy of it if you wish. HSL will ensure that all records abide by the requirements of the Data Protection Act. Information you share with us will be held securely.

What do I do next?

If you are willing to take part in this research please read and complete the **consent form** and return it either as an attachment via email or by post to the address below. If you are returning it via email please indicate your consent by typing your name on the signature line.

If you have any question, please contact Simon Bates by email simon.bates@hsl.gov.uk or by telephone 01298 218565.

7.4 ANNEX 4 – CONSENT FORM FOR FOCUS GROUP PARTICIPANTS

Research title: Human Factors that lead to non-compliance with Standard Operating Procedures

I confirm that I have read and understood the Information Sheet for the above research, and have had the opportunity to ask questions.

(Write or type initial here).....

I understand that participation is voluntary and that I may withdraw at any time, without giving any reason for doing so.

(Write or type initial here).....

I understand that I will be interviewed for no longer than 2 hours and that the interview will only be audio recorded if I am happy for an audio recording to be made.

(Write or type initial here).....

I understand that any recordings will only be used for the purpose of this research, and will not be stored beyond the duration of this research.

(Write or type initial here).....

I understand the reason for this research and agree to participate.

(Write or type initial here).....

Name of Volunteer (your Name).....
Date.....
Signature..... (Please type your name if returning via email)
Name of Researcher.....
Date.....
Signature.....

7.5 ANNEX 5 – VIGNETTES FOR USE IN THE FOCUS GROUPS

1. A trainee researcher was working alone in an influenza laboratory. Following incubation and prior to harvesting, the tray of eggs, infected with virus, was placed into a fridge but during this process two eggs were damaged and the contents leaked out into the fridge. The trainee attempted to clean up the spillage, rather than exiting the room immediately as they should have done according to the SOP for spillages of influenza.

Issues: Trainee working alone, tried to clean up – suggests not aware of SOP, Inexperience / lack of competency, expectation would be that the egg tray would be in some form of secondary containment to eliminate the possibility of leakage.

2. 18 positive cultures, suspected of containing *Mycobacterium tuberculosis* (HG3), were opened in a class I Microbiological Safety Cabinet (MSC) in a CL3 lab. The cultures were processed without the MSC extraction fan being switched on, resulting in a potential exposure of the MSC operator, and three other staff present in the lab, to MTB. Although the light in the MSC was turned on, the MSC operator had not performed a visual inspection of airflow gauge to ensure the extraction fan was operational before use, as set out in the SOP for this work.

Issues: Extractor fan not switched on, no visual inspection, workload/job pressure, maintenance, awareness of SOPs, presence of surrogate indicator that would lead the operator to believe that the cabinet is switched on (e.g. light in the cabinet is on).

3. In order to closely observe a mouse that was potentially infected with Transmissible Spongiform Encephalopathy (TSE), a laboratory technician picked up the animal in order to observe it at eye level. The animal bit the technician. All staff should have attended a recent training session about handling techniques that were now considered to be poor and unsafe by management. The relevant SOPs were due to be updated to reflect the change. However, this individual was not on site on the day of the training and no further training dates had been arranged.

Issues: Handling of animals, training/communication of safety critical information (Organisational failure).

(NB: This is interesting as you may handle a TSE infected mouse very differently from Hepatitis B virus infected mouse, where the relative risks of onward infection may be different - its unlikely the former would result in any infection. This may affect risky behaviour).

4. A spinal abscess was submitted to a laboratory on-call service for routine microscopy. The differential diagnosis had been TB, therefore an urgent investigation was requested and the possibility of TB was detailed on the referral form. However, the specimen was processed on the open bench at CL2 thereby exposing the Biomedical Scientist (BMS) to *Mycobacterium tuberculosis*. The request had been dealt with across two shifts and while neurosurgeons had verbally informed the earlier shift that the theatre specimen would be imminent and that TB investigation was necessary, this detail was not communicated to the oncoming shift. The oncoming shift had missed the information on the referral form and processed the material on the bench.

Issues: Communication – information passed between shifts, checks on work requirements, changes in organisational structure.

5. A member of staff received a bite from a ferret that had been inoculated with highly pathogenic influenza (H5N1). The risk assessment for this work was clear on the issue of handling infected ferrets and required staff to wear protective gauntlets, however the staff member proceeded with the work wearing two pairs of nitrile gloves. The ferret was handled because the scanner used to read the telemetry chip was running low on batteries and could only be used at close range.

Issues: Handling of animals, maintenance of equipment, PPE. (NB: The relevance of H5N1 is that it is highly pathogenic).

6. During routine laboratory work a biomedical scientist got a droplet of plasma in her eye whilst pipetting a centrifuged blood specimen (with a high likelihood of an HG3 pathogen being present) on the open bench. Mandatory eye protection for this activity was clearly detailed in the SOP and RA, but the BMS was not wearing any eye protection at the time.

Issues: PPE.

7. A member of staff was infecting mammalian cells with a GM strain of *Francisella tularensis*. The procedure involved centrifuging the 24-well culture plates to enhance infection. During the procedure, the centrifuge made an unusual noise and would not stop (appear to speed up) when the control panel was activated. Consequently the researcher turned off the centrifuge at the mains switch. However, the lid was opened immediately and, as one of the culture plates was observed to be empty and not seated correctly on the plate carrier, three individuals were potentially exposed to an aerosol of GM *F. tularensis* and were subsequently put on a course of antibiotics by their occupational health provider. The genetic modification was unlikely to enhance the pathogenic properties of the bacteria but was considered to be equivalently pathogenic to wild-type *F. tularensis*.

Issues: Agent transmissible by aerosol, failure to use sealed buckets (as specified in the risk assessment), failure to wait for aerosol to settle before opening lid (as specified in the Code of Practice), involving other colleagues therefore getting them exposed.

- 8 A laboratory worker removed a plastic flask from a freezer (-80 degrees). The flask contained frozen liquid containing Newcastle Disease Virus. As part of a process to recover virus, the cells in the flask were subjected to a freeze-thaw cycle. In order to speed the thawing process, the flask was rinsed under a running tap for a short period of time, set on the side of the sink for a few minutes, and then transferred to a microbiological safety cabinet (MSC). Shortly afterwards, it was discovered that only a small quantity of liquid was left in the flask. A hole was found in one of the corners of the flask. There was no evidence of liquid within the MSC. The standard operating procedure requires all pathogen cultures to be handled in two layers of containment when outside of the MSC.

Issues: Not using two layers of containment when outside of the MSC.

- 9 Whilst using a syringe filter to purify a culture of blue tongue virus, the laboratory worker exerted too great a force such that the filter blocked and the resulting back-pressure caused discharge of liquid beyond the confines of the MSC onto the floor of the laboratory. The laboratory worker mopped up the spillage and discarded the contaminated waste through the autoclave. The emergency procedures specified evacuation of the laboratory, informing his supervisor, who would have instructed the laboratory to be fumigated.

Issues: Syringe skills, not informing supervisor and evacuating laboratory.

- 10 A laboratory worker was cataloguing stocks of frozen vials containing rift valley fever virus in the CL3 laboratory. However, given the number of vials involved, the procedure was undertaken on the floor of the laboratory. Whilst examining one of the trays, the laboratory worker observed that several vials were broken and the contents had thawed on the floor of the laboratory. The laboratory Code of Practice specifies that all virus-handling procedures should be undertaken within an MSC.

Issues: Virus handling on the floor instead of within MSC.

7.6 ANNEX 6 – TOPIC GUIDE FOR USE IN THE FOCUS GROUPS

For researcher information – aims of the research (from proposal)

- *Identify the key human factors that influence the behaviour of laboratory workers at CL3 laboratories (specifically relating to cutting corners with respect to Standard Operating Procedures)*
- *Determine what can be done to reduce such behaviours.*

For researcher information – human factors themes (from RIDDOR review)

- *Job factors – training, monitoring.*
- *Individual factors – competence, risk perception.*
- *Organisation factors – communication, overstretched resources, poor safety culture.*

1. Questions to follow each vignette

Aim: To establish briefly the validity of the vignette.

- Can you relate to this scenario?
- Have I missed anything in this scenario?
- Why might this scenario happen?
- What could be done to reduce the likelihood of this type of scenario happening again?

2. Perceptions of risks

Aim: To identify lab workers' perceptions of the major risks at CL3.

- What do you think is the main risk when working with pathogens?
- What other risks do you think there are?

3. Perceptions of risk controls and safety management systems

Aim: To find out about the perceived efficiency of the control systems.

- What do you think would be the main reasons for lab workers to cut corners in CL3 work?
- Are there any particular situations in which people are more likely to cut corners in CL3 work?
- Are there any controls in place to avoid this?
- What are the more likely near misses in CL3 work?
- How are these reported and communicated?

4. Standard Operating Procedures (SOPs)

Aim: To establish perceptions on the usefulness and practicality of SOPs.

- How useful are the SOPs?
- Are SOPs up-to-date?
- Do SOPs contain the right level of detail?
- How practical are the SOPs?
- Do SOPs reflect how the task is performed?
- Are SOPs easy to use?
- Were you / your colleagues / TU representatives involved in developing the SOPs?

5. Human factors (non)-compliance with SOPs

Aim: To identify the human factors that lead to (non)-compliance with SOPs

- Is there anything that makes it difficult to follow SOPs?
(Probe: Job, Individual, Organisation factors)
- What could make it easier to follow SOPs?
(Probe: Job, Individual, Organisation factors)

6. Organisational learning and communication

Aim: To find out about individuals and organisations learning from experience.

- Is information from incidents and near misses gathered and analysed? How?
- Has the organisation made any changes following analysis of incidents and near misses?
What / How?
- Is information from analysis of incidents and near misses communicated to lab workers? How?
- Are these 'lessons learned' communicated to other organisations? How?
- Does this organisation receive 'lessons learned' information from other organisations?
How?

Human factors that lead to non-compliance with standard operating procedures

The Advisory Committee on Dangerous Pathogens categorises biological agents into Hazard Groups 1 (negligible hazard) to 4 (highly pathogenic) according to their potential to cause human infection, the likelihood that infection could spread in the community, and the availability of effective treatment. For laboratories where biological agents are handled, controls proportionate to these hazards are specified and laboratories are designated Containment Levels 1 to 4. These controls are a combination of structural requirements and working procedures. To protect the health of workers, especially with more pathogenic biological agents, it is important that these controls are applied stringently.

This report presents results from the Health and Safety Laboratory's study on the Human Factors that lead to non-compliance with Standard Operating Procedures (SOPs) in Containment Level 3 (CL3) laboratories. The research stemmed from recognition by HSE intervention managers that RIDDOR investigations in CL3 laboratories were often identifying non-compliance with SOPs and organisational learning deficiencies as contributory factors.

Understanding the human factors influences on CL3 laboratory workers that could lead to non-compliance with SOPs will inform HSE HID-SI intervention strategy, thereby helping to drive up safety performance standards in the CL3 laboratory sector.

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