Witness Name: Richard Gregory Brunt
Statement No.: 2
Exhibits: RGB/66 – RGB/209
Dated: 17 November 2023

UK COVID-19 INQUIRY

WITNESS STATEMENT OF RICHARD GREGORY BRUNT

I, Richard Gregory Brunt, will say as follows: -

Introduction

1. I am Richard Brunt and my position at The Health and Safety Executive ["HSE"] is Director of Engagement and Policy Division. I am authorised to make this statement on behalf of HSE. This statement is provided to the UK Covid-19 Inquiry to explain HSE activity during the pandemic as it related to, and impacted upon, the healthcare sector.

HSE's General Role, Function and Responsibilities

2. The Health and Safety Executive ["HSE"] is a UK Government agency, sponsored by the Department of Work and Pensions ["DWP"]. It is Britain's national regulator for workplace health and safety and operates across England, Scotland and Wales and its mission is protecting people and places.

3. HSE was established by the Health and Safety at Work etc Act 1974 ["HSWA"] to prevent work-related death, injury and ill-health through enforcing workplace health and safety in certain workplaces, mainly through HSWA (and relevant Regulations). HSE is a Category 2 Responder under the Civil Contingencies Act 2004.

4. HSE's general duty is set out in section 11(1) of HSWA, namely to "do such things and make such arrangements as it considers appropriate for the general purposes of this Part". HSE is provided with a variety of powers, including enforcement powers, to assist it in achieving that duty.

5. Responsibility for enforcing HSWA is divided between the HSE and other regulators – principally, and most importantly for the purposes of the Covid-19 Inquiry, by the Health and Safety (Enforcing Authority) Regulations 1998 ("the EA Regulations"). Under the EA Regulations, Local Authorities are the enforcing authority for certain premises, dependent upon the main activity carried out there. This includes, for example, office activities, residential care homes, accommodation provision such as hotels, the sale of goods (shops), church worship and religious activities, and beauty treatments. Conversely, HSE is the enforcing authority for HSWA purposes over a wide range of workplaces, including some of those in the health and social care sector, such as hospitals and nursing homes.

6. HSE works collaboratively with other regulators, agencies and Government departments to ensure the most appropriate organisation takes responsibility when a health and safety issue arises and there are potential overlaps in regulatory responsibility. In order to facilitate this, HSE has entered into a number of agency agreements and Memoranda of Understanding ["MoU"] with other regulators. These agreements are all published on the HSE website.

7. HSE carries out its regulatory function to prevent workplace death, injury or ill-health by using a variety of methods to influence change and assist dutyholders manage risks in the workplace, including:

   a. promoting safer working environments;

   b. developing policies, strategies and procedures for health and safety; ensuring compliance with all health and safety laws through targeted inspections and investigation;

   c. enforcement action;

   d. providing advice, guidance and information,

   e. operating permissioning and licensing activities in major hazard industries and raising awareness in the workplace by influencing and engagement.

HSE's Regulatory Role in relation to Healthcare Settings

8. HSE is not the primary regulator for healthcare in Great Britain. Healthcare is a devolved matter and there are different regulators in England, Scotland and Wales. In England, the Care Quality Commission ["CQC"] is the independent regulator for healthcare. In Scotland, Healthcare Improvement Scotland ["HIS"] is the national improvement agency for healthcare services fulfilling a range of regulatory functions including scrutinizing the quality and safety of healthcare. The Healthcare Inspectorate

Wales ["HIW"] is responsible for reviewing and inspecting NHS and independent healthcare organisations in Wales. HSE's role in relation to regulating healthcare systems and how it works with other Regulators is explained in "Who regulates health and social care" which is available on HSE website (exhibit RGB/66 - INQ000269842).

9. HSE has an MOU with the CQC *"Memorandum of Understanding between the Care Quality Commission (CQC) and the Health and Safety Executive (HSE)"* (*December 2017)* exhibited at RGB/3 - INQ000101585[1], HIS "*Memorandum of Understanding between Health and Safety Executive and Healthcare Improvement Scotland" (April 2019)* exhibited at RGB/67 - INQ000269835 and HIW "*Memorandum of Understand (MOU) Healthcare Inspectorate Wales (HIW) and Health and Safety Executive (HSE)"* exhibited at RGB/68(a) - INQ000269848 (version in place since April 2021) and RGB/68(b) - INQ000269861 (version in place from March 2020 to April 2021). The MOUs set out the working arrangements between HSE and the other Regulators, promoting effective working and information sharing on relevant matters.

10. In general, HSE does not investigate or prosecute matters of clinical judgement and practice, and the training, systems of work etc to deliver those of doctors or matters relating to the level of provision or quality of care (exhibit RGB/69 - INQ000269841). In England, the CQC is the more appropriate regulator to investigate matters of this nature. It also deals with major non-clinical risks to patients, for example trips, falls, scalding, electrical safety etc and has a wide range of enforcement powers that can be used if healthcare services are not meeting fundamental standards.

11. Similarly in Wales, HSE does not, in general, investigate or prosecute matters of clinical judgement or matters relating to the level of or quality of care. However in Wales, HSE deals with major non-clinical risks to patients (examples of which are outlined in para 10 above) (exhibit RGB/68(a) - INQ INQ000269848 at paras. 19 – 20).

12. In Scotland, HSE will not generally investigate or act in relation to service users where other Regulators have patient / service user safety within their remit. The MOU with HIS sets out that HSE may investigate where there is evidence of systemic health and safety management failings or when established standards have not been followed, except those that may apply to clinical treatment or patient care that fall within the vires of bodies such as the General Medical Council or Nursing and Midwifery Council (exhibit ref RGB/67 - INQ000269835 at para. 17).

[1] Exhibited to Witness Statement of RGB No 1 (submitted in relation to Module 1).

13. Dependent on the nature of an incident, it may be reportable to HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 ["RIDDOR"]. If incidents are reported to HSE, it will follow its published incident selection criteria (exhibit RGB/70 - INQ000130556) and HSE's Policy on s3 HSWA 1974 (exhibit RGB/71 - INQ000269833) when deciding whether to investigate, or in England, forward reports to the CQC. HSE also has guidance that assists Operations staff to make these decisions (exhibits RGB/72 - INQ000269881, RGB 73 - INQ000269806 and RGB/74 - INQ000269859).

Summary of HSE's Role during the Covid-19 Pandemic

14. Throughout the Covid-19 pandemic, HSE retained its role as the enforcement body for health and safety in the workplace under HSWA, but was not an enforcing body for the Coronavirus Regulations. This limited the scope of HSE's responsibilities during the pandemic. HSE was concerned with ensuring employers took reasonably practicable measures, such as following Covid Secure guidelines, to mitigate the additional risks to health and safety arising from work activities during the pandemic. HSE did not regulate workplaces to ensure specific compliance with Covid-19 Regulations. That enforcing role lay primarily with the police and local authorities.

15. HSE's role during the pandemic included the following:

    a. Advising on PPE ["Personal Protective Equipment"] and RPE ["Respiratory Protective Equipment"];

    b. Granting easements to allow PPE and RPE that provided appropriate protection but had not undergone full conformity assessment to be used in health care settings for Covid-19 purposes;

    c. Being the approval body for biocides. In response to the increased demand for hand sanitisers and significant pressures played on supply chains, HSE took two main actions:

        i. Short term derogations – Article 55(1) of the Biocidal Products Regulation (EU) No 528/2012 ["BPR"] enables HSE in cases of danger to public health, animal health or the environment which cannot be contained by other means, to provide short term derogations from the requirements for product authorisation. During the pandemic, HSE provided short derogations enabling the rapid supply of hand sanitisers meeting the World Health Organisation ["WHO"] specified product formulation based on propan-2-ol via a simple notification system. The notification system

required companies to submit minimal information that would allow HSE to maintain sufficient oversight of the safety and efficacy of hand-sanitisers supplied under the derogation;

ii. Supply chain requirements – In accordance with Article 95 of BPR biocidal products cannot be sold on the EU market unless the substance supplier or product supplier is a listed company for the relevant product type. The European Chemicals Agency ["ECHA"] maintains the list of suppliers in respect of BPR. Following the UK's exit from the EU, HSE maintains its own independent list of biocidal active substances suppliers in respect of GB BPR. During the pandemic, HSE adopted a pragmatic and proportionate approach to the regulatory requirements under Article 95 of BPR. In cases where HSE inspectors encountered hand sanitisers that were not strictly in line with normal Article 95 supply chain requirements, the focus was to ensure that those products were effective in combating coronavirus and did not pose an unacceptable risk to people or the environment.

HSE explained the steps that it was taking in relation to the manufacture and supply of biocidal hand sanitizer products on its website (exhibit RGB/75 - INQ000269864).

d. Supporting Public Health England and Scotland and Wales in the review of guidance for workers, including general infection prevention and control, and secondary care;

e. Providing advice and guidance to assist dutyholders to assess and manage Covid-19 related risks arising from work activities and maintain safe workplaces;

f. Providing advice and signposting workers and members of the public to relevant information and guidance (for example, through the operation of the Covid Concerns and Advice Team ["CAT"]);

g. Providing advice to Government departments, other agencies and regulators in relation to the management of Covid-19 related risks arising from work activities, including reviewing guidance on returning to work;

h. Working with Government departments and the devolved nations on social distancing, for example and establishing a social distancing virtual team which dealt with a large number of queries relating to Covid-19; and

i. Undertaking 'spot checks' and 'spot inspections' of business to ensure they were "Covid Secure," and using its existing enforcement powers where necessary.

15(a) & (b) and (d) - (i) are explained in more detail in sections below.

16. As part of its advisory work, HSE developed guidance on PPE use for healthcare. HSE also conducted research on decontamination of and reuse of PPE; and conducted work on understanding Covid-19 transmission.

17. HSE was involved in a number of discussions within Government and with its advisors in relation to non-pharmaceutical interventions. HSE's role was to provide evidence, as opposed to advising on what policy decisions should be made in relation to the national lockdowns, local and regional restrictions, circuit breakers and working from home.

18. HSE had involvement in the discussions on the use of face coverings, although its advisory role in relation to these was focussed on the distinction between face coverings, RPE and PPE, and the provision of advice to businesses and workers.

19. HSE did not have any role in relation to:

a. The impact of Covid-19 on people's experience of healthcare.

b. Core decision-making and leadership within healthcare systems during the pandemic. HSE's role was not as decision maker nor was HSE advising the decision makers on what decisions they should take. HSE's focus was on considering and presenting scientific evidence to decision makers via SAGE and ensuring those decision makers understood what evidence was showing so that policy decisions could be informed by it.

c. 111, 999 and ambulance services, GP surgeries and hospitals and cross-sectional co-operation between services.

d. Healthcare provision and treatment for patients with Covid-19, healthcare systems' response to clinical trials and research during the pandemic. The allocation of staff and resources. The impact on those requiring care for reasons other than Covid-19. Quality of treatment for Covid-19 and non-Covid-19 patients, delays in treatment, waiting lists and people not seeking of receiving treatment. Palliative care. The discharge of patients from hospital.

e. Decision-making about the nature of healthcare to be provided for patients with Covid-19, its escalation and the provision of cardiopulmonary resuscitation,

including the use of do not attempt cardiopulmonary resuscitation ["DNACPR"] instructions.

f. Communication with patients with Covid-19 and their loved ones about patients' condition and treatment, including discussions about DNACPR instructions.

g. Characterisation and identification of Post-Covid Condition (including the condition referred to as Long Covid) and its diagnosis and treatment.

h. Issues concerning availability of healthcare staff, the NHS surcharge for non-UK healthcare staff and the decision to remove the surcharge.

i. Critical care capacity or the establishment and use of Nightingale hospitals (save for some input into advising on the storage of its oxygen supplies) or use of private hospitals.

j. The rules imposed for visiting those in hospital.

20. HSE provided advice and guidance to dutyholders and workers in relation to the approach to shielding and application in the work environment. HSE was not involved in discussion on the wider public health issue or setting the approach to shielding.

21. HSE played a limited role in issues concerning staffing levels, however those issues were linked to staff safety, health and/or the working time regulations and appear to fall outside of the Inquiry's Module scope.

22. HSE had a partial role in relation to the impact of the pandemic on doctors, nurses and other healthcare staff, including on those in training and specific group of healthcare workers (for example by reference to ethnic background) through proactive inspections work looking at hospitals in the NHS, spot checks, reactive investigations and concerns. The impact on healthcare staff may well include matters pertaining to the levels to which staff were protected from the transmission of Covid-19 and the safety of the environment in which they worked.

23. HSE captured data as part of the COVID-OUT (Covid-19 Outbreak Investigation to Understand Transmission) study. The National Core Study was led by HSE's Chief Scientific Adviser. It undertook epidemiological studies which looked at the risk of developing Covid-19 in healthcare workers as well as other occupational groups (exhibit RGB/76a – INQ000269851, 76b - INQ000269865and 76c - INQ000269856).

24. HSE did play a role in preventing the spread of Covid-19 within healthcare settings, including infection prevention and control, the adequacy of PPE and rules about visiting

those in hospital. Any spread amongst patients would be an area for those bodies with oversight of the delivery of clinical and health services, namely DHSC and CQC.

25. HSE has a regulatory role in relation to the protection of those at work from any infectious agents. Employers must take proportionate measures to protect those deliberately working with the virus, for example, someone who undertakes work in a pathology laboratory on samples containing Covid-19, or if they are incidentally exposed to the virus, for example, working in environments where people are known to have Covid-19, such as a hospital ward containing Covid-19 patients. During the pandemic HSE also expected that under general health and safety duties, all workplaces should take proportionate measures to protect workers from the risks of Covid-19 in the workplace.

26. HSE was involved in the development of the Public Health England ["PHE"] / UK Health Security Agency ["UKHSA"] Infection Prevention Control ["IPC"] Guidance for health and social care providers and the UKHSA/DHSC guidance for health care professionals. HSE's input was aimed to promote the clarity and update of such guidance with the overarching benchmarks being set by public health leads and advice from SAGE.

27. Insofar as the adequacy of PPE, HSE is the market surveillance authority for PPE for use at work. This means that HSE is responsible for monitoring the safety and conformity of PPE against product safety law. HSE is also the regulator for the supply aspects of PPE for use at work (manufacturers, importers and distributors). HSE's role was therefore limited to agreeing to regulatory easements and technical specification for Covid-19 PPE, to ensure that the RPE and PPE met suitable design performance standards and such equipment was suitably worn and face fit tested.

28. HSE played a limited role in the recording and reporting of deaths caused by the Covid-19, in terms of the numbers, classification and recording of deaths, including the impact on specific groups of healthcare workers, for example by reference to ethnic background and geographical location. The Office for National Statistics would be the primary source of this information. HSE received RIDDOR reports in relation to Covid-19 related worker deaths. HSE provided guidance for the reporting of Covid-19 under the RIDDOR. Data relating to age, gender and the type of worker involved in an incident (ie employed, self employed, etc) is captured through RIDDOR reports received by HSE. However RIDDOR reporting does not directly capture specific groups of workers, for example, worker ethnicity. It exists to address general work-related

incidents and risks. HSE collected Covid-19 specific RIDDOR reporting management information from 10 April 2020. This is detailed further in paras 158 – 164 below.

29. HSE's Chief Scientific Adviser was a SAGE participant and co-Chaired the SAGE EGM subgroup of SAGE. The work of the subgroup included a paper looking at masks for healthcare workers, on which HSE's Chief Scientific Adviser was a co-author (exhibit RGB/77 - **INQ000075022**).

HSE's Statutory Framework in the Healthcare Setting

30. In order to better understand the role of the HSE in healthcare, it is important to start with the HSE's underlying legal duties and purpose. The key legislation is set out below.

The Health and Safety at Work Act 1974

31. Under s2 HSWA there is a general duty for every employer to ensure, so far is reasonably practicable, the health, safety and welfare at work of all its employees. The general duty extends to those employers working within the healthcare setting to look after the health, safety and welfare of its healthcare staff.

32. There is also a general duty on every employer to conduct its undertaking in such a way as to ensure, so far as is reasonably practicable, that those not in an employer's employment, are not exposed to risks to their health and safety (s3 HSWA). The general duty extends to those who are not healthcare staff employees but who nevertheless are involved with the provision of healthcare services, for example, patients and contractors.

33. Employers within the healthcare setting must comply with s9 HSWA which provides that they shall not levy or permit to be levied on any employee, any charge in respect of anything done or provided in pursuance of a specific requirement. In the context of healthcare, the specific requirement was to provide PPE and therefore no charge could be made to a worker for the provision of PPE which was used only at work.

The Personal Protective Equipment at Work Regulations 1992 ["PPEW"]

34. The PPEW Regulations are the main set of Regulations relating to the use of PPE. PPE provided to protect against hazardous substances are dealt with under separate Regulations.

35. Every employer shall ensure that suitable PPE is provided to its employees who may be exposed to a risk to their health or safety while at work, except where and to the extent that such risk has been adequately controlled by other means which are equally

or more effective. In the context of healthcare, employers should provide appropriate PPE and training in its usage to their employees wherever there is a risk to health and safety. In order to meet with the requirement to provide PPE for their employees, it must be readily available for them, or at the very least employees must have clear instructions on where they can obtain it.

The Personal Protective Equipment (Enforcement) Regulations 2018 ["PPE(E)"]

36. Before PPE can be placed on the market it must comply with product supply legislation. The European Union ["EU"] Recommendation (2020/403) was made to Regulation EU 2016/425 for implementation in the UK by the PPE(E) Regulations, which sets out the essential health and safety requirements that must be met before PPE products can be placed on the GB market. The PPE(E) Regulations provide a system for the enforcement of the 2016/425 Regulation and is enforced by HSE for PPE manufactured and designed for its intended use in the workplace in Great Britain. There is a requirement on manufacturers, import and distributors of all PPE to ensure its products are Conformité Européenne ["CE"] marked, approved and safe.

37. In the context of RPE and PPE the presence of a CE marking shows that the manufacturer of the product had checked it against the relevant essential health and safety requirements of the 201/425 Regulation and it is deemed to be compliant.

38. Respirators that are CE marked are deemed to meet EU essential health and safety requirements and comply with the PPE Regulation EU 2016/425 and are regarded as safe and suitable for use in medical settings. Filtering Face Piece ["FFP"] respirators are subject to the requirements of the PPE(E) Regulations for supply, and the COSHH Regulations ["Control of Substances Hazardous to Health Regulations 2002"] for use. These regulations set out the health and safety requirements of RPE that users must use suitable products and this use mut be in line with the manufacturer's instructions.

The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (England) Regulations 2020

39. Before these regulations, easements could be agreed by HSE using the EU Commission Recommendation 2020/403 of 13/03/2020.

40. The Regulations were made under section 45C of the Public Health (Control of Disease) Act 1984 which implemented temporary arrangements to facilitate the production and supply of PPE necessary for use during Covid-19 only. The arrangements were similar to the proposals in the EU Commission's Recommendation 2020/403 of 13/03/2020 on conformity assessment and market surveillance procedure

within the context of Covid-19. However, the arrangements in these Regulations were specific to England and could only be relied on if HSE had authorised it by a specified date.

41. Regulation 2 permitted PPE to be placed on the market while undergoing conformity assessment procedures, but before these had been completed and before any conformity marking affixed.

42. Regulation 3 permitted PPE to be procured without undergoing conformity assessment procedures and without any conformity marking being affixed but this PPE was only made available to healthcare workers and other frontline workers. In both cases, the PPE must have been assessed by the HSE and found to be compliant with the relevant elements of the essential health and safety requirements in Annex 2 of Regulation EU 2016/425. Once the conditions were met, the obligations in Regulation 2016/425 were treated as satisfied for the purposes of the PPE(E) Regulations.

43. In respect of PPE for healthcare workers and other frontline workers, the market surveillance authority would not require the non-compliance to be brought to an end. This was solely in cases where the conformity assessment procedure has not been completed and the conformity mark had not been affixed due to reliance on regulation 2 or 3 of these Regulations.

The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020 / The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Scotland) Regulations 2020

44. These Regulations came into force on 31 December 2020 and applied to Wales and Scotland respectively. They set out national legislation and temporary regulatory arrangements to facilitate the production and supply of PPE during the Covid-19 pandemic. Regulation 2 permitted PPE to be made available in the market before conformity assessment had been completed and before conformity marking had been affixed, provided the PPE had been submitted for conformity assessment and after submission, HSE had assessed the PPE as being compliant with the EHSR relevant to the assessment process and provided notification of this.

The Workplace (Health, Safety and Welfare) Regulations 1992 ["WHSW"]

45. The WHSW Regulations require that every employer shall ensure that every workplace complies with them and associated Approved Code of Practice ["ACOPs"] and guidance. In the context of healthcare settings, this encompasses all welfare facilities,

to include welfare, rest facilities, workplace transport, temperature and general ventilation to ensure the working environment is healthy and safe for all concerned.

The Provision and Use of Work Equipment Regulations 1998 ["PUWER"]

46. The PUWER Regulations place duties on people and companies who own, operate or have control over work equipment. They also place responsibility on businesses and organisations whose employees use work equipment to ensure all equipment is safe and maintained. Work equipment incudes any machinery, appliance, apparatus, tool or installation for use at work. The use of work equipment is widely defined and means "any activity involving work equipment and incudes starting, stopping, programming, setting, transporting, repairing, modifying, maintaining, servicing and cleaning".

The Management of Health and Safety at Work Regulations 1999 ["MHSW"]

47. The MHSW Regulations require every employer to provide competent advice and make a suitable and sufficient assessment of the risks to health and safety of its employees and persons not within their employment to which they are exposed. During the relevant period those in the healthcare setting were required to ensure Covid-19 was covered in any risk assessment to ensure adequate protection from those that come into contact with the virus due to their work activity.

The Control of Substances Hazardous to Health Regulations 2002 ["COSHH"]

48. The COSHH Regulations set out the requirements in relation to the use of PPE when protecting against substances hazardous to health, where other control measures, such as engineering controls, ventilation or prevention at source cannot be achieved. The objective of COSHH is to prevent, or to adequately control, exposure to substances hazardous to health in the workplace, that cause ill health. The Regulations are supplemented by an ACOP.

49. The regulations listed below are of particular relevance:

    a. Regulation 6 – Assessment of the risk to health created by work involving substances hazardous to health

       All employers must make a suitable and sufficient risk assessment of any risk created by work which is liable to expose its employees to any substance hazardous to health before that work can be carried out, and take appropriate steps to meet the requirements of the Regulations.

    b. Regulation 7 – Prevention or control of exposure to substances hazardous to health

All employers must ensure the exposure to substances hazardous to health is prevented or adequately controlled. The application of protection measures must be appropriate to the activity and consistent with the risk assessment. A hierarchy of priority exists at sub-paragraph 3 with the provision of suitable PPE at the bottom of the hierarchy when an adequate control of the exposure cannot be achieved by other means.

c. Regulation 9 – Maintenance, examination and testing of control measures

All employers who provide control measures to meet the requirements of Regulation 7 shall ensure that, where relevant, it is maintained in an efficient state, in efficient working order, in good repair and in clean condition.

Where RPE is provided, all employers must ensure a thorough examination, and if required, testing of that equipment is carried out at suitable intervals.

d. Regulation 11 – Health Surveillance

Employees must be placed under suitable health surveillance for the protection of their health if they are liable to be exposed to a substance hazardous to health.

50. Under COSHH all employers within healthcare settings must protect workers who come into contact with Covid-19 directly through their work, for example in researching the virus in laboratories or due to their work activity, such as health and social care workers caring for infectious patients. In these cases, employers must still do a risk assessment and implement control measures. Employers are responsible for providing, replacing and paying for PPE for use by its workers.

51. Paragraph 18 of the ACOP states that COSHH does not cover situations where one employee catches a respiratory infection from another or a member of the public has infected an employee with a respiratory infection through general safety. This is because Regulation 2(2) specifies that COSHH only applies in those circumstances where risks of exposure are work related, and not those where they have no direct connection with the work being done.

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 ["RIDDOR"]

52. RIDDOR reporting requires employers, self-employed and those in control of premises to report specified workplace incidents. In the context of healthcare workers working in a healthcare setting, those incidents include cases of disease or deaths arising from

Covid-19 only apply when an employee has been infected with the virus through deliberately working with the virus, such as in a laboratory or being incidentally exposed to the virus. Incidental exposure can occur within the healthcare setting where people are known to have Covid-19.

53. A report under RIDDOR should only be made if an accident or incident at work has, or could have, led to the release of the virus (this must be reported as a dangerous occurrence); where a worker has been diagnosed as having Covid-19 attributed to an occupational exposure to the virus through deliberately working with it or being incidentally exposed to it (this must be reported as a case of disease due to exposure to a biological agent); where a worker dies as a result of occupational exposure to the virus through either deliberately working with it or being incidentally exposed to it (this must be reported as a work-related death due to exposure to a biological agent).

Other Relevant Statutory Provisions

Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012

54. The Regulation was applicable in the UK until 31/12/2020 (remains applicable in NI now), and the retained version of EU BPR (GB BPR – applicable in GB from 1 January 2021) prior to the end of the Implementation Period to ensure it was operable in GB.

55. The Regulation concerns the placing on the market and use of biocidal products. Biocidal products are used to protect humans, animals, the environment, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. Biocidal products will typically be a mixture of chemicals including an "active substance" but can also be 100% active substance (with no other components), articles that are impregnated with an active substance (for example disinfectant wipes) or bacteria, viruses or other micro-organisms. The regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans, animals and the environment. Their applicability in the healthcare setting concerns the use of disinfectant product types, including those applied to human skin and surface/equipment etc. for the protection of human health.

56. All new active biocidal products intended to be made available in Great Britain required authorisation under these Regulations.

57. The Regulation operates a two-stage process: first the active substances must be assessed for their efficacy and risks to humans, animals and the environment; once

an active substance is approved, biocidal products containing it must then also be assessed and authorised. Whilst an active substance is being assessed, biocidal products containing it may be able to be made available on the market and used without an authorisation under the Regulation.

58. All biocidal products intended to be made available in the UK were required to comply with these Regulations.

Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 and The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020

59. Outline the same purpose as above, but from a GB perspective.

The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

60. Sharp instruments, for example, needles, scalpels and other medical instruments are necessary for carrying out healthcare work and pose a well-known risk in the health care sector and could cause injury. The Regulations only apply to employers, contractors and workers in healthcare settings. NHS Trusts/Boards, independent healthcare businesses and other employers whose main activity is the management, organisation and provision of healthcare are subject to the Regulations.

The Manual Handling Operations Regulations 1992

61. All employers must protect their workers from the risk of injury from hazardous manual handling in the workplace. Manual handling means transporting or supporting a load by hand or bodily force and includes lifting, putting down, pushing, pulling, carrying or moving loads. A load can be an object or a person, i.e. handling patients.

The Ionising Radiations Regulations 2017

62. Radiation types used in medical research can cause harmful exposure to risks which must be effectively controlled. Radiation is generally classed as ionising, for example, x-rays and are typically used in medical exposures or non-ionising, for example, radiofrequency. Employers should reduce exposure as far as possible, for example, by ensuring appropriate shielding and PPE.

The Supply of Machinery (Safety) Regulations 2008

63. All machinery and other products in scope must be designed and constructed to be safe, meeting all of the relevant essential health and safety requirements listed in the Regulations. They must have a technical file compiled, have appropriate conformity marking, be supplied with comprehensive instructions in English and be accompanied by a declaration of conformity before they are placed on the market or put into service for the first time. The Regulations apply to responsible persons including manufacturers.

The Lifting Operations and Lifting Equipment Regulations 1998

64. The requirements imposed by these Regulations on an employer in respect of lifting equipment shall apply in relation to lifting equipment provided for use or used by an employee of his at work. In the context of the healthcare settings, this requires an examination and maintenance of lifting equipment, for example passenger lifts and patient hoists. Any lifting equipment for lifting persons must prevent a person using it to be crushed, trapped or struck or from falling from its carrier. Where the equipment is put into service for the first time, it must be thoroughly examined for any defects unless the equipment has been used before or is subject to an EC declaration of conformity of not more than 12 months is in place.

The Pressure Systems Safety Regulations 2000

65. The duties imposed by the Regulations relate to pressure systems for use at work and the risk to health and safety. The aim of the Regulations is to prevent serious injury from the hazard of stored energy as a result of the failure of a pressure system or one of its component parts. In particular, industrial steam boilers used in hospital heating systems and compressed gases.

The Dangerous Substances and Explosive Atmospheres Regulations 2002

66. The Regulations require employers to control the risks to safety from fire, explosions and substances corrosive to metals. In the context of the healthcare sector, it covers the assessment and use of solvents, paints, varnishes and flammable gases.

The Confined Spaces Regulations 1997

67. The Regulations contain duties on employers to avoid entry to confined spaces, for example, by doing work from the outside. If entry to a confined space is unavoidable there must be a safe system of work followed and adequate emergency arrangements

put in place before work starts. In the context of healthcare settings, some service ducts in hospitals where gases or water are piped through are confined spaces.

The Health and Safety (First Aid) Regulations 1981

68. The Regulations set out the duty on employer to provide immediate first aid when an employee is injured or taken ill at work, to include availability of trained first aiders, contents of a first aid box and whether a first aid room is needed.

The Safety Representative and Safety Committees Regulations 1977 and The Health and Safety (Consultation with Employees) Regulations 1996

69. The Regulations set out an employer's duty to consult members of its workforce about health and safety whether employees are members of recognised trade unions or not. The Regulations are designed to enable employers and employees to work together to develop, maintain and promote measures that ensure health and safety a work; and check the effectiveness of those measures.

The Working Time Regulations 1998

70. The Regulations implement the European Working Time Directive and incorporated the work of junior doctors from 1 August 2004. The Regulations set maximum weekly working time limits of not more than 48 hours for each seven days on average, night work limits of not more than eight hours for each 24 hours and provide free health assessments for night workers prior to their assignment, all of which are enforced by HSE. Some exemptions for hospitals apply, for example, the activities of doctors in training or where 24-hour staffing is required, an employee may have to work more than the 48 hour average.

Explosives Regulations 2014

71. The Regulations apply within Great Britain to anyone who has duties under the security provisions of the Regulations, particularly employers, private individuals and other people manufacturing explosives, storing larger quantities of explosives or storing explosives that present higher hazards. The Regulations provide overarching guidance on how the security provision should be met. Insofar as how they apply to healthcare settings, explosives used as medicine, for example a solution of the explosive substance nitro-glycerine found in alcohol and is intended for use as an active pharmaceutical ingredient falls under the Regulations, but these are specifically exempted from the requirement to hold an explosives certificate within the restrictions set out in Schedule 2, Part 2.

The Carriage of Dangerous Goods and use of Transportable Pressure Equipment Regulations 2009

72. The Regulations sets out the standards that transportable gas cylinder must meet. They implement the 2017 European Agreement concerning the international carriage of dangerous goods by road ("ADR"). In the context of healthcare settings, some medical staff are required to carry items such as compressed oxygen or nitrous oxide mixtures in their vehicles. The cylinder is likely to form part of a ready to use set which includes a regulator, hose and mask. As such it is regarded as exempt from the ADR by virtue of paragraph 1.1.3.1.(b) providing measures have been taken to prevent any leakage of contents in normal conditions of carriage. Providing the equipment is carried in purpose made bags or cases, this would be regarded as satisfactory.

Control of Electromagnetic Fields at Work Regulations 2016

73. The CEMFAW Regulations require a dutyholder to assess the levels of electromagnetic fields ["EMF"] and ensure that exposure is below a set of exposure limit values ["ELVs"]. The Regulations allow sensory effect ELVs to be exceeded when certain safety conditions are met. In the context of healthcare settings, exemptions also apply during the development, testing, installation, maintenance, use of and research related to MRI equipment for patients provided exposure is at the lowest level reasonably practicable and employees are protected against health effects and safety risks arising from their exposure.

HSE Powers, Enforcement Management Model & Enforcement Policy Statement

74. HSE uses a wide variety of enforcement powers to encourage and assist dutyholders to manage health and safety risks in a proportionate, targeted, consistent, transparent and accountable way. HSE's emphasis is on prevention but where appropriate, enforcement action will be taken to ensure dutyholders deal with serious risks so that they prevent harm; comply with HSE takes enforcement action in line with HSE's Enforcement Policy Statement ["EPS"][2] (RGB/78 - INQ000269858) and HSE's Enforcement Management Model ["EMM"] (exhibit RGB/79 - INQ000269863).

75. HSE has a range of enforcement powers to secure compliance with the law and to ensure a proportionate response to any breaches. HSE inspectors may provide written information and advice regarding breaches following an inspection or investigation. This can include a warning to a duty-holder, withdraw approvals, vary licence

[2] Made in accordance with the Legislative and Regulatory Reform Act 2006, the Regulators Code 2014 and Deregulation Act 2015.

conditions or exemptions, issue simple cautions (in England and Wales only). Where a material breach is identified and written advice is provided to the dutyholder detailing the action that they must take to remedy the failings, this is also referred to by HSE as a Notice of Contravention ["NOC"].[3]

76. Where appropriate, HSE may serve an improvement notice if an inspector is of the opinion that a person is contravening a relevant statutory provision in circumstances which make it likely the contravention will continue (s21 HSWA). Alternatively, under section 22 of HSWA, HSE may serve a prohibition notice if an inspector is of the opinion that an activity carried on by or under the control of a person involves a risk of serious personal injury.

77. HSE's fundamental approach to enforcement is enshrined in the EPS. The EPS sets out the principles that inspectors should apply when determining what enforcement action to take. The EPS sets out the purpose and principles of enforcement, the enforcement methods available and how those principles relate to investigations and prosecutions. Where a prosecution is being considered in England and Wales, HSE must apply the evidential stage and public interest factors within the Code for Crown Prosecutors. A prosecution cannot go ahead unless there is sufficient evidence to provide a realistic prospect of conviction and that a prosecution is in the public interest.

78. The EMM is a decision-making framework which guides HSE inspectors and Local Authorities in their exercise of discretion and professional judgement when making enforcement decisions that meet the principles in the EPS. It is a guide which provides inspectors with a framework for making consistent enforcement decisions; helps monitor the fairness and consistency of enforcement decisions; and assists less experienced inspectors in making enforcement decisions. It provides a straightforward linear model that cannot capture all of the nuances and complexities of discretionary decision making. It is not a procedure in its own right and should not fetter an inspector's discretion.

79. The EMM includes a determination of the risk gap and identification of the initial enforcement expectation. Determination of the risk gap requires a comparison to be made between the actual risk observed and the benchmark risk which would exist if all the controls required by law or guidance were in place. When considering the actual and benchmark risks, inspectors must assess both the likelihood of the harm

[3] NOCs derive from the Fee for Intervention framework rather than being a specific enforcement tool.

happening and the consequence and extent of that harm. Broad categories are used in the EMM to determine both actual and benchmark risks.

80. The EMM contains a flowchart of the EMM together with a summary of the associated steps (RGB/79 - INQ000269863 at page 7).

    a. Enforcement Priorities – takes all circumstances into account, establishes appropriate priorities for enforcement action in relation to risk presented, relevant permissioning issues and any non-risk based compliance.

    b. Risk of serious injury – assesses the actual risk of serious personal injury unless there has been non-risk based compliance.

    c. Determines the risk gap through establishing the risk, setting the benchmark and assessing the outcome.

    d. Identifies the initial enforcement expectation taking the authority of the relevant standards into account.

    e. Application of duty-holder factors

    f. Application of any strategic factors

    g. Enforcement conclusion

81. The EMM and its associated procedures aids review of the decision-making process and inspectors' enforcement actions to ensure the purpose and expectations of the EPS have been met. For the enforcement decision to be appropriate inspectors must also consider whether the action will deal with all the risks and secure sustained compliance.

HSE's Inspection Framework & Regime

Inspections conducted in Healthcare Settings prior to the Pandemic

82. Inspections are arranged on a case-by-case basis and differ by industry sector, but is generally through either prior contact between the inspector and the dutyholder or unannounced. Information is published for dutyholders on the inspections process (exhibit RGB/80 - INQ000269846). During an inspection, an inspector will speak to relevant employees, observe a sample of workplace activities, conditions and practices, assess relevant documents, check whether risk controls are effective (where necessary), identify any breaches of the law and consider appropriate enforcement action. An inspector will also engage with Trade Union appointed Safety Representatives and / or Worker Safety Representatives as part of inspection activity.

83. HSE undertakes several types of inspections that are carried out by HSE staff (which includes Principal Inspectors, Inspectors, Specialist Inspectors, Visiting Officers and Regulatory Compliance Officers).

84. Inspections are carried out for the purposes of targeting high risk sectors / activities, for benchmarking, following an incident and responding to local intelligence. Inspections are also undertaken in relation to sites that are subject to a permissioning regime.

85. When planning inspections, HSE target's those sectors and activities with the most serious risks and where the risks are least well-controlled. Similarly, HSE takes a risk-based approach when preparing intervention plans for sites subject to a permissioning regime (such as major hazards), using information and intelligence from a number of sources, including safety cases and reports, previous performance and intrinsic hazard.

86. Within healthcare settings, there are six different healthcare codes used by HSE when recorded inspection and investigations data to differentiate between types of healthcare provision as follows:

    a. 86101 - Hospital Activities

    b. 86102 - Medical Nursing Home

    c. 86210 - General Medical Practice

    d. 86220 - Specialist Medical Practice

    e. 86230 - Dental Practice

    f. 86900 - Other Human Health Activities

87. The number of inspections conducted by HSE in healthcare settings from 1 April 2017 has been extracted from HSE's database and is set out in exhibit RGB/81a - INQ000269777 and 81b - INQ000269850)[4]. The data is recorded as per financial year (1 April – 31 March). It can be summarised as follows:

    a. 2017/18 - 55 inspections

    b. 2018/19 – 161 inspections

    c. 2019/20 (to 29 February 2020) – 95 inspections

[4] This dataset is for financial years 2017/18 to 2019/20 so includes the details of 2 inspections conducted after 29 February 2020 which are included in data set out in paras 95 – 97 below.

88. Of the inspections conducting between 1 April 2017 and 29 February 2020, the number of inspections recorded for the various types of healthcare provision are as follows:

a. 86101 – Hospital Activities – 195

b. 86102 – Medical Nursing Homes – 7

c. 86210 – General Medical Practice – 5

d. 86220 – Specialist Medical Practice – 6

e. 86230 – Dental Practice – 12

f. 86900 – Other Human Activities - 86

89. With regard to regulatory outcomes during this period, these can be summarised as:

a. 166 inspections where dutyholders were found to be in compliance with health and safety law.

b. 107 inspections where dutyholders were found to be in breach of health and safety law resulting in the issuing of written advice.

c. 38 inspections where dutyholders were found to be in breach of health and safety law resulted in the issuing of enforcement notices.

90. Examples of failings that resulted in an enforcement notice being issued included the lack of a suitable and sufficient assessment of risk to employees and other people regarding exposure to ionising radiation; failure to ensure the use of safer sharps where reasonably practicable to do so, inadequate arrangements to ensure, so far as reasonably practicable, the health, safety and welfare of employees from the risks of manual handling and inadequate arrangements to protect employees and others from the risk of violence and aggression in the workplace.

Inspections conducted in Healthcare Settings during the Covid-19 Pandemic

91. HSE continued to undertake inspections during the relevant period but its approach to activity took account of the pressures that were being faced across healthcare settings. HSE recognised that it was important that its regulatory approach took a flexible and proportionate account of the risks and the challenges around the public health emergency (as detailed in HSE's Covid-19 Rolling Brief (11 May 2020), exhibited as RGB/82- INQ000269857) There was no formal suspension of inspections under the permissioning regime but operational decisions were taken to initially cut back on inspections as the sector was under strain, for example what are known as high risk sector ["HRS"] inspections looking at arrangements relating to the risk of violence and

aggression and a separate programme looking at muscular skeletal disorders were undertaken the following business year (2021/22). Where an in-person, face-to-face inspection was necessary, these were carried out following the relevant Covid-19 guidance.

92. Information regarding inspections during the relevant period has been extracted from HSE's database and is set out in exhibit RGB/83a - INQ000269810 and 83b-INQ000269776). It shows that HSE conducted 223 inspections in healthcare settings during the relevant period which can be summarised as follows:

    a. 2019/20 (from 1 March 2020) – 2 inspections

    b. 2020/21 – 81 inspections

    c. 2021/2022 – 134 inspections

    d. 2022/2023 (to 22 June 2022) – 6 inspections

93. 104 of the inspections conducted during the relevant period were specifically focused on Covid-19 work arrangements. Of the 119 inspections that were not specific to Covid-19, 38 of them included consideration of Covid-19 working arrangements ("spot inspections" referred to in more detail in para 190).

94. In terms of regulatory outcomes from these inspections, this can be summarised as follows:

    a. 146 inspections where dutyholders were found to be in compliance with health and safety law.

    b. 60 inspections where dutyholders were found to be in breach of health and safety law resulting in the issuing of written advice.

    c. 16 inspections where dutyholders were found to be in breach of health and safety law resulting in the issuing of enforcement notices.

    d. 1 inspection (in Scotland) was referred to the Procurator Fiscal to make the decision to prosecute in respect of an investigation into a fatality (non-Covid-19 related).

95. Looking specifically at regulatory outcomes across the 104 inspections that were focussed entirely on Covid-19 arrangements, the following results are recorded:

    a. 85 inspections where dutyholders were found to be in compliance with health and safety law.

b. 18 inspections where dutyholders were found to be in breach of health and safety law resulting in the issuing of written advice.

c. 1 inspection where the dutyholder was found to be in breach of health and safety legislation resulting in the issuing of an enforcement notice.

Inspections conducted in Hospitals during the Covid-19 Pandemic

96. Of the 223 inspections conducted in healthcare settings during the relevant period, 157 of these were undertaken in hospitals across England, Scotland and Wales. 90 inspections were programmed inspections (including spot inspections) and 67 inspections were focused specifically on the management of Covid-19.

97. During the inspections, 62 sites were found to be in breach of health and safety legislation that required an inspector to issue written advice (49 cases) or an enforcement notice (13 cases).

98. In relation to cases where written advice was provided by the inspector, the most common Covid-19 related failings were in relation to social distancing, cleaning, RPE and PPE. Common failings that were not related to Covid-19 included control of ionising radiation, manual handling and management of violence and aggression.

99. In the cases where enforcement notices were issued, notices were issued in respect of the following failings:

i) 5 notices were issued in relation to the control of ionising radiation;

ii) 4 notices were issued in relation to manual handling (including training);

iii) 1 notice was issued in relation to the management of risks of falling;

iv) 1 notice was issued for management arrangements for dementia patients;

v) 1 notice was issued in relation to machinery safety, and

vi) 1 notice was issued in relation to health and safety training to senior executives with responsibilities for health and safety.

100. As part of the programme of inspections focused on Covid-19 arrangements, between December 2020 and January 2021 inspections were conducted at 17 acute hospitals, in 13 Trusts in England and in 2 Health Boards in Scotland and Wales. HSE analysed the outcomes of these inspections so that it could share learnings and enable the different Trusts / Health Boards to identify common areas for improvement.

101. The inspections focused on seven specific areas:

a. Risk assessment

b. Management arrangements specific to Covid-19

c. Social distancing

d. Cleaning and hygiene measures

e. Ventilation

f. Dealing with suspected cases

g. PPE

If other health and safety concerns were identified during an inspection, these were also dealt with.

102. The inspections were led by Occupational Health inspectors, assisted by inspectors from Field Operations Division ["FOD"]. The scope of the inspections is set out in guidance that was compiled for inspectors from FOD prior to the commencement of the programme (exhibit RGB/84 – INQ000269820).

103. A summary of the findings was prepared in February 2021 (exhibit RGB/85a - **INQ000323772**) with recommendations with the stated aim of the recipients using the reports in a constructive way to ensure that their respective Covid-19 arrangements were as robust as possible. The report was sent to Trusts / Health Boards at the beginning of March 2021 (exhibit RGB/85b - INQ000269837).

104. During the relevant inspections, HSE identified a range of compliance both in terms of comparing the hospitals with each other but also within individual hospitals. Five were highly compliant; 4 were given advice and 8 were issued with written advice. The contraventions of health and safety law identified included:

a. 8 contraventions in relation to risk assessment

b. 6 contraventions in relation to management arrangements for Covid-19

c. 8 contraventions in relation to social distancing

d. 6 contraventions in relation to cleaning and hygiene measures

e. 5 contraventions in relation to ventilation

f. 0 contraventions in relation to dealing with suspected cases

g. 5 contraventions in relation to PPE

105. Common themes that emerged were:

a. Leadership - Higher levels of compliance were seen where the leadership team were visible to staff on the front line and the IPC leads worked alongside health

and safety teams. Lower levels of compliance were generally found where there were limited or no monitoring arrangements in place to ensure the control measures identified in the risk assessments were implemented and/or maintained.

b. Clinical and non-clinical areas - Higher levels of compliance were seen in patient facing clinical areas across most of the 7 areas inspected. Lower levels of compliance were frequently found in in non-clinical areas, even when adjacent to clinical areas. Reasonably practicable control measures were often available but not utilised in a variety of locations. Arrangements for staff who were displaying Covid-19 symptoms were well established.

106. The report recommended that NHS Trusts and Boards take a number of actions to reassure themselves that adequate Covid-19 control measures were in place and remained so during the pandemic:

a. Review their risk management arrangements to ensure they are adequately resourced.

b. Consider how well the various parts of the risk management system coordinate with each other, including the health and safety team, departmental managers, infection control and occupational health colleagues and whether they could be improved.

c. Ensure compliance with their legal obligations to consult with trade unions and employee representatives by ensuring they are engaged in the risk assessment process.

d. Review all non-patient facing areas to ensure a suitable and sufficient risk assessment has been carried out and the control measures identified have been implemented. Consider how well the risk assessments for these areas have applied the hierarchy of control and whether they have:

- Identified the maximum room occupancy numbers and the optimum layout and seating arrangements in all areas.
- Considered how ventilation could be improved in all areas.
- Implemented mitigating measures where it is not possible to maintain social 2m distancing.
- Checked the adequacy of their cleaning regimes in non–clinical areas.

e. Review the provision of lockers and welfare facilities to ensure they can accommodate the number of staff on shift in a Covid secure manner.

f. Establish routine monitoring and supervision arrangements to ensure control measures identified in the risk assessment are implemented and are being maintained.

g. Review arrangements regularly to ensure they remain valid and act on any findings.

107. Annex 1 of the report set out the findings broken down into the seven key areas, giving examples in each key area of good practice and where improvement was required (exhibit RGB/85a - **INQ000323772** at pages 3- 9).

Inspections during the Covid-19 Pandemic resulting in action in relation to RPE/PPE/IPC.

108. The data recorded on HSE's database indicates that there were 26 cases[5] where material breaches were identified in relation to RPE, PPE and IPC, resulting in the issuing of written advice or an enforcement notice.

Investigations in Healthcare Settings during the Covid-19 Pandemic

109. Data regarding investigations conducted by HSE during the relevant period has been extracted from HSE's database and presented in a spreadsheet (exhibit RGB/86 - INQ000269871). This contains details for fatal investigations, non-fatal investigations and concerns referred for investigation.

110. During the relevant period, the following number of investigations were conducted in healthcare settings:

a. 148 fatal investigations

b. 104 non-fatal investigations

c. 456 concerns referred for investigation

111. With regard to regulatory outcomes, the following outcomes are recorded in relation to investigations in healthcare settings:

a. Fatal investigations - 18 written advice and 1 enforcement notice

b. Non-fatal investigations – 6 written advice and 1 enforcement notice

[5] This data derives from information input onto HSE database and has not been verified against individual case records.

c. Concerns referred for investigations – 15 written advice and 1 enforcement notice

Investigations conducted in Hospitals during the Covid-19 Pandemic

112. The data extracted from HSE's database indicates that 116 fatal investigations were conducted in hospitals during the relevant period. Of the 104 non-fatal investigations conducted across healthcare settings during the relevant period, 75 of these related to hospitals activities. A further 229 investigations were conducted in hospitals following the receipt of concerns.

113. The investigations conducted in hospitals resulted in 32 cases where written advice was issued and 1 case where an enforcement notice was issued to the dutyholder.

114. The enforcement notice was issued because the Trust had failed to ensure that reusable respiratory protective equipment used by employees in the Emergency Department to control exposure to a substance hazardous to health, namely coronavirus, was properly stored in a well- defined place, checked at suitable intervals and when defective repaired or replaced before further use.

Investigations during the Covid-19 Pandemic resulting in action in relation to RPE/PPE/IPC

115. The data available indicates that 15 of the cases investigated resulting in action being taken in relation to RPE/PPE and IPC requirements, either the issuing of written advice or an enforcement notice. However, there are a number of cases where this information cannot be determined from the database records.

Decisions on Enforcement Action during the Covid-19 Pandemic

116. HSE's approach to regulating exposure to coronavirus was developed in accordance with the principles in the EPS i.e. that enforcement action should be proportionate to the risk and to the seriousness of the breach. Due to the rapid onset of the pandemic, HSE considered the developing circumstances and applied the EMM principles to the risk of exposure to a public health emergency in the workplace.

117. The Covid-19 pandemic was the first time HSE applied the EMM framework to protecting workers and others from the risk of exposure to a public health emergency in the workplace. Historically, the EMM was designed to deal with conventional occupational health and safety risks arising from work, to include health risks in the workplace from working on public health viruses in laboratories, but in the absence of a specific pandemic decision making framework, HSE applied the EMM principles,

determining the most credible health outcome for the population of those exposed to the risk.

118. Within the EMM, there is categorisation of the actual consequence of harm. To assist proportionate decision-making, HSE characterises '*serious*' harm as that having an effect which is permanent, progressive or irreversible, permanently disabling a life-long restriction of work capability or a major reduction in quality of life. It characterises '*significant*' harm as being non-permanent or reversible, non-progressive and any disability is temporary. When considering the consequence of exposure to health risks and the likelihood that harm may occur, the most credible health effect arising from occupational exposure should be used. The effect of exposure to a health risk should be determined by the likely response of the working population as a whole and no account should be taken of an individual's resistance or susceptibility.

119. In April 2020, HSE produced guidance to assist inspectors to make enforcement decisions in relation to matters concerning social distancing (exhibit RGB/87a - INQ000269803, 87b - INQ000269791, 87c - INQ000269770, 87d - INQ000269767, 87e - INQ000269782 and 87f - INQ000269764). The guidance focused on the application of EMM and EPS, including consideration of whether the health effect of Covid-19 was significant or serious for the purpose of applying EMM (exhibit RGB/87a - INQ000269803 at para 13). The guidance confirmed that the effect would be significant, taking account of the fact that the working population is generally healthier than the population at large. This decision was informed by the scientific knowledge that was available at the time and advice was provided by HSE's Chief Scientific Adviser (exhibit RGB/88 - INQ INQ000269554).

120. As part of HSE's pandemic response, the approach to enforcement underwent a formal internal review in November 2020 to evaluate the appropriateness of regulatory decision making between April-October 2020 (exhibit RGB/89 – INQ000269880). The review was considered by HSE's Director of Regulation and the Operations Directors on 24 November 2020 who confirmed that HSE's regulatory decision making had remained proportionate throughout the pandemic (exhibit RGB/90 - INQ000269817).

121. The review concluded that HSE's regulatory decision making remained proportionate in relation to Covid-19 and that the EMM, including the assigned consequence descriptor of '*significant*', for workplace exposures to the virus in a public health context, continued to support proportionate regulatory decision-making. The review considered evidence available in relation to the transmission of, and consequences of Covid-19. The review noted that whilst Covid-19 transmitted in the workplace could

give rise to the most serious consequences, the evidence in respect of workplace Covid 19 related fatalities had to be viewed in the context of the number of people who had likely been exposed to the virus at work, or elsewhere[6]. The review highlighted that the majority of workers exposed to the virus suffered no symptoms, and of those that did, a large majority recovered from those symptoms relatively quickly with no indication of permanent effects. Various internal stakeholders were consulted as part of the review, including HSE's Chief Scientific Adviser, Chief Medical Officer, Chief Statistician and Head of Operational Strategy (exhibit RGB/91 - INQ000269823).

122. The review undertaken in November 2020 did take into consideration the Advisory Committee on Dangerous Pathogens ["ACDP"] classification of Covid-19 as a hazard category 3 biological agent and how this may impact on the consideration of health effect for the purpose of EMM. HSE took the view that the hazard groupings and containment levels were aimed at those responsible for managing work in microbiological containment laboratories rather than a wider public health scenario.

123. As part of HSE's ongoing review of its proportionality of enforcement decision making in the pandemic, a further formal review was carried out in April 2021 (exhibit RGB/92 - INQ000269869) which concentrated on the risk associated with exposure to the coronavirus in the public health context in a workplace setting.

124. The April 2021 review report was based on scientific information and evidence from published research, reports and papers; relevant HSE and externally produced guidance and a review of information and intelligence from enforcement decision making in the pandemic by HSE and some local authorities.

125. The outcome of the review concluded that:

    a. The EMM consequence category of *'significant'* remained an appropriate guide to regulatory decision making when enforcing public health risk in the workplace during the pandemic.

    b. There would be no change to the approach taken when assessing the *'likelihood'* of exposure to the virus when enforcing public health risk in the workplace during the pandemic.

    c. The authority of the Government guidance on controlling the risk of transmission of the virus in the workplace, for example, social distancing,

[6] At the time of the review, HSE was investigating 16 Covid 19 fatal incidents where transmission may have occurred in the workplace and was reviewing a further 42 cases.

hygiene and fresh air, would be considered in totality as '*established*', though guidance on, for example, ventilation may still be *interpretive*.

d. The approach to enforcement of the public health risk in the workplace under the classification of '*significant*', through application of EMM, facilitated a proportionate enforcement approach during the pandemic.

e. The significant classification was the subject of political, media and public attention. Concerns were raised that as a consequence of the classification, inspectors were unable to use the full range of their enforcement powers. The decision to classify the health effect of Covid-19 as significant did not impact on the level of enforcement action that an inspector could take in respect of a Covid-19 related matter. EMM gives inspectors flexibility to exercise their professional discretion to move across the full potential range of enforcement responses. As highlighted above in para 82, EMM is a guide which cannot capture the complexities and nuances of the decisions that have to be made by inspectors on a case-by-case basis. The review considered the enforcement profile across inspections and the spot check programme, noting that enforcement notices had been served, demonstrating that inspectors would take appropriate enforcement action where it was required (exhibit RGB/92 at paras 7.17 - 7.19).

The Reporting of Issues and Incidents to the HSE during the Covid-19 Pandemic

Concerns

126. Workers, members of the public and others can raise 'concerns' about workplace safety via the HSE website or by telephone.[7]

127. In spring 2020 issues around PPE provision and use resulted in HSE receiving an increased level of concerns from healthcare settings, including increased concerns regarding availability of PPE and inadequacy of face fit testing for FFP3 face masks.

128. Consequently, HSE's Health and Social Care Services Unit ["HSCSU"] devised a more transparent and streamlined process for dealing with concerns coming in from healthcare settings. The revised process categorised concerns as green, amber or red.

129. The following factors would tend to lead to a concern being categorised as green:

[7] Concerns are not reports under RIDDOR which must be made by the responsible person.

a. The concern failed to specify a specific infringement of social distancing guideline or was too vague to determine any potential breach.

b. The concern related solely to:

   i. Individuals not self-isolating in accordance with current COVID legal requirements

   ii. Employers insisting or allowing people who should be self-isolating to attend work including:

      - People who recently tested positive for COVID 19
      - People who have been contacted by NHS Test and Trace and advised to self-isolate
      - A member of the person's household has tested positive for COVID 19 and are required to self-isolate for 14 days
      - A person who has developed COVID symptoms and is awaiting a test result

   iii. Face coverings and RPE (in non-healthcare settings)

   iv. Travel to and from work, unless this was part of the work activity

   v. Issues relating to pay, sick leave or other employment contract problems

   vi. Allegations that work was non-essential or not necessary

   vii. Sleeping arrangements and accommodation

   viii. Lack of a COVID risk assessment for an individual in a higher risk (for COVID) group

   ix. Ventilation on public transport

   x. Social distancing of passengers on public transport

130. Examples of concerns rated as green included:

a. The Government and NHS have failed to provide sufficient and suitable PPE to medical and nursing/care staff to enable them to work safely, as you know the use of PPE is supposed to be the final solution once all other options have been exhausted via a suitable risk assessment. Therefore employees are being put at unnecessary risk and many have already been harmed or have died. Employees are having to make their own PPE or reuse possibly infected PPE.

b. The hospital's policy after having symptoms of coronavirus is to get a test, and if negative, to return to work. This contradicts the legal requirements set by the Government.

c. Caller wishes to remain anonymous. He is involved with cleaning of plates and cutlery from wards, including the Covid ward. Last week the hospital have changed their policy to revert back to using regular plates and cutlery, instead of disposable. Concerns raised that items are taken from the wards to a kitchen area, along a corridor which is accessible by patients, and if items are accidentally dropped, this could spread infection. He is provided with standard clothes for washing up, including visor, gloves and mask and has concerns that the gloves will not protect him.

131. The criteria for a concern to be categorised as amber was that concern raised one or more of the following issues:

a. Lack of provision of and access to suitable washing facilities for staff and those visiting workplaces.

b. Failing to complete or implement Covid-19 risk assessments and consequent control measures to achieve a COVID Secure workplace and failing to consult unions and/or workplace safety representatives about the same.

c. Lack of regular cleaning and disinfection procedures of shared workspace / equipment, including a failure to deep clean after a Covid-19 case.

d. Lack of adequate ventilation.

e. Scotland and Wales Only – Staff allegedly required to work routinely in close proximity of one another, and there has been no attempt to organise work to ensure (so far is is reasonably practicable) 2m distancing.

132. Examples of concerns rated as amber included:

a. I had covid 19 January 2021. This is almost certainly caught at work with lack of PPE. I have been unwell and off work ever since. I have asked my employer to report it under RIDDOR but it has not been done despite asking months ago.

b. The corridors have no fresh air or ventilation and no one way system to allow for social distancing to take place. Staff are expected to "hot desk" however some stations do not allow social distancing as they are close to other communal amenities such as fridge. There is no need for employees to be hot desking as staff are permanently employed in this office and there are sufficient work stations for this to be made unnecessary. DSE assessed work stations cannot be adjusted to suit the needs of other users. The current cleaning regime for shared equipment consists of hand sanitiser and wipes for the use of cleaning equipment before and

after use. This is entirely up to individual staff to implement and inconsistently complied with. Insufficient toilets available for use, given the number of people in the building.

c. Current Covid Risk Assessment doesn't identify all hazards, doesn't identify all people affected, doesn't cover all accessible areas of building, doesn't provide adequate controls, doesn't provide monitoring or enforcement, isn't available for reading. Management putting possible outcome not risks and control measures therefore hiding the issues.

133. Red concerns were those that fulfilled the criteria for amber but additionally possessed the following strategic factors:

a. Cases that involved extremely vulnerable and vulnerable people, including the elderly, and work in people's homes.

b. Welfare cases (provision of suitable washing facilities) where the standards were allegedly significantly below the legal minimum.

c. Dutyholder was the subject of previous enforcement in the previous 12 months.

134. The following are some actual examples of concerns categorised as red:

a. NHS Phlebotomists . . . My Sister is a Phlebotomist . . . not only does she not receive any PPE equipment but they ask that Nurses share a mask which in itself is unhygienic. These Nurses have to take blood from all kinds of people but her clients also include drug users / homeless etc who would probably have a higher risk of contracting COVID-19 19 people have already died . . . Please can you do something about this.

b. No stocks of PPE for a covid triage ward, even basic red plastic aprons and masks and visors were absent. Patients were being accepted onto this ward despite this being the case and frontline staff were forced to work at significant risk to themselves. The trust is further stopping FIT testing of masks and respirators due to running out of supplies.

c. As a community nurse I am caring for the most vulnerable patients in their homes. Carrying out nursing care involves getting right beside patient and touching patient. We are not allowed to wear face masks unless symptoms of covid. This leaves nurses and patients at risk if they are asymptotic but maybe incubating disease. Over 70s and shielded patients are what our caseload comprises. This means

nurses and social cares will potentially become super spreaders when rest of population is maintaining social distance. Short gloves and thin plastic aprons are not effective PPE. This is not best practice and our organisation seems to be rationing PPE.

135. The revised process had the effect of routing any concerns from healthcare settings, other than the most straightforward (categorised as green), to what became known as the Virtual Concerns Team ["VCT"]. The VCT was made up of 20-22 inspectors and specialist inspectors. A single inspector acted as single point of contact ["SPOC"] and developed lines to take for recurring issues, triaged the amber and red concerns in relation to PPE and social distancing concerns and dealt with the most complex or sensitive issues in person. The remainder of the team took concerns as allocated by the SPOC and conducted inquiries and investigations as necessary, contacted duty holders and closed cases out when dealt with. A document setting out the procedures entitled Handling Procedure for all Concerns in Health and Social Care Settings During the Covid-19 Pandemic Guidance for HSCSU is exhibited as RGB/93 - INQ000269814.

136. The VCT enabled HSE to monitor the frequent changes in IPC guidance and ensure that inspectors in the field were up to date with current guidance. IPC guidance was changing rapidly as the understanding of Covid-19 developed.

137. The VCT produced reports detailing concerns received in healthcare and social care settings (example at exhibit ref RGB/94 - INQ000269849). The report separates the number of concerns and outcomes between the following sectors: NHS trust/hospital, ambulance/patient transfer service and care in the community.

138. The VCT was stood down in March 2021.

139. Data from HSE's CAT team confirms numbers of concerns raised in healthcare settings for the period 1 March 2020 to 30 June 2022 as follows:

    a. Total Concerns - 118,998

    b. Total Related to Covid-19 – 25,313

    c. Total Related to Covid-19 in healthcare settings – 1,587

140. The 1587 concerns from healthcare settings were reported by the following:

Employee –	722
Employer –	141
Ex-employee –	60

Local Authority –	50
Member of the Public –	317
Other –	200
Other Enforcing Body –	21
Self-Employed –	16
Union Representative –	39
Work/Safety Representative –	20
Regulatory Body –	1

141. Reports classified as 'Other' are reports where the reporter does not wish to categorise themselves. This can be because they are an ex-employee who does not wish to be identified or they consider themselves to be a whistle-blower.

142. Of the 1587 concerns raised in healthcare settings, 192 were categorised as red concerns.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013

143. The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 ["RIDDOR"] were made under the HSWA and provide the national reporting framework for responsible persons (usually employers, the self-employed and people in control of work premises) to report certain cases of injury, diseases and specified dangerous occurrences to the relevant enforcing authority (HSE or local authority).

144. The regulations apply to all sectors and workplaces in Great Britain, including healthcare settings.

145. The purpose of RIDDOR is to inform the enforcing authority in a timely fashion that an incident or event has occurred and allow an appropriate regulatory response to be made.

146. In making a report under RIDDOR, the responsible person is not admitting blame or wrongdoing, they are simply discharging their statutory duty to report an incident or event to the regulator. A failure by the responsible person to report as required by the regulations amounts to an offence punishable with a fine and/or imprisonment.

147. In relation to Covid-19, reports should only be made under RIDDOR when one of the following three conditions applies:

    a. Dangerous Occurrence

An accident or incident at work has, or could have, led to the release or escape of coronavirus. This must be reported as a dangerous occurrence (under Regulation 7 and Schedule 2). This is usually where work is deliberately taking place with the virus, e.g. in a laboratory.

b. Case of disease

A worker has been diagnosed as having Covid-19 that is attributed to an occupational exposure to coronavirus. This must be reported as a disease due to an occupational exposure to a biological agent (under Regulation 9 (b)). "Attributed" means that there is reasonable evidence that the workplace exposure was the likely cause of the disease.

c. Case of fatality

A worker dies as a result of an occupational exposure to coronavirus. This must be reported as a work-related death due to exposure to a biological agent (under Regulation 6(2)). "As a result of" means that there is reasonable evidence that workplace exposure was the likely cause of the worker's death.

148. RIDDOR was drafted to capture single one-off unexpected events (accidents and incidents). It was not intended to be used in a pandemic involving thousands of instances of infection, where an employer may be required to make a judgement as to whether a worker caught the infection as a result of a workplace exposure or from the wider community.

149. Reporting of work-related incidents has always been subjective; the responsible person will need to exercise their own judgement as to whether an incident was work-related or not. Therefore, the strength of the RIDDOR reporting system relies heavily on two elements:

a. A responsible person making a report; and,

b. The quality of the information in that report.

150. Due to this reliance on employer submitted information HSE does not rely on RIDDOR as its sole intelligence source. While not a source of definitive statistics as to reportable workplace incidents, RIDDOR enables the broader monitoring and analysis of trends over time and prioritisation and targeting of risks in particular industries/ sectors.

RIDDOR Guidance During the Pandemic

151. During the pandemic HSE guidance for reporting occupational exposure changed, as did the reporting form to enable Covid-19 cases to be more readily identifiable. The

guidance changed to reflect the sharp increase in Covid-19 related reports from the healthcare sector. There were a number of updates to guidance in the early stages of the pandemic but from May 2020 the guidance was settled before reverting back to pre-pandemic advice from 1 April 2022.

152. Guidance published on 2 April 2020 (exhibit ref RGB/95 - INQ000269762) set out that the responsible person was required to make a RIDDOR report if there was reasonable evidence that a worker diagnosed with Covid-19 was exposed while at work.

153. Further guidance published on 7 April 2020 (exhibit ref RGB/96 - INQ000269763) confirmed the need to report a fatality where the cause of death was confirmed by a medical practitioner as resulting from workplace exposure to coronavirus. This guidance was necessary as the pre Covid-19 RIDDOR reporting form had no clear way to record a fatal outcome attributable to Covid-19. The guidance was accompanied by a change in the format of the RIDDOR reporting form and guidance (exhibit ref RGB/97 – INQ000346204).

154. Subsequent to the April 2020 guidance being published on our internet, HSE received a large volume of queries from employers across all sectors (including NHS Trusts) as well as organisations such as the Institute for Occupational Safety ["IOSH"] and Public Health England ["PHE"], seeking clarification as to the types of dangerous occurrences that should be reported, what constitutes "reasonable evidence" in the case of disease reporting and who should make the link to an occupational exposure in the absence of a registered medical practitioner.

155. HSE published amended guidance on 30 May 2020 (exhibit ref RGB/98(a) - INQ000269882 and 98(b) - INQ000269884). This provided greater detail to assist responsible persons in understanding when a work-related exposure would require a RIDDOR report. The guidance provided can be summarised as follows:

    a. For a case of disease to be reportable due to occupational exposure to a biological agent there must be reasonable evidence suggesting that a work-related exposure was the likely cause of the Covid-19 infection.

    b. For a fatality to be reportable as a death due to an occupational exposure to a biological agent, there must be reasonable evidence that an occupational exposure to coronavirus caused the worker's death.

    c. It is the employer (responsible person) who decides when a report is required. They must make a judgement, based on the information available, as

to whether a confirmed diagnosis of Covid-19 (i.e. a positive test) is likely to have been caused by an occupational exposure at work.

d. This means that not all Covid-19 infections or deaths of workers are reportable as not all infections will have been contracted by an occupational exposure at work - they could have been caught from family members or in the community.

e. There is no requirement under RIDDOR to report cases of Covid-19 infections or deaths of members of the public, patients, care home residents or service users as such cases do not arise out of an occupational exposure to the virus.

156. The guidance published on 1 April 2022 (exhibit ref RGB/99 - INQ000269883) confirms that RIDDOR reporting requirements relating to Covid-19 infections, or deaths from Covid-19, only apply where an employee has been infected with coronavirus through:

a. Deliberately working with the virus, such as in a laboratory; or

b. Being incidentally exposed to the virus (incidental exposure can occur when working in environments where people are known to have Covid-19, for example in a health or social care setting).

157. The change in guidance from April 2022 was introduced as HSE returned to its core role of regulating workplaces to ensure the safety of workers and others affected by the risks created by work activity. It resulted in the requirement to report general workplace transmission ceasing from 1 April 2022. The change was consistent with the Government's move towards living with Covid-19. HSE anticipated that the change would likely lead to a reduction in the number of RIDDOR reports received now that it was no longer necessary to report general workplace transmission. HSE continued to publish the numbers of RIDDOR reports via its website.

RIDDOR Reporting During the Pandemic

158. As noted above, RIDDOR does not provide for definitive health and safety at work statistics as there is known under-reporting in some industry sectors, such as agriculture, and over-reporting in others – for example education and leisure.

159. HSE collected Covid-19 specific data from 10 April 2020. This broadly coincided with publication of the revised RIDDOR reporting guidance referred to above and was enabled through modifications to the online disease reporting form that resulted in Covid-19 cases being readily identifiable.

160. The data was initially presented weekly as internal management information. In response to demand for information around Covid-19 related RIDDOR reports, and

following ministerial and HSE senior management approval, it was published on HSE's website on a monthly basis from June 2020 (example at exhibit RGB/100 - INQ000269879).

161. The data was management information rather than "statistics" and is subject to the following limitations:

a. The data is "as reported"; the only validation that HSE applied was to exclude reports that related to members of the public rather than workers.

b. Because the data is as reported, there is a risk that non-fatal Covid-19 cases could have been reported as fatal and vice versa.

c. Misallocation of industry codings may result in workers from healthcare settings being categorised as another type of worker (e.g. healthcare workers being categorised social care workers) and vice versa.

d. For the period 1 March 2020 to 9 April 2020, the way disease was reported under RIDDOR made it difficult to identify with any accuracy whether the disease being reported was Covid-19.

e. From 1 April 2022 to 28 June 2022 the requirement to report workplace transmission under RIDDOR stopped as HSE returned to its core role of regulating workplaces to ensure the safety of workers and others affected by the risks created by work activity. The data for that 3 month period is therefore not comparable with the data up until 1 April 2022.

162. The data is intended to provide an indicator of the numbers of suspected cases being reported to the enforcing authority and how this changed over time rather than an accurate count of the absolute number of occupational Covid-19 cases in the workplace.

163. The data is contained within an Excel spreadsheet that details data across all industry sectors (exhibit ref RGB/101 - INQ000269828). Table 4 divides the reports into standard industrial classification codes ("SIC"). Section Q (86-88) of the SIC scheme is human health and social work activities, which divides into:

86 – Human health activities

87 – Residential care activities

88 – Social work activities without accommodation

164. The figures below are based on reports under division 86, human health activities.

Occupational Disease Reports

165. Occupational Disease Reports between 10 April 2020 and 31 March 2022:

Non-fatal reports – 12,330

Fatal reports – 170

166. The total reports across all industry sectors in this period was:

Non-fatal reports – 43,999 (including human health activities)

Fatal reports – 459 (including human health activities)

167. Between 1 April 2022 and 30 June 2022 (the period for which employers were no longer required to report general workplace transmission)

Non-fatal reports – 385

Fatal reports – 0

168. The total reports across all industry sectors in this period was:

Non-fatal reports – 1412 (including human health activities)

Fatal report – 2 (including human health activities)

Dangerous Occurrences

169. HSE cannot produce robust data isolating reports of Covid-19 as a dangerous occurrence for the relevant period. An incident at work which has, or could have, led to the release or escape of coronavirus was - and still is - reportable as a 'biological agent' dangerous occurrence under Regulation 7. However, there is no explicit marker on these 'biological agent' dangerous occurrence reports to explicitly identify 'Covid-19' incidents. Any count would involve text searches of words like 'corona' and 'covid' in the freetext provided by the notifier. As this is dependent on the voluntary detail provided by the notifier it does not necessarily provide an accurate measure. HSE therefore refrained from publishing any counts of coronavirus dangerous occurrence reports.

RIDDOR Under-reporting

170. HSE recognised, and our guidance reflected, that the responsible person for the purposes of RIDDOR faced sometimes difficult judgements in assessing whether there was reasonable evidence to support a workplace exposure.

171. In relation to cases of disease, HSE carefully considered whether "diagnosed" in regulation 9 required diagnosis by a medical professional or confirmation by way of

positive test. HSE resolved that to conclude the former would likely have resulted in very few reports as it was difficult to see how a medical professional could conclude, in the absence of the worker deliberately working with the virus, that the disease was attributable to a workplace exposure as opposed to exposure outside of the workplace or work activity. HSE therefore took the more pragmatic approach that a positive test would count as "diagnosed" for the purposes of potential RIDDOR reporting.

172. For a case of disease (or a death as a result of disease) to be attributed to a workplace exposure, HSE confirmed in the updated guidance published in May 2020 that there had to be reasonable evidence of workplace exposure and the guidance assisted dutyholders in determining that issue. The decision as to whether to make a RIDDOR report at all times remained with the responsible person.

173. As the pandemic progressed, it became apparent to HSE that there may have been both over and under reporting via the RIDDOR scheme. The initial concern was for over-reporting based on clusters of reports.

174. A paper presented to HSE's ORCo on HSE's Operational Response to Covid-19 Disease Notifications highlighted some of the challenges in relation to Covid-19 reporting, including in healthcare settings (exhibit RGB/102- INQ000269829). These issues were then considered further by HSCSU.

175. Statistical analysis of reports conducted by the HSCSU showed significantly different levels of reporting across the NHS (exhibit RGB/103 - INQ000269831[8]). The number of cases reported per trust/board varied considerably, with some reporting no cases and others reporting over 100. A review of reports highlighted that some of the reports were not reportable under RIDDOR (exhibit RGB/104 - INQ000269761).

176. HSE conducted extensive internal discussions to consider what, if any, action HSE should take to address the different levels of reporting (exhibit RGB/105 – INQ000269872). HSE considered whether it was appropriate to contact NHS Trust and Boards to remind them of their reporting responsibilities under RIDDOR or whether to take no further action in view of existing advice. HSE took the decision to engage with NHS Trust and Boards to share lessons learnt and ask that Trusts and Boards to review their arrangements to ensure they could satisfy themselves that they were complying with RIDDOR (exhibit RGB/106 – INQ000269773).

177. This must though be considered in the context of the existing published advice on RIDDOR reporting and HSE advice on Covid-19 RIDDOR requirements throughout the

[8] The data produced for analysis was subject to caveats in relation to data quality.

pandemic. HSE advised various stakeholders and NHS groups, including the Quality, Governance and Risk Directors ["QGUARD"]) (example at RGB/107 - INQ000269596), The Health, Safety and Wellbeing Partnership Group ["HSWPG"] (example at RGB/108 - INQ000269836), IOSH (example at RGB/109 - INQ000269834) and NHS England & NHS Improvement (example at RGB/110 - INQ000269595). HSE also assisted the National Ambulance Risk and Safety Forum ["NARSF"] in seeking to develop their own RIDDOR guidance but HSE understands that NARSF did not complete this work. HSE understands that DHSC and the CQC also sent reminders regarding the RIDDOR reporting requirements to the healthcare sector (RGB/111 – INQ000269555 and RGB/112 – INQ000269868).

178. The data painted a complex and contradictory picture. To aid the gathering of intelligence regarding fatalities, HSE was in contact with and met the National Medical Examiner ["NME"]. The numbers of fatalities recorded by the NME exceeded those reported under RIDDOR. On review, HSE identified a number of cases that would not have been RIDDOR reportable. The test applied by the NME, based upon a review of medical records and any information gathered from a deceased's family, was whether there was a "reason to suspect" that the disease was acquired at work and it seemed that if the deceased had been a frontline healthcare worker, it would be marked as an infection acquired at work. Mere suspicion has been held to mean 'a possibility which is more than fanciful that the relevant fact existed'[9]. This was in contrast to the requirement to report under RIDDOR, which required 'reasonable evidence' that the disease was attributable to workplace exposure. Factors to take into account when deciding whether such evidence exists could include:

    a. whether or not the nature of the person's work activities increased the risk of them becoming exposed to coronavirus.

    b. whether or not there was any specific, identifiable incident that led to an increased risk of exposure.

    c. whether or not the person's work directly brought them into contact with a known coronavirus hazard without effective control measures, as set out in the relevant PHE guidance, in place such as PPE or social distancing.

179. This imposes a substantially higher standard than mere suspicion based on assumptions drawn from the fact that the deceased was a healthcare worker.

[9] *R v Da Silva* [2006] EWCA Crim 1654.

180. HSE provided assistance to DHSC (exhibit RGB/113 - INQ000269594), from whom medical examiners had sought advice, around who the responsible person might be in respect of agency workers and who they should write to where they suspected a death was work related. This was of general application across industry sectors but it is well known that agency workers are common in the healthcare sector.

Spot Checks and Spot Inspections

181. On 11 May 2020, the then Prime Minister ["PM"] of the UK, the Rt Hon. Boris Johnson, made a statement in the House of Commons setting out a conditional plan for the easing of Covid-19 restrictions (extract from Hansard exhibited as RGB/114 - INQ000269860). The term 'spot inspections' was used by the PM during this parliamentary session, specifically with regard to workers who would be returning to work because they could not work at home. He stated:

> "We are going to insist that businesses across this country look after their workers and are covid-secure and covid-compliant. The Health and Safety Executive will be enforcing that, and we will have spot inspections to make sure that businesses are keeping their employees safe. It will, of course, be open to employees who do not feel safe to raise that with not just their employers but the HSE as well." (exhibit RGB/114 - INQ000269860 at column 34).

182. Consequently, HSE introduced two regulatory interventions which were referred to as 'spot checks' and 'spot inspections' (explained in more detail at paras 190 – 195) on all types of business in all areas to ensure that they were Covid-secure. Spot checks and spot inspections were undertaken by HSE and Local Authorities. Their introduction provided a means to check how businesses within all areas were implementing the Covid-secure guidance and associated control measures they had put in place to protect employees, visitors and customers.

183. The spot check programme was to be funded by a ring-fenced funding allocation for the financial year 2020 / 2021 of £13.5 million and £15.1 million in financial year 2021 / 2022.

Developing the Spot Check Programme

184. Following the May announcement, a team was formed to establish the foundations of the operational approach to assess Covid-19 control measures in business across Great Britain. The spot check programme was designed as a way of checking how businesses were implementing the Covid Secure guidance. The key workstreams were

developed and set out in a paper for HSE's ExCo Gold Group (considered on 1 June 2020) (exhibit RGB/115 - INQ000269852).

185. The spot check programme adapted during the pandemic response to ensure HSE maintained alignment with policy and guidance changes and created a scalable solution to ramp up and ramp down quickly and efficiently, utilising an agile approach to cope with unexpected scenarios such as Covid-19 variants, implementation and removal of lockdowns and ultimately the closure of the programme in March 2022.

186. The selection of data for HSE spot checks initially followed the sectors covered by HSE's enforcement authority. HSE targeted high-risk sectors such as waste and recycling, metal fabrication and manufacturing (as outlined in the spot check intervention plan drafted in October 2020 (exhibit RGB/116 - INQ000269797) and overlaid this with a focus on priority geographic areas following local outbreaks and then local lockdowns. The programme also delivered specific campaigns with spot checks on schools, transport/logistics and health and social care settings. HSE also adapted approaches and methodologies to fit with surge testing and variant prevalence.

187. The spot check programme adopted an informal agile approach with the levels of governance in order to deliver solutions at pace during the pandemic. Daily governance calls were set up from the start of implementation that provided overviews of daily performance, overall workflow, resource allocation and review of outcomes to ensure consistency, continuous flow of work and to ensure wider objectives met.

188. A Programme Board was established and met twice monthly, although urgent escalations to Programme Board were facilitated by extraordinary meetings or via correspondence for expedience. Escalations were channelled up through to ExCo along with daily reporting of operational activity.

189. An overview of the key stages of the development and implementation of the spot check programme, along with a summary of the assurance measures adopted, outcome and lessons learnt was presented to HSE's Board in June 2022. This presentation is exhibited as exhibit RGB/117 - INQ000269876).

Spot Checks and Spot Inspections – the Process

190. A 'spot check' was a proactive telephone call, visit or inspection to a (or of a) workplace, undertaken applying a 3-stage process. HSE highlighted the purpose and its approach to spot checks on its website "Regulating health and safety spot checks" (exhibit RGB/118 - INQ000269778).

191. The spot check process established by HSE consisted of three stages, specifically:

a. Stage 1 - a questionnaire linked to Covid Secure / Working Safely guidance (examples exhibited as RGB/119(a) - INQ000269826 and RGB/119(b) - INQ000269844). The questionnaire was completed either during a telephone call with the dutyholder or visit ["spot check visit"] to the dutyholder's premises / site. Where potential non-compliance was identified, the case was referred to Stage 2.

b. Stage 2 - a more detailed discussion with the dutyholder (during a telephone call or spot check visit) where evidence was gathered, information was provided to the dutyholder in relation to relevant requirements and guidance and a decision was made as to compliance. Where a case was deemed to still be non-complaint at the end of Stage 2, it was referred to Stage 3.

c. Stage 3 - an inspection by HSE/LA inspector.

192. If a dutyholder failed to engage in the conduct of a spot check, the matter would be escalated to the next stage of the process. All spot checks were recorded (an example completed spot check in exhibited as RGB/120 - INQ000269800).

193. The questionnaire used at Stage 1 of the process was continually reviewed and updated during the pandemic, for example amendments were made in July, August and December 2021 to take into account changes in Covid-19 restrictions (detailed in exhibit RGB/117 - INQ000269876). A specific health and social care sector questionnaire was developed and implemented by October 2020 (exhibit ref RGB/121 - INQ000269794).

194. In September 2021, following piloting with our Stage 2 team the programme implemented a video calling solution to allow dutyholders to facilitate virtual tours of their sites in order to better assess control measures implemented.

195. In addition to spot checks, where inspectors were carrying out an inspection or investigation unrelated to Covid-19, checks were also made of whether Covid-19 measures were in place and adequate. These were referred to as "spot inspections".

Conduct of Spot Checks by HSE

196. Telephone calls made at Stage 1 of the spot check process were conducted by both HSE employees and staff contracted by the third-party delivery partners used by HSE to support delivery of the spot check programme. Training and call scripts were provided to non-HSE staff in the call centres (exhibit RGB/122- INQ000269870).

197. Spot check visits undertaken at Stage 1 were undertaken by third party delivery partners. Spot Check Support Officers ["SCSO"] visited workplaces and undertook the spot checks using the HSE pre-defined questionnaire (as per the questionnaire used for telephone spot checks). If a SCSO identified potential non-compliance, they would conduct Stage 2 of the process whilst on-site.

198. Calls at Stage 2 of the spot check process were made by Concerns Handling Officers from HSE's Customer Service Teams, Visiting Officers from the HSE's Operational Divisions and also by Health and Safety Qualified contractors on-boarded by HSE to work on the spot check programme.

199. If a matter progressed to stage 3, any physical inspection would be conducted by HSE Inspectors.

Assurance of Spot Check Process

200. In addition to the design and launch of the spot checks programme, assurance was identified as crucial to the process. Third party delivery partners of the spot check programme were required to put in place processes and checks to provide assurance to themselves and to HSE, that the personnel undertaking the spot checks were following the defined processes and that the data collected, and subsequently provided to HSE, was of high quality and representative of the spot checks that took place.

201. Furthermore, HSE also undertook quality assurance activity on the work of the third-party delivery partners. Delivery partners support this activity and worked with HSE to remediate issues by carrying out actions such as reviewing process, staff deployed on the work, and spot check data, etc.

202. To validate that calls were an effective method of checking that workplaces were Covid secure, HSE undertook an assurance exercise in August and September 2020, with HSE nspectors physically inspecting workplaces that had "passed" as Covid secure via a telephone call.

203. As at May 2021, 277 cases were quality checked, with 96% requiring no further action, and 4% requiring follow-up through written correspondence. Based on these outcomes, HSE was content that a call was an effective method of undertaking spot checks (exhibit RGB/123 - INQ000269811).

204. In addition to the Stage 1 telephone assurance checks, similar checks were made by HSE inspectors on the outcomes of spot visits by external supplier partners. Again, as with the phone calls, the assurance inspections demonstrated high levels of

compliance and that the visit methodology using supplier SCSOs was working as expected.

205. Across HSE operational teams quality and process control checks were implemented using a call listening approach where call handlers were scored across a series of standards relating to the process, guidance and customer service interaction. Throughout the programme operational teams consistently achieved weekly quality scores of 94-98%.

206. In addition to internal assurance checks, the spot check programme was reviewed by Government Internal Audit Agency. A copy of their report is exhibited as RGB/124 - INQ000269866).

Number of Spot Checks and Spot Inspections conducted by HSE

207. The spot check programme commenced on 22 May 2020 and concluded on 31 Match 2022. During this period HSE conducted a total of 404,629 spot checks, including 220,124 telephone Stage 1 and Stage 2 telephone calls and 184,505 site visits and inspections (RGB/125 - INQ000269760).

208. Due to the high number of guidance changes and variations and divergence by the devolved administrations in Wales and Scotland, a workstream was established for repeat spot checks to call and re-visit duty holders who had previously undertaken a Covid-19 spot check to not only ensure that changes required had been implemented, but that the control measures had kept pace with the development of guidance during the pandemic.

Spot Checks and Spot Inspections in Healthcare Settings

209. During the spot check programme, 483 spot checks and spot inspections were conducted in healthcare settings (as detailed in exhibit RGB/125.- INQ000269760). It is important to recognise that the spot check programme was being implemented alongside other inspections and investigations. Across healthcare settings, HSE was undertaking a range of interventions that enabled it to assess compliance with Covid-19 related requirements whilst also recognising the critical nature of the services being provided across healthcare settings.

210. Spot check intervention planning took account of planned inspection activity in healthcare settings. Targeted Covid-19 inspections and spot inspections were conducted across a range of healthcare settings during the relevant period (as described in paras 96 - 110). This included the programme of inspections of acute

hospitals, NHS Trusts and Health Boards conducted between December 2020 and January 2021 (referred to above in paras 103 – 110).

211. As part of its data selection process for spot checks, businesses and certain industry sectors that had already been spot checked or the subject of targeted spot check activity were removed from the dataset for selection. Healthcare settings were added to the list to be excluded from the dataset for selection in April 2021.

212. The data shows that across healthcare settings, 18 dutyholders were issued with written advice following interventions conducted as part of the spot check programme.

HSE's Role in Relation to Response to Outbreaks and Clusters

213. Outbreaks and clusters were principally public health matters that were managed by PHE, PHW and local Health Protection Teams. However in circumstances where the potential source of transmission was identified as a workplace for which HSE was the enforcing authority, upon notification of an outbreak or cluster, HSE would provide assistance and advice to public health teams and also consider whether any regulatory intervention was necessary. HSE produced guidance to assist public health teams to understand its role in outbreak response (exhibit RGB/126a - INQ000269807, 126b – INQ000269788, 126c – INQ000269785 and 126d - INQ000269838).

214. HSE set up a virtual team to record and process cluster and outbreak notifications and outcomes. At an operational level, steps were also taken to analyse information from RIDDOR reports, with a view to gathering further information about potential clusters or outbreaks which may have been caused by poor risk management in the workplace.

215. The data indicates that HSE received notification of 23 potential outbreaks or clusters in healthcare settings during the relevant period. Four of these notifications resulted in HSE attending the site (as detailed in exhibit RGB as detailed in exhibit RGB/125.- INQ000269760).

216. HSE led Theme 1 of the National Core Study which considered outbreaks and clusters from a scientific and modelling perspective (referred to above at para 23). This work was carried out in partnership with UKHSA, University of Manchester and London School of Hygiene and Tropical Medicine.

Covid-19 and High Consequence Infectious Diseases ["HCIDs"]

217. On 13 March 2020 the Advisory Committee on Dangerous Pathogens ["ACDP"] unanimously agreed that Covid-19 should not be classified as a "HCID" (exhibit RGB/127 - **INQ000223384**). HSE is not a party on the ACDP but attends as an

observer. Subsequently on 19 March 2020, the Government updated external guidance to confirm Covid-19 was officially no longer classified as a HCID (exhibit RGB/128 - INQ000269843).

218. The decision to no longer classify Covid-19 as a HCID had no bearing on HSE's approach to the conduct of inspections. HSE applies a risk assessment-based approach, based on hierarchy of control. The categorisation did not impact on this approach.

219. The decision also had no bearing on the conduct of spot checks and spot inspections. These were introduced after the decision to no longer classify Covid-19 as a HCID was made.

220. With regard to PPE, HSE's IPC guidance sets out the activities which require PPE and/or RPE, with specific sets of PPE and RPE required for treating HCIDs.

221. There are two management pathways for treating HCIDs. Contact transmission (such as Ebola and haemorrhagic diseases) and the airborne route. There are only a limited number of hospitals that can treat HCID. At the onset of the pandemic, Guys and St Thomas's would treat those infected via the airborne route and Royal Free London would treat those infected via contact transmission. Each has a specific type of PPE to manage these diseases.

222. Once Covid-19 itself was removed from the HCID list, patients were managed in Trusts and hospitals as well as Guys and the Royal Free London.

223. The decision to declassify Covid-19 as an HCID did not affect the guidance on the appropriate PPE and/or RPE. The published guidance under COSHH ACOP L5 and HSG53 (detailed below at para 237), remained unchanged throughout the relevant period.

Workplace Risks related to exposure from Biological Agents at Work

224. COSHH implemented, for Great Britain, the European Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work. The Directive required Member States to classify biological agents that are or may be a hazard to human health. Annex III to the Directive contains a list of the Community Classifications of biological agents. The classifications of biological agents approved by HSE is referred to as the 'Approved List'.

225. The Approved List is relevant to any risk assessment for work with biological agents and the application of appropriate control measures. Risk assessments must identify

the steps to adequately control exposure to biological agents (where it is not reasonably practicable to prevent exposure), taking into account the hazard(s) that they present.

226. The classifications in the Approved List assign each biological agent listed to a hazard group according to its level of risk of infection to humans, where Hazard Group 1 agents are not considered to pose a risk to human health and Hazard Group 4 agents present the greatest risk.

227. The ACDP is the expert group tasked with the classification approval of biological agents having considered evidence as to:

a. the likelihood that it will cause disease by infection or toxicity in humans;

b. how likely it is that the infection would spread to the community;

c. the availability of any treatment or any treatment which will prevent infection and/or may reduce the effect of an exposure or an infection. This will include vaccines.

228. HSE works on behalf of ACDP to put the list together. HSE does not categorise or classify the risk. HSE describes how to assess and manage it.

229. Biological agents are grouped according to the following definitions:

Group 1: Unlikely to cause human disease.

Group 2: Can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.

Group 3: Can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available.

Group 4: Causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

230. The Approved List applicable immediately before the relevant period was published in July 2013 (exhibit RGB/129 - INQ000269670). Middle East Respiratory Syndrome Coronavirus ["MERS"] was previously an unlisted virus and was classified as Hazard Group 3. The closely related Severe Acute Respiratory Syndrome ["SARS"] associated coronavirus had also previously been classified by ACDP as Hazard Group 3.

231. HSE presented a paper to the ACDP to establish a classification for the Covid-19 agent. The reason for the preparation of the paper was that laboratories were starting to see cases of Covid-19 and there were research facilities that wanted to work with the agent. The issue raised was to agree / propose the provisional ACDP Hazard Group classification. (exhibit RGB/130 - INQ000269620).

232. The minutes of the ACDP on 13 February 2020 show that the Panel endorsed the provisional classification of SARS-CoV-2 as Hazard Group 3 (exhibit RGB/131 - **INQ000251902**).

233. COSHH Schedule 3 (Additional Provisions Relating to Work with Biological Agents, Part I (Provisions of General Application to Biological Agents)) at sub-paragraph 2 sets out the requirements of Regulation 7(10) in respect of work with biological agents.

234. Part I of Schedule 3 COSHH at para 2 sets out the approach taken by HSE in provisionally classifying Covid-19 prior to preparation of the report to ACDP referred to above. Part I Para. 2(2) shows the groupings between 1-4 set out above. SARS-CoV-2 was allocated to Hazard Group 3 by HSE.

235. Sub-paragraph 4 of Part I sets out that subject to sub-paragraph (5)[10] the minimum containment level shall be:

(a) level 2 for activities which involve working with a Group 2 biological agent;

(b) level 3 for activities which involve working with a Group 3 biological agent;

(c) level 4 for activities which involve working with a Group 4 biological agent;

(d) level 2 for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a biological agent but work with materials in respect of which it is unlikely that a Group 3 or Group 4 biological agent is present;

(e) level 3 or 4, where appropriate, for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a Group 3 or Group 4 biological agent but where the employer knows, or it is likely, that such a containment level is necessary; and

(f) level 3 for activities where it has not been possible to carry out a conclusive assessment but where there is concern that the activity might involve a serious health risk for employees.

[10] [The Health and Safety Executive] may approve guidelines specifying the minimum containment measures which are to apply in any particular case (COSHH Schedule 3 Part II sub-paragraph 5).

236. Part II of COSHH Schedule 3 sets out Containment Measures for Health and Veterinary Care Facilities, Laboratories and Animal Rooms and shows the difference of the control and containment measures required between Containment Levels 2-4.

Infection Prevention and Control

Guidance & Regulations pre-pandemic

237. There are no Regulations specific to healthcare workers in relation to IPC. However, the control of occupational exposure to biological agents, which includes within the healthcare setting, is covered by the COSHH regulations. COSHH sets out the requirements in relation to the use of PPE when protecting against substances hazardous to health, where other measures, cannot be achieved.

238. Controls might include engineering, ventilation and/or organisational systems. Where these cannot achieve adequate control, then, in addition, PPE should be provided. These measures have to be considered first, and put in place, with PPE being the last resort to deal with residual risk that still is not adequately controlling exposure.

239. The general duties of COSHH apply to incidental exposure to, and deliberate work with, biological agents. COSHH does not cover a situation where, for example, one employee catches a respiratory infection from another. This is because Regulation 2(2) specifies that COSHH only applies in circumstances where risks of exposure are work related, and not those where they have no direct connection with the work being done.

240. Complementing COSHH are the pervasive Regulations referred to above and below at paras 239 - 240.

241. Before the Covid-19 pandemic, HSE had published a number of guidance documents relating to applicable Regulations. Dutyholders in the healthcare setting, and indeed those in other sectors, could refer to these. Where guidance is produced in relation to a specific set of Regulations, HSE may publish legal guidance in the form of Approved Codes of Practice ["ACOP"], approved by the Secretary of State. ACOP issued by the HSE are not compulsory unless specifically stated and dutyholders may take alternative action which will achieve the same outcome. Where dutyholders do follow the guidance they will normally be doing enough to comply with the law. However, in the event of prosecution, where it is proved the dutyholder did not follow the relevant provisions of the ACOP, the dutyholder will need to show how they have complied with the law in some other way (s16 & 17 HSWA).

242. HSE guidance documents relevant to the IPC were as follows:

a. L5 - Control of substances hazardous to health 6th (ed 2013) (exhibit RGB/132-INQ000269676). This book contains the Approved Code of Practice (ACOP) to COSHH and covers all substances to which the Regulations apply. It outlines the preferred or recommended methods that can be used to comply with the Regulations and the accompanying guidance also provides advice on achieving compliance, such as the control of carcinogenic substances or those causing occupational asthma, monitoring control measures and conducting health surveillance.

b. HSG283 – Managing infection risks when handling the deceased 2018 (exhibit RGB/133 - INQ000269678). This publication provides guidance on managing the risks of infection from work activities which involve handling the deceased. It covers the safe handling, storage and examination of bodies and pathological specimens in hospitals, mortuaries and post-mortem rooms.

c. Safe working and the prevention of infection in clinical laboratories and similar facilities 2003 (exhibit RGB/134 - INQ000269675). This book provides health and safety guidance for managers, health and safety officers and employees in clinical pathology laboratories. The guidance is relevant to the collection and handling of diagnostic specimens in patient care areas as well as the laboratory. The book helps identify and assess the risks of infection and how to take appropriate precautions to control such risks. It also focuses on preparing standard operating procedures and ensuring that everyone is aware of the risks and how to manage them.

243. Prior to the pandemic HSE also had webpages available where the above guidance documents could be accessed. For example, in relation to the healthcare workers specifically, a Healthcare page from 2020 discusses and provides guidance in relation to infection prevention (exhibit RGB/135 - INQ000269645).

244. The PPEW Regulations are the primary set of Regulations relating to the use PPE. However, most of the requirements do not apply to PPE which has been provided to protect against substances hazardous to health as COSHH deals with these. The PPEW Regulations are accompanied by HSE guidance documents:

a. L25 – Personal protective equipment at work 3rd (ed 2015) (exhibit RGB/136 - INQ000269664). This guidance is for those who have responsibility for the health, safety and welfare of people at work or for the safe operation of a workplace. It provides guidance on the steps to take to try to manage risks without resorting to PPE which should be used as a last resort. It includes

details of specific areas of risk and examples of the kind of PPE to consider using where the risk cannot be adequately controlled in other ways.

b. HSG53 – Respiratory protective equipment at work 2013 (exhibit RGB/137 - INQ000269685). This book provides guidance on the selection and use of adequate and suitable RPE in the workplace, in order to comply with the law. It helps users to decide the adequate level of protection for a given hazardous substance and how to select RPE that is suitable for the wearer, task and work environment. It also contains advice on how to make sure that the selected RPE keeps working effectively.

c. INDG479 – Guidance on RPE fit testing 2019 (exhibit RGB/138 - INQ000269542). This guide gives advice on fit testing for the employer and those conducting fit tests. This guide provides:

i. information on fit test methods;

ii. information on what can be achieved from a fit test; and,

iii. the core information to be included in a fit test report.

245. Also of relevance are the Management of Health and Safety at Work Regulations 1999 ["MHSW"], specifically:

a. Regulation 3 Risk assessment

Employers must make a suitable and sufficient assessment of the risks to the health and safety of its employees whilst they are at work and to any persons not in their employment where a risk arises out of or in connection with the employers undertaking, so that they can identify the measures needed to comply with the requirements imposed by the Regulations.

b. Regulation 4 – Principles of prevention to be applied

Where an employer implements any preventative and protective measures he must do so in accordance with the principles specified in Schedule 1 to the Regulations. Those principles include, inter alia, avoiding risks, evaluation of risks which cannot be avoided, combating the risks at source, adaptation of the work to the individual and giving appropriate instructions to employees.

c. Regulation 5 - Health and safety arrangements

Employers must make and give effect to arrangements, having regard to the nature of the activity and the size of the undertaking for effective planning,

organisation, control, monitoring and review of the preventative and protective measures.

d. Regulation 6 – Health surveillance

Employees must be provided with health surveillance having regard to the risks to their health and safety as identified in the risk assessment.

e. Regulation 7 – Health and safety assistance

Competent persons must be appointed to assist employers in undertaking the measures required to comply with the requirements imposed by Regulations, unless the employer is self-employed and not in a partnership, or where an employer is carrying on a partnership and has sufficient training and experience or knowledge to undertake the measures required.

246. As well as the Workplace (Health Safety and Welfare) Regulations 1992 ["WHSW"], more specifically:

a. Regulation 6 - Ventilation

Effective and suitable provision shall be made to ensure enclosed workplaces are ventilated by a sufficient quantity of fresh or purified air. The provision to control exposure to biological agents is covered under the COSHH (paras 219 – 231 above).

b. Regulation 9 - Cleanliness and waste materials ,

Every workplace, including furniture, furnishings and fittings shall be kept sufficiently clean. The surfaces of the floors, walls and ceilings of all workplaces inside a building shall also be kept sufficiently clean.

c. Regulation 10 - Room dimensions and space

The rooms where persons work shall have sufficient floor area, height and unoccupied space for the purposes of health, safety and welfare.

d. Regulation 11 - Workstations and seating

Workstations must be arranged so that they are suitable for persons at work in the workplace and a suitable seat must be provided where the work includes operations which can or must be done sitting.

e. Regulation 17 – Organisation etc. of traffic routes

Workplaces must be organised in such a way that pedestrians can circulate in a safe manner.

f. Regulation 21 – Washing facilities

Provision must be made for suitable and sufficient washing facilities, including showers if required by the nature of the work or for health reasons. Washing facilities includes a supply of clean hot and cold or warm water and cleaning means, for example, soap. The washing facilities must be sufficiently ventilated and lit.

CE Marking

247. CE marking is an indicator on many products that are traded in the European Economic Area, including PPE, which the UK was recognising at the time of the pandemic. A CE mark is a European mark of conformity. In the case of RPE/PPE, the CE marking shows that the manufacturer of the product has checked it against the relevant "essential health and safety requirements" of the PPE Regulation 2016/425 and had deemed it to be compliant. It also afforded the product the freedom of movement across the European market.

248. As stated above, Regulation 2016/425 is implemented in the UK by the PPE(E) Regulations and enforced by HSE for PPE manufactured and designed for use in the workplace.

249. Products could also be CE marked as medical devices in accordance with the Medical Devices Regulations 2002, enforced by the Medicines and Healthcare Products Regulatory Agency ["MHRA"].

250. The principal difference between PPE and a medical device is that PPE is designed to protect the wearer whilst medical devices protect the patient and prevent contamination during, for example, examinations and surgery. Some products may be considered dual purpose and would be expected to do both, in which case the product should have been subjected to both the PPE and medical devices Regulations.

251. It is possible to have equipment which performs at the same level but does not carry a CE marking because it has not been through the testing process. Conversely, some items may be marked with 'CE' which have been forged.

252. The presence of a CE marking on a product indicates to the purchaser, and end user, that the PPE has been designed and manufactured – and in many cases type-approved by a notified body – to a standard where it will offer the protection it claims. Where possible, the CE marking should be placed on the product itself so it is visible and gives the end users, in particular, reassurance that this process has been followed.

253. As part of the CE marking process, many products, such as respirators, will also be tested against relevant British, European or International Standards which set out more specific and detailed testing, marking and other requirements. Where this standard is harmonised (EU) or designated (UK), compliance with the standard allows a presumption of conformity with the Regulations and, whilst compliance with a standard is not mandatory in the case of PPE, this is a widely taken approach to complying with the EU 2016/425 Regulations.

Derivation / Easements

254. EU Recommendation 2020/403 (exhibit ref RGB/139 - INQ000269669) allowed deviation from Regulation EU 2016/425 on PPE on 13 March 2020. The deviation allowed PPE that had been shown to be suitably protective for protection against Covid-19 to be placed onto the market, even if not yet fully CE marked.

255. On 25 March 2020, the Deputy Chief Executive of OPSS (Office for Product Safety and Standards) wrote to me asking HSE to provide regulatory easement to allow for much needed equipment to be supplied to those who need it quickly (RGB/140 - INQ000269653). HSE were asked to be both speedy and pragmatic in its assessment of PPE needed urgently across the NHS. I will detail how HSE utilised the deviation below.

Types of Respirator & Mask

256. RPE protects the wearer from inhaling hazardous microorganisms and other particles via the nose and mouth. Respirators are classified on the level of protection they provide to the wearer. In the UK and Europe the relevant categories are filtering facepiece FFP2 and FFP3 respirators; the latter provides the highest degree of protection. In the UK, the standards for FFP respirators are set by the British Standards Institute ["BSI"]. In the United States the category of respirator comparable to FFP2 is classified as the N95.

257. For the products which protect against the most serious hazards (category III), this would involve conformity assessment of the product and the quality assurance system for the production process by an independent third-party. For example, an FFP3 respirator is a category III product. Products can be category I to III and need different levels of assessment and, in relation to category II and III products, independent verification as well. FFP3 which has been CE marked followed by the identification number of the notified/approved body that verified the quality assurance system for the production process shows it has gone through an independent assessment.

258. There are three types of surgical mask defined by BS EN 14683:2019 'Medical face masks – Requirements and test methods'. These are Type I, Type II and Type IIR. The Type IIR (sometimes referred to as Type 2R) provides the highest performance and is splash resistant, which is indicated by the 'R'. The Type IIR, is commonly referred to as a Fluid Resistant Surgical Mask ["FRSM"].

259. FRSMs are used as source control (all surgical masks provide varying degrees of source control), this means they are intended to limit the transmission of infective agents from staff (the wearer) to patients (non-wearer) during surgical procedures and in other medical settings. They can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms if they are able to wear them. The aim of universal masking in hospital settings using surgical masks was to reduce the emission of virus particles by everyone wearing a surgical mask.

260. While FRSMs have a certain bacterial filtration efficiency this is not to the same level as needed to be classed as RPE. Whilst surgical masks provide source control, they are not RPE so are classed as medical devices. This means where a COSHH assessment identifies that RPE is needed, a surgical mask would not be suitable. As a result, their manufacture and supply are not regulated by HSE but the MHRA.

261. HSE was not involved in the decision to replace RPE by medical practitioners with FRSMs in clinical settings when treating patients. The decision was made following the reclassification of Covid-19 by WHO.

262. The position around when to use FRSMs and when to use respirators was established by the Four Nations Guidance led by the PHE, UK Government and devolved nations). The position was considered further within HSE when new WHO guidance and SAGE Environmental Monitoring Group ["EMG"] papers were produced (exhibit ref: EMG 'Masks for healthcare workers to mitigate airborne transmission of SARS-CoV-2). However, the position did not change, in that RPE was used where AGPs were being undertaken, otherwise FRSMs should be used.

263. Neither COSHH nor PPEW were amended during the relevant period, save for the PPEW (Amendment) Regulations 2022 which came into force on 6 April 2022. The amendment was not prompted by Covid-19[11] and extended the application of the PPEW to include protection for workers, not merely employees.

[11] The amendment came about because of the ruling in *R (Independent Workers' Union of Great Britain) v Secretary of State for Work and Pensions and another* [2020] EWHC 3039 (QB) (Admin).

264. The published guidance referred to above also continued in its unaltered state.

265. Whilst the law and published guidance remained relatively unchanged during the pandemic, guidance issued by HSE through its website and other communication channels was routinely updated. Due to the dynamic nature of events, HSE were generally unable to consult with other stakeholders.

N95 and FFP2 Respirators as an alternative to the FFP3 Respirator

266. On 8 March 2020, HSE made drafting recommendations and comments in relation to PHE collaborative guidance for processing diagnostic samples in laboratories which was to alleviate the pressures of processing samples in the existing laboratory infrastructure. (exhibit ref RGB/141- INQ000269627).

267. Later in March, HSE were asked to comment on the PPE ensemble tables regarding FAQs for FFP3 (exhibit ref: RGB/142 - INQ000269625). On 31 March 2020, HSE provided advice in relation to the Four Nations PHE guidance (exhibit ref RGB/143 – INQ000269546, RGB/144 - INQ000269663 and RGB/145 - INQ000269654).

268. In summary, the choice of respirator must be based on an assessment of the risk. The UK recommended the use of FFP3 respirators when caring for patients in areas where high risk aerosol generating procedures ["AGPs"] were being performed. PHE provided guidance on when an FFP3 respirator was required. NHS trusts were told that if FFP3 respirators were unavailable, FFP2 respirators were recommended as a safe alternative.

269. Whilst FFP3 was the usual recommended control measure, it may not been reasonably practicable to use them if global supplies of FFP3 masks were low during a pandemic. In this scenario, an FFP2 could be used as an alternative where the risk assessment shows an FFP2 respirator is suitable for the activity being conducted. This was supported by Part One of the Rapid Evidence Review dated 27 March 2020 (exhibit RGB/146 - INQ000269674) where evidence was being examined in relation to FFP2 respirators forming part of the PPE ensemble when caring for patients with Covid-19.

270. In March 2020, WHO advised the use of a particulate respirator at least as protective as a US National Institute for Occupational Safety and Health ["NIOSH"] certified N95 when undertaking procedures likely to release Covid-19 into the air.

271. The Rapid Evidence Review produced key findings which were based on the limited studies available to March 2020 and intended to inform decisions on use of PPE in healthcare settings during the Covid-19 pandemic only. The key findings were as follows:

a. There is no material difference between N95 and FFP2 respirators in the protection they provide against inhalation of Covid-19 if the user has passed a face fit test to ensure the mask seal prevents inward leakage of the virus.

b. The evidence that aprons and gowns offer effective protection is limited.

c. Goggles and visors are necessary when there is a risk of contamination of the eyes from exhaled droplets containing Covid-19.

d. The selection of appropriate PPE should be determined by local risk assessment and reference to the UK Covid-19 guidance for healthcare settings.

Portacount Machines

272. There are two basic types of RPE fit testing – qualitative and quantitative. Qualitative fit testing ["QLFT"] is a pass/fail test based on the wearer's subjective assessment of any leakage through the face seal region by detecting the introduction of bitter or sweet tasting aerosol as a test agent. Quantitative fit testing ["QNFT"] provides a numerical measure of how well a facepiece seals against a wearer's face; this is called a fit factor. These tests give an objective measure of face fit, the 'fit factor', which is calculated by the fit test equipment.

273. Portacount machines are used within the health and social care sector as a means of quantitative face fit testing of RPE. There are currently 2 models available, the model without N95 technology incorporated and a model with incorporated technology.

274. The sector routinely use Portacount machines without incorporated N95 technology to face fit test for FFP3 respirators, however, these models are unable to deliver a face fit pass rate for FFP2 of 100 as stated in INDG479.

275. On 2 April 2020, the British Safety Industry Federation ["BSIF"] and, the organisation for accredited face fit testers, advised HSE that the NHS had numerous older machines that could potentially be deployed if the fit factor when using these machines was reverted back to the previous fit test HSE guidance, OC282/28, from 2003 (exhibit RGB/147 - **INQ000130552**).

276. On 7 April 2020, HSE agreed a temporary deviation (exhibit RGB/148 - INQ000269550) from the INDG479 guidance and accepted a face fit factor of 25 for FFP2 in line with previous guidance set out in OC282/28.

277. This is because the criteria of achieving a fit factor of 100 could not be measured using the older Portacount models 8030 and 8040 which do not have N95 technology. The requirement for a fit factor of 25 for FFP2s replicated HSE's previous fit testing

guidance which was in place before INDG479 was published in March 2019. This temporary deviation only applied to fit testing using the older Portacount models (8030 and 8040). Portacount models with the incorporated N95 technology should still have applied a fit factor of 100 for FFP2s.

FFP2/FRSM

278. HSE examined the use of FFP2 respirators as an alternative to FRSMs in non-surgical setting prior to Covid-19 in its 2008 report 'Evaluating the protection afforded by surgical masks against influenza bioaerosols'. The report concluded that surgical masks that are worn correctly should provide adequate protection against large droplets, splashes and contact transmission. This report is detailed further below at paras 391 - 398.

279. The findings helped inform and develop lines to take in relation to FRSMs and FFP2s during the pandemic. If risk assessment identifies a need for FFP2 respirators the user must be face fit tested to ensure they are providing the intended level of protection. In circumstances that a lower level of user protection is required, such as that provided by a surgical mask, an FFP2 worn without a face fit test will offer protection similar to the levels from a surgical face mask. This is because the respirator would only be performing the function of a FRSM which are loose fitting i.e. a barrier against droplets, splashes.

280. HSE considered this a pragmatic approach for times of severe shortage of RPE. Although FFP2 respirators being used in this way will not be carrying out the function they were designed to perform.

281. FFP2 respirators could be used without fit testing in place of FRSM in non-surgical scenarios only. If testing evidence of conformance for splash protection is not available, then a visor would need to be worn over the top.

282. All healthcare settings were reminded that, where their risk assessment has identified the requirement for a tight-fitting respirator, users must pass a face fit test for that respirator model before it can be used. Employers and users of respirators need to be assured protective equipment is protecting the wearer.

Essential Technical Specification

283. HSE also advised on the development of the PPE essential technical specification. This was used for companies developing new RPE and also the Government procurement of RPE.

284. New guidance was published in May 2020 (exhibit RGB/149 - INQ000269668) concerning essential technical requirements for new High-Volume Manufacture of PPE and Medical Devices during Covid-19 in conjunction with MHRA in order to assist DHSC with procurement and manufacturing opportunities.

285. The aim of the guidance was to set out the essential technical specifications that needed to be met for PPE to be used to protect health and care workers from Covid-19 and the item does not have a CE marking. These evolved over the course of the outbreak as more information and evidence became available, for example, designs that were not typically seen on the UK market, such as ear-loop respirators (which were non-compliant with the essential technical specifications, Table 2 page 9, exhibit RGB/150 - INQ). Amendments were discussed and agreed at the cross-departmental PPE Decision Making Committee with revised versions published in August and October (the October guidance is exhibited as RGB/150 - INQ000269667).

286. Guidance for manufacturers on evidence required by regulators (for FFP3 and FFP2 respirators, single-use isolation gowns, re-usable isolation gowns and visors and goggles) was developed in conjunction with the DHSC Make Cell in order to assist new manufacturers to be able to design and manufacture products to the meet the desired Covid-19 protection needs for healthcare. These incorporated the relevant Essential Technical Specification for that item of PPE. These documents were not published on gov.uk but were provided to BEIS on 7 August 2020 (exhibit ref RGB/151 - INQ000269589, RGB/152 - INQ000269647, RGB/153 - INQ000269655, RGB/154 - INQ000269636 and RGB/155 - INQ000269642).

Safety Notices & Alerts in relation to IPC in Healthcare Settings

287. Safety alerts are issued when there is a specific safety issue that without immediate action being taken could result in a serious or fatal injury. When dangerous equipment, processes, procedures or substances are identified during or after an investigation or as the result of a notification from Europe or industry, HSE may need to notify users and other stakeholders of the danger. HSE may also need to notify other users of the steps that need to be taken to rectify the fault or protect people against it; a safety alert is one way of achieving this.

288. Safety notices are issued where, under certain circumstances, an unsafe situation could arise. For example, where instructions or labelling for use are not clear, additional guarding may be required, operating parameters or procedures need to be changed, where this could, in some cases, lead to an injury. Action should be taken although it may not need to be immediate.

289. When potentially dangerous equipment, process, procedures or substances have been identified, and depending on the probability of the incident reoccurring and the possible severity of the injuries, HSE may want to inform all users and other stakeholders of the situation and the steps that should be taken to rectify the fault via a safety notice. Safety notices will be issued after consultation with stakeholders and may result in industry-led notices being issued at the same time.

290. During HSE's normal activities of inspection, investigation and dealing with concerns, we come across information that needs to be passed on either to a wide audience or to a specific group or sector of industry. HSE will use the most appropriate means to do this and it could be in the form of a safety alert, a safety notice or as part of communication via a range of media which will ensure the message is received by those who need to take action.

291. In June 2020, HSE published a safety alert in relation to the use of respirators which were designated as KN95 (a Chinese Standard), with ear-loop attachments (exhibit RGB/156 - INQ000269635). HSE became aware through the enforcement team receiving concerns and the number of enquires coming into Tech team of a considerable number of products which were unable to provide the level of protection they claimed. These respirators were being seen on a regular basis with fake or fraudulent paperwork and in many cases, because of the ear-loop attachments, were often failing the face fit testing requirements.

292. Prior to the pandemic, HSE had not seen ear-looped respirators in widespread use in healthcare settings so were unaware of the concerns around their suitability and effectiveness. Despite ear-loop RPE not being compliant with the essential technical specification, once HSE became aware, we made our position public and NHS procurement teams ensured that ear-looped respirators were no longer purchased. I exhibit the safety notice published in April 2022 as RGB/157 - INQ000269666.

293. In consultation with PHE, a safety alert was issued on 4 August 2020 following identification that TSI Portacount machines for quantitative fit testing had been calibrated to USA rather than UK guidelines. The alert was distributed via the Emergency Preparedness, Resilience and Response ["EPRR"] alert system in England, and shared with counterparts in Scotland and Wales for them to distribute. The alert included a reminder of the requirement for users to be fit tested (exhibit RGB/158 - INQ000269622).

294. During the summer of 2020 concerns were raised in relation to the use of PPE in the heat and risk of heat stress. HSE advised PHE in relation to an alert which was also distributed via EPRR (exhibit RGB/159 - INQ000269651).

Fit Testing

295. COSHH Regulation 7(1) requires that the exposure of employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled. In order to achieve this, several measures will be required, and providing RPE will be the last line of defence for the individual.

296. Where RPE is used, it must be able to provide adequate protection for individual wearers. RPE can't protect the wearer if it leaks. A major cause of leaks is poor fit. Tight-fitting RPE, such as disposable FFP3 masks and reusable half masks, rely on having a good seal with the wearer's face to be effective. A face fit test should be carried out to ensure the RPE can protect the wearer (as detailed below). Face fit testing is required as a control measure to comply with health and safety legislation, specifically para 160 of L5 ACOP.

297. The performance of tight-fitting facepieces depends on achieving a good contact between the wearer's skin and the face seal of the facepiece; inadequate fit can reduce the protection provided and lead to immediate or long-term ill-health, or can even put the RPE wearer's life in danger.

298. As people's faces are different shapes and sizes it is unlikely that one particular type or size of RPE facepiece will fit everyone. Fit testing will ensure that the equipment selected is suitable for the wearer.

299. HSE guidance on fit testing, INDG479, defines Fit testing as a method for checking that a specific model and size of tight-fitting facepiece matches the wearer's facial features and seals adequately to the wearer's face. It will also help to identify unsuitable facepieces which should not be used. A typical fit test is a brief (approx. 10 minutes) dynamic test which is administered and closely-controlled by a 'fit tester'. The whole process takes around 20 minutes.

300. On other the hand, BS EN 529 defines a 'fit check' as a simple assessment of the correct fitting of a facepiece, based on the opinion of the wearer. BS EN 529 further states that Fit checking methods are quick and simple, but can be relatively insensitive to small leaks. They are used as a daily pre-use check for a facepiece already matched to the wearer by use of a fit testing method. INDG479 gives additional information that

the fit check is a check to determine whether the wearer has correctly donned a facepiece before entering a contaminated work area.

301. In an email, the lead Chief Executive for NHS Trusts asked HSE to remove the requirement for fit testing, and replace it with a fit check (exhibit RGB/160 - INQ000269549). Given the shortages of RPE, healthcare were purchasing different models of RPE which resulted with workers wearing different models of RPE on a daily basis. This required fit testing of each worker on each new RPE model. The increased amount of fit testing was putting a strain on resources within healthcare.

302. Fit testing is integral to ensuring that FFP3/FFP2 and N95 respirators (required by PHE guidance and local risk assessment) are suitable and afford frontline workers the intended level of protection. In short, fit testing is essential to ensure that respiratory protective equipment actually protects.

303. HSE cannot provide a derogation of the requirement to fit test. Not only could this lead to frontline staff being inadequately protected, it would also undermine the regulatory requirements and established expectations of HSE guidance. Employers who have suspended face fit testing or who do not have in place robust arrangements for ensuring that employees are fit tested for their filtering face piece respirators will not be able to demonstrate that they are adequately controlling the risk to their front-line workers exposed to Covid-19, leading to potential consequences for their own health, and further burden on the NHS.

304. As with all health and safety at work legislation, HSE expects to see employers discharge their duty by having in place arrangements to manage risks their employees and others are exposed to. Given the supply chain issues, it is foreseeable that at times meeting the requirement will be challenging, for example, potentially low stocks of qualitative testing fluid or a different variety of respirator being delivered.

305. The employer should have in place contingency arrangements to ensure risks are appropriately managed. A package of measures would be required: for example, having additional personnel trained to carry out fit testing to accommodate a short-term increased demand when a new type of respirator is provided; or putting in place emergency arrangements to call in a third party to assist. Employers could also provide a back-up supply of alternative RPE that does not require a fit test, such as a loose-fitting powered hood conforming to BS EN 12941 with a minimum Assigned Protection Factor of 20.

306. Therefore, in reply to the request to relax 'fit testing' to 'fit checking', HSE advised NHS Trusts that 'a fit-check should never be used as a substitute for a fit test' (exhibit ref RGB/160 - INQ000269549).

307. That position was reiterated and clearly set out in the letter from NHS England and NHS Improvement ["NHSE/I"] to the Shelford Group (a collaboration of 10 large teaching and research NHS trusts in England) by way of letter dated 9 April 2020 (exhibit ref RGB/161 - INQ000269646).

308. This exchange followed earlier meetings with PHE on 22 March 2020 (exhibit ref RGB/162 - INQ000269543) and PHE, DHSC, and the New and Emerging Respiratory Virus Threats Advisory Group ["NERVTAG"] on 25 March 2020 (exhibit ref RGB/163 - INQ000269543), where HSE had adopted the same approach.

309. In response, HSE provided support to increase the availability of fit testing fluid and liaised closely with BSIF to support NHS access to qualified fit testers as well as providing technical input to PHE in relation to the use of N95/FFP2 respirators through the rapid review mentioned above at paras 264 - 266.

310. As a result of the increased demand of fit testing there was a temporary shortage of fit testing solutions. Qualitative Fit Test solutions should be compliant with the requirements of BS ISO 16975-3:2017. HSE provided information about how to make fit testing solutions according to information given in ISO including the chemicals and concentrations. HSE also provided information about using different salt compounds if the ones described in ISO 16975-3 were no longer available (examples at exhibit ref RGB/164 - INQ000269541, **RGB/138 - INQ000269542** and RGB/166 - INQ000269552).

311. To promote the proper donning and use of disposable respirators, HSE also produced a guidance poster (exhibit ref RGB/167 - INQ000269684) on how to don RPE correctly and how to perform a user seal check in March 2020.

312. FFP respirators cannot be worn by healthcare workers with facial hair as they won't be able to pass a fit test. HSE advised that an alternative type of respirator is a powered respirator with a hood. This passes a flow of filtered air into the breathing zone of the wearer. Wearers of powered respirators, where there is not a tight-fitting mask, do not need to be clean shaven.

313. HSE also issued guidance in relation to reducing the spread of Covid-19 while carrying out fit testing (exhibit ref/168 - INQ000269614).

RPE Testing

314. HSE were not routinely involved in 'testing the adequacy or standard of RPE' prior to the pandemic. The role of ensuring that RPE is adequate and meets the relevant standard lies with the manufacturer of the product.

315. In order to provide more detailed, specific requirements for filtering face pieces (respirator) BS EN 149:2001+A1:2009 'Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking' was produced.

316. Clause 8 of this Standard details the testing procedures which the manufacturer should follow, including tests relating to simulated wearing of the product, practical performance and requirements relating to the total inward leakage. A specific requirement of this standard is that during the total inward leakage test, a panel of 10 test specimens should "...be selected covering the spectrum of facial characteristics of typical users...".

317. Products tested to BS EN 149 would be considered as tight-fitting and would not be suitable for wearers with facial hair, glasses, religious head coverings and other PPE (such as goggles or visors) which might also affect the tight fit of the respirator. This is why the face-fit test is important as not every respirator will fit every person.

318. HSE did undertake a rapid evidence review of N95 respirators (exhibit RGB/146 - INQ000269674) to see if they could be used by healthcare workers to maximise supply chains. The report was published on the HSE website and our findings were:

    a. The N95 respirator has been assessed by HSE as providing protection equivalent to that of an FFP2 disposable respirator, as long as the wearer has passed a face-fit test. N95's have only been agreed for use in a healthcare setting where there is a shortage of FFP3 and FFP2 respirators.

    b. The UK recommends the use of FFP3 respirators when caring for patients in areas where high risk AGPs are being performed.

    c. When FFP3 respirators are not available, then FFP2 respirators may be used.

319. HSE itself did not undertake testing of RPE, other than that identified above, during the relevant period. Where testing was required to get PPE to market, it was conducted by OPSS on the instruction of the lead regulator, depending on whether the item a medical device or PPE (para 12 of RGB/169 - INQ000269662).

320. The COSHH Regulations require RPE that is provided to be suitable and sufficient. The L5 ACOP at para 160 details what should be considered in terms of suitability.

HSE guidance at the time, HSG53, details suitability factors to consider at Table 3, this includes wearing glasses and facial hair and requires wearers of tight-fitting RPE to pass a fit test. Not everyone will be able to wear tight-fitting RPE, but in such circumstances other RPE types that are loose-fitting should be considered.

321. HSE Science Division did embark on research in relation to fit testing of CE marked ear loop respirators (exhibit RGB/170 - INQ000269659), but this was not published within the relevant period.

322. Ninety quantitative face fit tests were undertaken on nine different models of respirator obtained from a number of manufacturers. Ten different test volunteers were included to cover different face sizes, both male and female. Out of the ninety tests, only two tests had overall fit factors which achieved the pass rate of 100.

323. The findings also showed that the ear loop straps failed to provide adequate tension to securely hold the respirator in place. This lack of tension, combined with the fit of the nose clip around the wearer's nose, resulted in visibly large gaps around this area. Test volunteers reported that the respirators fitted too loosely on their faces, and they detected substantial leakage of air, mainly due to the lack of tension provided by the ear loop straps.

324. The results of this research led to the publication of the HSE safety notice: "Ear loop respirators/masks do not provide protection as tight fitting RPE" (exhibit RGB/157 - INQ000269666).

325. HSE issued an easement in relation to 'ClearMask' on 23 May 2020. At that time, PHE believed Covid-19 was not transmissible via the airborne route. The ClearMask offered considerable advantages for certain patients and staff with communication difficulties and the product offered similar splash protection to that of a FRSM, but was not CE marked. I exhibit the notes regarding the use of ClearMask as exhibit RGB/171 - INQ000269616.

326. Its use was subject to risk assessment by the clinicians, however, we received multiple queries about when and where it could be used, as there seemed to be a lack of ability or confidence in being able to conduct a risk assessment of where it's use would be more beneficial than not.

HSE Advice to NHS in Relation to IPC Measures

327. From mid-March 2020 onwards HSE was actively engaged with PHE, NHS, and other stakeholders including BSIF to ensure there was a clear understanding about the

standards of RPE required as set out in the Four Nations IPC guidance, the importance of fit testing and to support the effort to increase the supply of fit testing fluid.

328. Through the PPE Unit, HSE responded to hundreds of enquiries from the public, employers and other stakeholders which included healthcare organisations throughout the pandemic. Lines to take were developed and updated as the pandemic progressed to ensure that HSE were consistent with the advice being provided

329. It was a dynamic and challenging period. Meetings were ad hoc and in many instances comments on various documents were invited by close of play the same day. Not all contacts were recorded due to the fast nature of events.

330. Examples of where HSE provided advice include:

331. In April 2022 HSE provided comment on the National IPC Manual (exhibit RGB/172 - INQ000269686). The guidance had already been published before HSE were invited to comment, and was intended to replace the Four Nations Covid-19 guidance in England. The guidance included the protection of workers but was primarily written from a patient safety perspective.

332. HSE received a request to contribute to the proposed National Patient Safety Alert on use of valved respirators (including PAPRs) during surgical procedures. It was produced in response to the alleged risk of contamination / surgical site infection from unfiltered exhaled breath from valved respirators. The main HSE concern was if the risk assessment means theatre staff were required to wear RPE, but cannot be fit tested to tight fitting respirators, are they then excluded from participating in operations as PAPRs also exhale the wearer's breath? HSE advised on the importance of ensuring if RPE is needed and no non-valved options available, then the worker must wear suitable RPE for their protection, even if valved is all that is available (exhibits RGB/173a - INQ000269639, RGB/173b - INQ000269619, RGB/173c - INQ000269621 and RGB/173d - INQ000269602).

333. HSE was asked to provide advice in relation to queries received by UK IPC cell on patient use of FFP3s in the Republic of Ireland guidance and suggestions of extended FFP2 use in Trafford CCG. HSE advised that the roll out of jurisdiction and patient safety in England is for CQC, but if applied here patients requiring RPE would need to be successfully fit tested. In relation to extended FFP2 use, we advised if Risk Assessment indicates RPE then guidance says it should be FFP3 (exhibit RGB 174 - INQ000269605). In any event UK IPC reverted and confirmed Trafford CCG using FFP3 on risk assessment, and fit testing provided.

334. HSE responded several times to requests from NHS UK IPC cell for comments on NHS England IPC Manual. Examples include:

a. October 2021: Query on what version of IPC Guidance used October 2021. A response to query from UK IPC Cell on what version of IPC guidance is used as the benchmark for HSE inspections. HSE advised the current version at that time is the one that is used. (exhibit RGB/175a - INQ000269604).

b. April 2022: Concerned a response to query from UK IPC Cell on use of FFP3s and splash resistance. We clarified that the British Standard requirement for FFP3 respirators does not include a test for splash resistance and if required a visor or similar will need to be used, unless there is an FFP3 that does claim suitably tested splash resistance (exhibit RGB/175b - INQ000269613).

c. June 2022: Commentary HSE provided on the IPC Guidance (exhibit RGB/175c - INQ000269634).

335. I also provide an example of a more technical query regarding the National Ambulance Resilience Unit and the Royal College of Nursing regarding the type of protective coveralls that were suitable (exhibit ref RGB/176a - INQ000269544, RGB/176b - INQ000269688 and RGB/176c - INQ000269551).

336. Other examples include supporting lines taken. For instance, in relation to fit testing, Cambridge University Hospitals advised they did not have the capacity to fit test, but they had undertaken a risk assessment and would carry out fit checks instead. HSE responded advising fit testing was integral to ensure that FFP3/FFP2 and N95 respirators (required by PHE guidance and local risk assessment) are suitable and affords your front-line workers maximum protection (exhibit ref RGB 177a - INQ000269631 and 177b - INQ000269661).

Re-use of PPE/RPE

337. Over Easter 2020, HSE worked with PHE regarding the 'Considerations for Personal Protective Equipment in the Context of Acute Supply Shortages for Coronavirus Disease 2019' guidance around extended wear time (over and above the usual recommended one-hour continuous wear time) and redonning/doffing the same RPE by the same wearer on the same shift when there was a shortage of supply.

338. The guidance permits that disposable PPE can be re-used providing that:

a. it remained adequate and suitable and is undamaged

b. it continues to provide the intended protection, and;

c. workers can put it back on without being exposed to risk.

339. The "disposable" term applies to the end of a period of reasonable use e.g. a working day or shift or possibly longer in some cases. A "disposable" mask may be taken off and re-used numerous times during a day. This will depend on specific circumstances of use. I exhibit a copy of HSE comments on the guidance as RGB/178a - INQ000269633 and the guidance itself as RGB/178b - **INQ000106358**

340. Advice was also given in relation to type 5 Cat III coveralls made from a higher density polypropylene. They will be stronger than lighter weight Type 5 Cat III coveralls which may be more susceptible to wear and tear.

341. HSE were represented on a cross-Government PPE Decontamination and Reuse Group. This was set up at pace and explored the technical feasibility of potentially decontaminating and reusing single use PPE. This technology was never deployed, however, there were some limited examples found of specific RPE models where decontamination technologies appeared to be effective at decontamination, whilst still retaining the protective characteristics of the PPE.

342. The group produced some draft guidance on the procedures necessary to ensure effective decontamination and the tests necessary to assure adequacy. This guidance was never published and remained in draft, as the supply situation eased.

343. HSE also undertook research at its laboratory in Buxton regarding the technical feasibility of decontaminating FFP3 respirator models with hydrogen peroxide vapour. This study is published internally as Science Division reports HG/2020/25 (exhibit RGB/179 - INQ000269680) and HG/2020/27 (exhibit RGB/180 - INQ000269679). HSE's policy position was explored, and it was determined that there were provisions within the COSHH for HSE to potentially authorise the use of decontaminated single use respirators if they could have been shown to have been suitable and adequate for use post-decontamination. This provision was never enacted and did not extend to other items of single use PPE.

344. The above papers did help inform HSE's Evidence Report ER004 on the decontamination and reuse of PPE in January 2021 (exhibit RGB/181 - INQ000269677). The report considered evidence published between January 2020 and August 2020 and was prepared to address a request from UK Government for information about the re-use of PPE, and whether after disinfection its performance as PPE will be compromised. The paper delivered the following key messages:

a. PPE designed for re-use can be disinfected using a range of methods including thermal treatment, chemical treatment and ultra-violet (UV) irradiation.

b. The most suitable disinfection approach will depend on the particular PPE item. Effective disinfection requires good protocols to be developed and followed. Damaged or heavily soiled PPE items should be discarded.

c. Re-use of PPE that is designed for single use should only be considered as a last resort. There is evidence that some items can be disinfected without compromising their performance as PPE. However, some methods can damage material integrity and reduce the effectiveness of the items. This is a particular risk for RPE.

d. If PPE needs to be re-used, behavioural aspects around its use need to be considered. There is evidence that employees can be uncomfortable about wearing RPE previously been worn by someone else, even when the PPE is designed for re-use and can be decontaminated without compromising its performance.

e. Reusable PPE manufacturers' instructions for use (including cleaning and disinfection procedures) should be followed. When considering the re-use of PPE users need to assess the likely reduction in its effectiveness if they use alternative cleaning/disinfection procedures not recommended by the manufacturer.

f. Medical masks are shown to be better than cloth face coverings to protect the wearer from infection, but there is little evidence yet on the most suitable methods of washing cloth face coverings or whether these degrade over time.

g. Any system for re-use of PPE would require strict procedures and instructions for users,and needs to recognise that the results from successful trials of PPE reuse can only be applied to the specific makes/models of PPE investigated and cannot be generalised and applied to all PPE of that type.

345. In Scotland the policy on re-use/sessional use had been set in a letter dated 28 May 2020 from the Scottish Government's, Chief Nursing Officer. The Scottish Government made it clear that single-use PPE must not be reused and should be disposed of after use into the correct waste stream.

346. Sessional PPE use in some circumstances has been agreed by HSE. This includes single use long-sleeved gowns, masks and eye protection which can be worn for a full session, without the requirement to be changed between patients. This decision was

taken to ensure that health and social care workers are able to safely carry out their work when they are working in areas where there is a high risk of Covid-19 transmission such as Emergency Departments or intensive care units. Sessional use is described as a period of time where a health or care worker is undertaking duties in a specific care setting. The session ends when the health or care worker leaves that care setting e.g. a person's home, private room or ward.

Cleaning and disinfecting reuseable RPE

347. HSE considered the appropriate cleaning methods for reprocessing (cleaning and disinfection) RPE in a healthcare setting. Employers should carry out a risk assessment before purchasing and deploying reusable RPE and if necessary, should contact the manufacturer for advice on the cleaning/disinfection (reprocessing) of these devices, and satisfy themselves that there is nothing further that may impact upon the risk assessment and decision made. For reusable RPE already purchased for use in a healthcare setting, where the manufacturer's instructions for use ["MIU"] do not clearly state how the RPE should be cleaned and disinfected, employers must satisfy themselves that any cleaning/ disinfection (reprocessing) will not degrade the RPE and that it will remain suitable and effective (adequate and suitable) for the intended purpose; this includes passing face-fit testing. Employers were advised to contact the manufacturer for advice on the cleaning/disinfection (reprocessing) of these devices.

348. Where the MIU does provide clear cleaning/disinfection (reprocessing) guidance and:

    a. the employer has deemed the RPE suitable for use in a healthcare setting where microbiological contamination may be a factor

    b. it is considered that the cleaning/disinfection (reprocessing) method described will not meet the healthcare decontamination/infection control requirements

    c. the manufacturer knows of no reason why the reusable RPE cannot be decontaminated

    Alternative cleaning methods may be used. These methods will need to be appropriate to the contamination of the RPE and produce an effect equivalent to, or better, than the method(s) set out in the MIU.

349. It remained the responsibility of the employer, e.g. NHS Trust or Board, to demonstrate or evidence that the alternative cleaning and disinfection (reprocessing) method employed did not compromise the integrity of the product or the safety of the user.

350. HSE was commissioned by SAGE to review the decontamination and reuse of PPE. The paper (exhibit ref RGB 182a - **INQ000075024** and 182b - INQ000269671) was endorsed at SAGE on 10 September 2020 (exhibit ref RGB/183 - **INQ000120554**). The paper found:

a. PPE that is designed for re-use can be safely disinfected using a range of methods including thermal treatment, chemical treatment and UV irradiation. The most suitable approach will depend on the particular PPE item. Effective disinfection requires good protocols to be developed and followed. Damaged or heavily soiled PPE items should be discarded.

b. Re-use of PPE that is designed for single use should only be considered as a last resort. There is evidence that some items can be safely disinfected, but some methods can damage material integrity and reduce the effectiveness of the items. This is a particular risk for respiratory protective equipment (RPE). Most studies have been carried out using surrogate microorganisms rather than the SARS-CoV-2 virus.

c. If PPE needs to be reused, behavioural aspects need to be considered. There is evidence that people are uncomfortable about wearing RPE that has previously been worn by someone else, even when this is designed for re-use and has been safely decontaminated.

d. Medical masks are shown to be better than cloth face coverings to protect the wearer from infection, but there is little evidence yet on the most suitable methods of washing cloth face coverings or whether these degrade over time.

Other Themes

351. I have dealt with the guidance as it related to RPE and fit testing. However, we received a number of enquiries in relation to fit testing for those with facial hair.

352. HSE received correspondence from the Sikh Council (exhibit ref RGB 184a - INQ000269687), which was taken up by NHSE/I, proposing a solution for Sikh's, who are unable to be fit tested, by wearing a FFP2 mask with an additional FRSM to be extended over the borders of the FFP2.

353. HSE responded by advising that tight fitting respirators needed to be fit tested and if the worker cannot be adequately protected from the risk of Covid-19 the employer should question whether the procedure can go ahead, or whether there is an alternative way of providing the treatment (exhibit ref RGB/184b - INQ000269630).

354. Queries from the NHS ranged widely. HSE were asked in relation to the application of a public mask exemptions for workers in healthcare settings. The issue arose from workers that have official exemptions on wearing masks in public but were required to wear at work. HSE only have a remit in relation to PPE, not merely face coverings. HSE advised if PPE was used for worker protection in a workplace, including healthcare settings, then must be worn and there could be no exemption under health and safety law. The inability to wear the required PPE at work, and possible exclusion, is an employment law matter and not for HSE (exhibit RGB/185 - INQ000269612).

355. In May 2020 we responded to a request from UK IPC Cell for advice on safe use of oxygen cylinders and alcohol-based hand gel. This was reflective of increased use of both at the outset of the pandemic and fire risk associated with both. HSE Process Safety specialists highlighting precautions that should be taken to control risk (exhibit ref RGB/186 - INQ000269615).

356. HSE also gave advice to the NHS UK IPC Cell in relation to NHS risk assessment tools. HSE advised PPE/RPE should only be considered once all other control measures further up the hierarchy have been exhausted and if RPE is identified as an appropriate control measure then the guidance in HSG53 should be followed (exhibit ref RGB/187a - INQ000269608 and RGB/187b - INQ000269626).

357. RPE, such as FFP2 or FFP3, which were manufactured in China, were being labelled as 'not for medical use' due to Chinese exporting regulations. In China, PPE and Respiratory Protective Equipment (RPE) are manufactured for a different purpose or sector, despite being used extensively in UK healthcare settings. UK legislation does not make sector specific considerations and products are judged to either meet the required essential health and safety requirements or not. Many of these products have been safely used in UK workplaces for many years and will have been certified by an independent European notified body and have been tested as suitable for use in the workplace as RPE (including in medical settings). FFP masks are not classed as medical devices, they are classed as PPE. This means they are subject to the requirements of the PPEW and COSHH. RPE labelled 'not for medical use' etc. can still be used as PPE in healthcare settings providing:

    a. it meets required health and safety standards,

    b. the 'not for the medical use' mark is removed or covered.

358. A 'not for medical use' label affixed to packaging or a product is an instruction relating to the use of the product and requires the user to follow the instructions provided by the manufacturer. Following a change to Chinese PPE exporting regulations, with

effect from April 2020 all PPE, including respiratory protective equipment (RPE), such as FFP2 and FFP3 respirators, must state 'not for medical use' on its packaging so that they are not subject to additional exporting processes by differentiating them from medical devices. This is not an issue in UK legislation where we do not make sector specific considerations as once products are judged to meet the required standards they can be used wherever they will be suitable and sufficiently protective.

359. The key concern was compliant Chinese FFP2 and FFP3 respirators that had been suitably tested and would be able to provide the necessary degree of inhalation protection for healthcare workers as they would be labelled by the manufacturer as 'not for medical use.' In such circumstances employers have a duty under the Personal Protective Equipment at Work Regulations 1992 and the Control of Substances Hazardous to Health 2002 Regulations (as amended) to ensure that any PPE is only used in line with manufacturer's instructions, as well as being suitable for use. In accordance with the guidance in paragraph 75 of the Respiratory Protective Equipment at Work Practical Guide (HSG53 Fourth Edition, published 2013)[1], employees must also use RPE in accordance with manufacturer's instructions and the training and instruction provided by their employers. Therefore, any PPE or RPE labelled as 'not for medical use' that would otherwise be safe and suitable could not be used in healthcare settings in the UK without the labelling being removed or covered.

360. Products marked with 'not for medical use' labelling have the potential to create concern and confusion amongst end users in terms of whether they are fit for purpose, hence why removal and/or covering is necessary so that clear information is provided to end users. The possible consequences and impact of not removing or covering the mark could create distrust amongst healthcare workers that they were given unsuitable or unsafe PPE which could result in healthcare workers refusing to use the PPE and the consequences which flow therefrom.

361. The NHS is the key stakeholder impacted by this issue with millions of items of RPE (and other PPE being imported) intended for use in the NHS supply chain including supplying care homes. PPE marked 'not for medical use' may also be found in other areas, such as dentists and health and social care settings.

362. As the GB market surveillance authority ["MSA"] for PPE, HSE was asked for advice on how these products can be used, despite them being labelled as 'not for medical use' and in light of the export declarations, HSE advised that, to supply RPE into healthcare the 'non-medical', 'not for medical use' or similar wording must be removed

[1] Respiratory protective equipment at work: A practical guide HSG53 (hse.gov.uk)

or covered. Outside of healthcare this marking is not a problem and does not need to be removed or covered.

363. The revised labelling caused concern and/or confusion amongst healthcare employers and employees so, to support and explain this change, the supply chain where they chose to supply to healthcare settings, should have provided relevant information to users, to demonstrate the items are still safe for use in a healthcare setting. I exhibit the DHSC paper which HSE advised on as RGB/188 - INQ000269755.

Liaison with Chief Medical Officer

364. The Chief Medical Officer ["CMO"] and Deputy CMO for Scotland along with HSE Chief Scientific Adviser were SAGE participants. All contact with CMOs, save for what is set out above, was conducted through SAGE.

365. HSE were also observers at the Advisory Committee on Dangerous Pathogens and the ACDP included the CMO England.

366. The Deputy CMO England sat on the New and Emerging Respiratory Virus Threats Advisory Group ["NERVTAG"] and where HSE occasionally attended, however, once again, this was in an observational capacity.

PPE Shortages

367. HSE would not ordinarily be expected to be notified of a shortage of PPE/RPE in any industry, however HSE was aware of a number of specific examples of shortages in PPE and RPE and specific steps taken to address those shortages were discussed above in relation to:

a. Re-use of PPE;

b. Decontamination;

c. Portacount machines;

d. FFP3 / FFP2 / N95 / FRSM provision and use; and,

e. Non-CE marked RPE easements.

368. As highlighted in para 250, HSE was written to on 25 March 2020 by the OPSS in a letter which requested HSE's assistance to "...provide regulatory easement to allow for much needed equipment to be supplied to those who need it quickly".

369. Historically HSE had a generic email for PPE related queries with a single point of contact which had been managed by one person. It was clearly evident from an early stage that further resourcing would be required. To help deal with queries in relation to

easements and product specifications, a Technical Working Group was established in the middle of March.

370. Large volumes of PPE were also arriving at a warehouse in Daventry. I visited the Daventry site over the Easter weekend of 2020 (13 April 2020). The visit was in response to an approach by DHSC to HSE as experts in PPE and the MSA. The visit was a scoping exercise so that HSE could understand the challenges faced in being able to identify the suitability of PPE at the distribution depot, consider how HSE could best support the on-site personnel to expedite the distribution of PPE and stand up a team big enough to work through the volume of equipment anticipated to be flowing through the warehouse at Daventry, also known as 'Clipper', and support the increasing number of queries being received.

371. The army personnel drafted to despatch PPE to the front-line NHS had quarantined product that amongst other things had:

a. Been donated and so were unaware whether the product could be used safely.

b. Arrived through procurement but with obvious flaws, for example torn gowns and gowns with sleeves that had not been attached properly.

c. Markings on the outer boxes only, that had been challenged by the end users over what it could be used for as the level of water resistance was unknown once distributed throughout the Trust.

d. Products that were inconsistent throughout the shipment such as colours and/or made from different materials.

e. Failed rudimentary tests in an attempt to overcome labelling and inconsistent shipments.

f. Insufficient information to determine the level of protection that the item was intended to provide and this could not be determined from visual examination.

372. Army personnel had picked samples of some of the products that had been quarantined and required a decision on release – I believe these had been prioritised based on NHS demand for equipment (operating gowns, respirators etc.). Some products were in huge volumes, stored on many pallets, others were single items donated as part of a mixed pallet from local businesses.

373. There were hundreds of samples, the majority were labelled in Chinese and appeared to refer to Chinese standards. Whilst it was not possible to read the labelling, it was

clear from inspection of the products that a significant percentage were regulated as medical devices.

374. It was clear from the volume of products that additional resource would be necessary to support the Technical Working Group.

375. By mid-May 2020, HSE had assembled a team of specialists made up of inspectors, specialist policy makers, scientists and administrative support. The team was known as the 'PPE Unit'. Details of the Unit were set out in a Key Information Document dated 13 May 2020 (exhibit ref RGB/189 - INQ000269718).

376. The purpose of the Unit was to co-ordinate and provide responses to questions that could not be answered using agreed lines to take and were sensitive, or required specialist technical input. Existing mechanisms for dealing with Covid-19 PPE questions (Resilience team, CAT team and Sector teams) would continue to answer questions based on the agreed lines to take. Particularly sensitive decisions, especially about health care derogations and other decisions to release PPE into the supply chain, would be agreed by the Decision-Making Group ["DMG"].

377. The PPE Unit consisted of the following teams in May 2020:

a. Centre for Workplace Health ["CWH"] Triage Team: Controlling the workflow using prioritisation guidelines (below), with a view to allowing the Technical team, Policy team and DMG to focus on matters that only they can resolve.

b. Resilience team: Dealing with all Covid-19 related questions, including those relating to PPE, which can be dealt with using LTT and sources of advice such as OPST Sectors and PPE Policy team.

c. Technical team: Provided HSE's expert opinion on all Covid-19 PPE matters.

d. Policy Team: Advised PPE Unit (and other policy leads) on implications of decisions and responses.

e. Decision Making Group: Made all decisions on health care derogations and particularly sensitive decisions on releasing PPE into the supply chain.

f. Supply Team: Reviewed suitability of specific consignments of PPE arriving at Daventry Warehouse. Decide on the suitability of such consignments where this can be done using pre-prepared criteria agreed by DMG. Considered whether testing was necessary for consignments which did not have the

necessary documentation to be used legally without testing. Investigated and took enforcement action where required[12].

g. Health & Social Care Sector: Continued working with Resilience team to respond to (or contribute to) non-technical healthcare PPE questions and those which could be dealt with using existing LTT.

h. Non-healthcare sectors: Advising PPE Unit (and other parts of HSE) on PPE matters for non-healthcare settings.

i. MHRA/OPSS liaison (to be identified): Promulgation of DMG decision to OGDs and other regulators.

j. Communications team: Developed internal communications content to ensure all relevant colleagues were aware of scope of PPE Unit and processes for referral.

k. Other Sector teams: Responded to routine questions using existing LTT.

378. The Unit was asked to ensure that PPE met the relevant essential health and safety requirements of the PPE Regulations and that any accompanying paperwork, such as certification and test reports, were in order. Where PPE met the essential health and safety requirements, but the item was non-compliant in some other minor way – missing the CE marking or the conformity assessment had not been completed – HSE were asked to allow the product to be supplied into healthcare settings to relieve some of the shortages being seen by staff on the frontline.

379. The DMG reviewed and, where appropriate, agreed easements to suppliers of such PPE where it was proven that it would protect the wearer, under easement in response to the EU derogation.

380. The Supply Team provided an escalation email (including Whatsapp group) to the MSA where necessary (for critical supply status) in advance of and over the weekends. This was priority based on unit number to assist in ensuring we were targeting our resource where demands were high and stock was low. Once the data had been migrated to OPSS, they also set up a system whereby each MSA would be sent an alert email advising that new products arriving had been uploaded. This ensured that MSA were working with live data and keeping up with requests.

[12] The work of the supply team is explored further below.

381. HSE has no vires or market surveillance responsibility for medical devices to enter the workplace. Consequently, a similar team from MHRA was needed to review such devices.

382. The HSE team also prepared and delivered training with colleagues from OPSS and MHRA to a team put into Daventry by DHSC to pick sample products in lieu of the army. The training included understanding what was PPE as opposed to a medical device, how to apply to HSE's Technical Team for easement of any products not CE marked or subject to an existing easement, contact arrangements for test houses to both procure their services and to check authenticity of certification supplied with the products.

383. The team at Daventry used its expertise to filter out products that would clearly not pass the agreed 'Essential Test' requirements to protect healthcare.

384. Despite release of all CE marked PPE the volume of quarantined stock grew from one floor of a single warehouse to over 25 warehouses with stock also being held in shipping containers. Product was arriving at the depot without evidence of it being tested to a standard that would provide protection to the wearer. In many cases where evidence was provided it was not bona fide; test houses confirmed they had not tested the product nor issued the certification. As this information flowed the OPSS database had to evolve to capture the information to prevent a different supplier from flooding the market with the same product and fake certification. The Daventry team pushed non-easement PPE supplier information to the market surveillance team to approach the suppliers.

385. HSE was also aware of a consignment of respirators manufactured by 3M respirators that formed part of the Government pandemic stock that had been previously 're-lifed' by 3M. However, 3M would not extend the life further following a second approach by the Government to do so.

386. HSE experts agreed with DHSC that if the respirators met certain tests they could be used. A number of product lines had been over labelled. The original expiry dates pre-dated those that had been subject to the re-lifing by 3M. These original dates were not included in the samples that HSE's experts had agreed could be retested. HSE quarantined the remaining stock at Daventry (exhibit RGB/190a - INQ000269557, 190b – INQ000269725 and 190c - INQ000269710). However, these were subsequently released due to demand that weekend. Some of these respirators were never within the batches tested and therefore the effectiveness and level of protection is unknown.

387. At its peak, there were approximately 35 million PPE units being dispatched during April 2020, this dropped to two million by August (as referenced letter from DHSC to LRFs on 14 August 2020 exhibited as RGB/191 - **INQ000058105**).

Action Taken in relation to the Supply of PPE / RPE

388. Between May 2020 and the end of April 2021, the HSE stood up a PPE Supply Team as part of the PPE Unit to address the increasing number of concerns received regarding the suitability of PPE/RPE being supplied to protect against the Covid-19 virus. As detailed previously, the Supply Team undertook the MSA function regarding PPE/RPE for healthcare until it was disbanded. This team dealt directly with concerns raised by purchasers and users of PPE/RPE as well as suppliers, public bodies and members of the public. The concerns predominantly focussed on the suitability of respirators/face coverings, rather than other types of PPE, although there were some concerns about gloves, aprons, coveralls and eye protection.

389. Whilst the suppliers of these products were not supplying directly into the healthcare system through either the NHS or the DHSC, it must be recognised that there was a time at the start of the pandemic that there were acute shortages of PPE and therefore products being supplied could potentially have been used in high-risk healthcare settings.

390. In the context of enforcement:

a. With specific reference to the respirators, the majority of products subject of concern were FFP2 respirators which did not on the face of it meet the requirements due to poor quality and lack of accompanying documentation to confirm the EHSRs was met. Within the category of respirator, it was also a significant feature that FFP2 respirators met the Chinese standard (KN95) which consistently failed to meet the European required standard in the EHSRs.

b. The role of the Team was to contact suppliers of potentially non-compliant products to request that the duty holder supplier provide evidence to demonstrate compliance with the EHSRs.

c. Once received from a duty holder supplier, the evidence was reviewed, either by the Team or by HSE's Technical team. If a product was deemed not in compliance with the EHSRs then the supplier was required to withdraw the product from the market. It followed that if the item was deemed compliant then it was allowed to go to / remain on the market.

d. In the event of the duty holder supplier failing to withdraw the item in question, the Team took enforcement action in the form of a Withdrawal Notice[13].

391. The Team followed up concerns raised against 231 suppliers and importers where non-compliance was identified. Of these, 16 companies could not be contacted or identified, only 9 were found to be in compliance, 28 were suppliers of 'medical products', where the easement did not apply.

392. The remainder removed products from supply after an email or formal letter. Their websites were periodically checked to ensure they continued to comply.

393. Withdrawal Notices were served on six suppliers who failed to heed advice. In total there were 22 Notices, all of which were complied with.

394. The Supply Team also worked with product safety colleagues to ensure that an EU Notified Body carrying out fraudulent testing and certification was removed from the Approved Notified Body register.

395. This PPE supply work transferred to HSE's Product Safety and Market Surveillance Unit ["PSMSU"] at the end of April 2021.

396. During the relevant period, PSMSU evaluated 27 products and, in the process, engaged with 28 duty holder suppliers associated with the supply of PPE that could foreseeably be used in healthcare. These product evaluations related to approximately 74 million individual items of PPE that have been placed on the market in Great Britain. I exhibit a spreadsheet containing the data in relation to PPE investigations as RGB 192 - INQ000269712.

397. Of the 27 evaluations, 15 have been concluded to the point where action has been taken by HSE. In these cases, HSE has written to the dutyholder suppliers requiring either the withdrawal of products, their recall, or other specified actions. In all cases to date, the requirements have been satisfied without further enforcement action being required. Some product evaluations relevant to the period are ongoing and further enforcement action is anticipated in relation to a number of these.

398. Collectively, the action taken by PSMSU has so far resulted in duty holder suppliers withdrawing approximately 4.2 million individual items of non-compliant PPE/RPE from the supply chain in Great Britain.

HSE Research Papers

[13] Further sanction was available – a Recall Notice and also prosecution, although neither had to be used.

'Evaluating the protection afforded by surgical masks against influenza bioaerosols'

399. The 2008 research paper 'Evaluating the protection afforded by surgical masks against influenza bioaerosols' prepared by the Health and Safety Laboratory ["HSL"] for the HSE was published on the HSE web site under the Research Report series as RR619 (exhibit RGB/193 - **INQ000101591**).

400. The context of the Report was the need to explore the limitations of any protection afforded by surgical masks worn by healthcare workers in the context of a perceived potentially imminent pandemic influenza outbreak at the time of conducting the study (2007). The outcome of the study was known to, and used by, the NERVTAG working group on provision of PPE for healthcare as part of influenza pandemic preparedness. As discussed above, surgical masks are not considered as PPE, but may provide some incidental protection.

401. The main route of transmission of influenza is believed to be via large droplets or direct contact with secretions and, in some circumstances, exposure to infectious aerosols. The relative contribution of aerosol transmission in natural influenza transmission is thought to be minor but was not ruled-out at the time. The likelihood of infection via this route will increase when in close proximity to the patient and especially when carrying out procedures likely to generate aerosols, such as intubation or dental drilling. Consequently, the then UK Pandemic Influenza Infection Control Guidance recommended the wearing of FRSM for those workers who are in close contact with symptomatic patients as protection from droplets/splashes and recommends the use of respiratory protection (i.e. FFP3 respirators) for circumstances in which aerosols are generated as a consequence of medical procedures.

402. Whilst surgical masks may, in principle, offer adequate protection against large droplets and contact transmission, the level of protection they offer against a residual aerosol risk is poorly understood. They are not designed, or certified, as respiratory protective devices. However, there is a common misperception that they will provide protection against aerosols.

403. The study aimed to measure the efficiency of surgical masks against airborne particles generated from a simulated sneeze (including those that contain live, infectious influenza virus) so that the contribution of surgical masks in the protection against any residual aerosol risk can be assessed.

404. Surgical masks and FFP respirators were tested on a human volunteer using an inert aerosol challenge. From the results of this study, it can be concluded that surgical masks will mitigate a mean reduction factor of around two against a simulated sneeze

of inert airborne particles compared to FFP respirators, which are capable of offering a mean reduction factor of 100 or higher.

405. Surgical masks were also tested on a breathing dummy head and subjected to an aerosol challenge containing live influenza virus. Infectious, viable virus could be detected in the air behind all surgical masks challenged. A mean reduction factor of six was measured.

406. In principle, surgical masks that are worn correctly should provide adequate protection against large droplets, splashes and contact transmission. They may also reduce to some degree any residual aerosol risk, although this level of protection might not sufficiently reduce the likelihood of transmission via this route. Consequently they should not be used in situations where close exposure to infectious aerosols is likely.

Related Research

407. In the context of Covid-19, with differing transmission dynamics including potential spread by cough, HSE Science Division undertook projects jointly funded by HSE, the PROTECT Covid-19 National Core Study programme and WHO, to develop a cough simulator. This was used, with a combination of non-hazardous virus surrogates and visualisation with UV fluorescent dyes, to determine the spread of droplets and airborne particles from a simulated cough, and the protectiveness of face coverings including face shields, goggles and safety spectacles.

408. These studies have been published in the following peer reviewed papers:

    a. 'Simulating the Environmental Spread of SARS-CoV-2 via Cough and the Effect of Personal Mitigations' (2022), Bailey C, Johnson P, Moran J, Rosa I, Brookes J, Hall S and Crook B (exhibit RGB/194 - INQ000269756). The paper found that interventions, such as coughing into the hand or elbow can change the environmental contamination pattern resulting from a human cough but may not reduce it greatly.

    b. 'A mixed methods study on effectiveness and appropriateness of face shield use as Covid-19 PPE in middle income countries' (2022), Brainard J, Hall S, van Der Es M, Sekoni A, Price A, Padoveze M, Ogunsola F, Nichiata L, Hornsey E, Crook B, Cirino F, Chu L and Hunter P (exhibit RGB/195 - INQ000269757). All face shields provided some protection but none gave high levels of protection against external droplet contamination. Respondents wanted facial PPE that considered good communication, secure fixture, good visibility, comfort, fashion, and has validated protectiveness.

c. 'Evaluation of face shields, goggles and safety glasses as a virus transmission control measure to protect the wearer against cough droplets' (2022), Hall S, Johnson P, Bailey C, Gould Z, White W and Crook B (exhibit RGB/196 - INQ000269758). Face shields, goggles, and safety glasses reduced, but did not eliminate exposure to the wearer from droplets such as those produced by a human cough.

d. 'WXAC047 – Evaluation of face shields, goggles and safety glasses as a virus transmission control measure to protect the wearer against cough droplets' (2022), Hall S, Johnson P, Bailey C, Gould Z, White W and Crook B (exhibit RGB/197 - INQ000269759). Results suggested that if a coughing person wears a face shield, it can provide some protection from cough droplets to those standing directly in front of the wearer.

409. The PROTECT Covid-19 National Core Study on transmission and environment is a UK-wide research programme which is focused on improving understanding of how SARS-Cov-2 is transmitted from person to person and how this varies in different settings and environments. The programme has 6 research themes, outbreak investigations, transmission modelling, sector specific studies, tools and methods, experimental infection and knowledge synthesis. More papers will be published as part of the core study, as they progress through the peer review process.

'Evaluation of existing PPE worn by NHS Staff for assessment of a patient with a suspected high consequence infectious disease'

410. The 'Evaluation of existing PPE worn by NHS Staff for assessment of a patient with a suspected high consequence infectious disease'[14] evaluated existing PPE worn by NHS staff for assessment of a patient with a suspected HCID. The study used fluorescent visualisation of dyes, invisible under normal light and visible only under UV light, incorporated into body fluid simulants. A manikin was used by healthcare workers in a simulation of undertaking medical assessment of a patient, during which the healthcare workers' PPE becomes contaminated with body fluids. The project was used to evaluate PPE ensembles, develop and validate a single ensemble for use by all HCID units and validate protocols for safe removal of PPE without personal cross-contamination.

411. In 2014-2016, there was an outbreak of Ebola Virus Disease ["EVD"] in West Africa. UK healthcare workers were deployed to treatment centres in Sierra Leone.

[14] Exhibited in my first statement as RGB/49 – INQ000176118.

Simultaneously in the UK, emergency preparedness plans were made in case visitors returned from West Africa with EVD symptoms.

412. Variations currently exist across the UK in the choice of PPE used by healthcare workers when caring for patients with suspected HCIDs. At the time of the outbreak there was no systematic, evidence-based assessment that existing PPE ensembles and safe removal procedures were effective.

413. The Department of Health and PHE's HCID programme proposed the development of a national unified suspected case PPE ensemble and doffing procedure, suitable for both contact and airborne transmissible infections.

414. The aim of this project was to ensure the correct selection and use of PPE to protect front line medical staff against HCID such as EVD and Middle Eastern Respiratory Syndrome. This was to be achieved by evaluating existing HCID PPE ensembles, developing a training package, and publishing and disseminating the findings.

415. A manikin was adapted to simulate a patient and to deliver bodily fluids containing different coloured fluorescent markers. Whilst wearing PPE, doctor and nurse paired volunteers participated in a simulated clinical scenario to assess a patient suspected of having an HCID. Contamination of PPE was visualised, photographed and recorded on a body map under UV light after the simulation and again after doffing. Observational findings and participant feedback, around its use as a training exercise, were also recorded. The exercise was named VIOLET, "Visualising Infection with Optimised Light for Education and Training".

416. One basic level PPE ensemble and five existing HCID PPE ensembles were evaluated, and strengths and weaknesses identified. A maximum of eight volunteers completed the exercise wearing each ensemble.

417. Review of the data at a workshop with an expert stakeholder group, allowed collaborative development and agreement of and a unified PPE ensemble, referred to as the "HCID assessment PPE". This ensemble was then tested using VIOLET by forty volunteers.

418. Each body map area could contain contamination from four bodily fluids. One of the bodily fluids noted in one body map area was described as a 'contamination event'. When evaluating a basic level PPE ensemble, eight volunteers had 147 post-simulation and 31 post-doffing contamination events.

419. For the five existing HCID PPE ensembles, each tested by a maximum of eight volunteers, 1584 post-simulation contamination events were recorded, from a possible maximum of 5110. Twelve post-doffing contamination events were also observed.

420. Forty volunteers completed the simulation exercise wearing the HCID assessment PPE, developed by the expert stakeholder group. This resulted in 1267 contamination events from a possible 5600 occurring post-simulation. Only one post-doffing contamination event occurred, on the neck of a less-experienced volunteer due to them reaching beneath their visor.

421. When questioned, all volunteers stated that they felt more confident in the use of PPE and caring for an HCID patient after the experience.

422. The paper reached the following conclusions:

a. A basic level PPE ensemble does not afford adequate protection in a clinical scenario such as the one simulated for this research.

b. Testing of the existing HCID PPE ensembles resulted in either post-doffing volunteer contamination or revealed other significant disadvantages associated with their use. Breaches were related either to protocol failure or complications in PPE doffing.

c. An HCID assessment PPE ensemble was developed and agreed by key stakeholders. Results showed that it would be protective if worn when assessing a patient with a suspected HCID, even with minimal training provided to the wearer.

d. Supervised doffing is advantageous. To minimise the number of people at risk of exposure, the buddy should only observe and instruct but not physically assist.

e. VIOLET was developed as an effective tool for PPE evaluation. Volunteer feedback also showed that it could be implemented as an effective training method.

f. Research outcomes have been shared with the wider scientific, healthcare, and infection control communities through peer reviewed publications and presentations at national and international conferences.

423. The following peer reviewed papers were published from this work[15]:

[15] Which fall outwith the Relevant Period.

a. 'Fluorescence Visualization as a Training Tool for Infection Control' (2018), Crook B, Makison Booth C, Hall S. The paper found that UV fluorescent tracers are a powerful training tool when used as a simulant for infectious agents.

b. 'Use of ultraviolet-fluorescence-based simulation in evaluation of personal protective equipment worn for first assessment and care of a patient with suspected high-consequence infectious disease' (2018), Hall S, Poller B, Bailey C, Gregory S, Clark R, Roberts P, Tunbridge A, Poran V, Evans C, Crook B. All suspected case PPE ensembles either had post-doffing contamination events or other significant disadvantages to their use. This identified the need to design a unified PPE ensemble and doffing procedure, incorporating the most protective PPE considered for each body area.

c. '"VIOLET" – a fluorescence-based simulation exercise for training healthcare workers in the use of personal protective equipment' (2018), Poller B, Hall S, Bailey C, Gregory S, Clark R, Roberts P, Tunbridge A, Poran V, Crook B, Evans C. Simulation exercises using VIOLET provide evidence-based assessment of PPE ensembles are a valuable resource for training of healthcare staff in wearing and safe doffing of PPE.

d. 'A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases: A consensus document on behalf of Public Health England and the Health and Safety Executive' (2018), Poller B, Tunbridge A, Hall S, Beadsworth M, Jacobs M, Peters E, Schmid ML, Sykes A, Poran V, Gent N, Evans C, Crook B on behalf of the High Consequence Infectious Diseases Project Working Group. A simulation-based exercise was developed to assess the safety of PPE ensembles. After exposure, healthcare workers were examined under UV lights to locate fluorescent contamination and were screened again after removing PPE (doffing) to detect any personal contamination. The simulation testing identified significant HCW contamination events after doffing, related to protocol failure or complications in PPE doffing, providing conclusive evidence that improvements could be made. At a workshop with an expert stakeholder group, the data were examined and a unified PPE ensemble agreed. This ensemble was then tested in the same simulation exercise and no evidence of any HCW contamination was seen after doffing. Following further review by the working group, a consensus agreement has been reached and a unified 'HCID assessment PPE' ensemble, with accompanying donning and doffing protocols, is presented in the paper.

424. More recently, a study was conducted to evaluate the PPE ensembles used in HCID units for ongoing care of patients where there is a reliance on the use of PPE for healthcare worker protection:

> 'Validation of personal protective equipment ensembles, incorporating powered air-purifying respirators protected from contamination, for the care of patients with high-consequence infectious diseases' (2023), Crook B, Bailey C, Sykes A, Hoyle M-C, Evans C, Poller B, Makison-Booth C, Pocock D, Tuudah C, Athan B, Hall S. The ensembles were tested under extreme 'worst case scenario' conditions, augmented by physical and manual dexterity tests. Participating volunteers considered the exercise to be beneficial in terms of training and PPE evaluation. Data obtained, including feedback from questionnaires and doffing buddy observations supported evidence-based decisions on the PAPR/PPE ensemble to be adopted by the HCID Network.

425. HSE Science Division is also currently involved, in collaboration with Sheffield Teaching Hospitals and a simulation training unit at Montagu Hospital, Mexborough, Yorkshire, in training healthcare workers on safe removal of HCID contaminated PPE. This is using the PPE ensemble and removal protocol developed in the project described in RGB/49 – INQ000176118.

Long Covid

426. The condition known as "Long Covid" is not reportable under RIDDOR as any occupational exposure to a biological agent that causes Covid-19 occurs at the time of initial infection. As "Long Covid" occurs later it is not reportable.

427. A responsible person who becomes aware of a diagnosis of Long Covid should consider whether there is reasonable evidence that the initial infection arose a result of an occupational exposure to Covid-19 that has not previously been reported to HSE and if there is, that should be reported as a case of disease under regulation 9(b) of RIDDOR.

428. A distinction should be made between diseases reportable under RIDDOR for the purpose of regulating risk in the workplace, and conditions considered as 'prescribed diseases' for the purpose of Industrial Injuries Disablement Benefit ["IIDB"] entitlement by the Department of Work and Pensions ["DWP"] on the advice of the Industrial Injuries Advisory Council. Both systems are independent and have different objectives. HSE, while it may be advised as to changes to the list of prescribed diseases, has no regulatory role in determining what diseases should be prescribed.

429. In relation to RIDDOR reporting, Covid-19 infections and deaths are already reportable where they have arisen as a result of deliberate work with, or incidental exposure to, the virus. Any changes to the list of prescribed diseases under IIBD do not impact the reporting requirements under RIDDOR.

430. As at 31 October 2023 there have been a total of 36 RIDDOR reports received relating to Long Covid, 31 received by HSE and 5 by Local Authorities.

The All-Party Parliamentary Group ["APPG"] Long Covid Report

431. HSE provided no formal response to the APPG on coronavirus in relation to its 'Long Covid Report'. HSE were contacted by the chair of APPG in November 2022 (exhibit RGB/198 INQ000269706) regarding data about Covid-19 outbreaks. HSE responded in correspondence (exhibit ref RGB/199 - INQ000269701) setting out that the data being sought was held by the UK Health Security Agency ["UKHSA"] (formerly PHE). HSE did though provide links to research that HSE was a part of via the Covid National Core Study and HSE's published statistical estimates of Covid-19 in the workplace.

'Return to work after long Covid: Evidence at 8 March 2021'

432. HSE commissioned a report entitled 'Return to work after long Covid: Evidence at 8 March 2021' (exhibit RGB/200- INQ000269715). The report was completed outside the HSE by a team of academics based in Belgium.

433. The report was commissioned by HSE's Science Division to inform HSE of the implications of Long Covid and facilitate an informed determination of whether guidance to support return to work would need to be modified or developed as a consequence. The Expenditure Request Approval Form (exhibit RGB/201 - INQ000269695) provides more detail as to the reasons why the report was commissioned.

434. The report is of general application to all industry sectors and is therefore not specific to healthcare settings but the findings are as relevant to healthcare as they are to any other sector.

435. The report identifies the following key messages:

    a. There is a lack of published research on the impact of Long Covid on work and return to work due to the recency of the pandemic. This study identified only seven relevant published studies after screening 2,545 publications. There is a global need for large and long-term cohort studies with mixed methods

(qualitative and quantitative) in order to better understand the long-term consequences of Covid-19.

b. Based on this limited evidence, the Long Covid symptoms that seem to have the greatest impact on work and return to work are fatigue, cognitive dysfunction (such as difficulty concentrating and memory loss), and changes in taste and smell.

c. There is currently no agreed scientific definition of Long Covid. Therefore, the authors suggest using the UK National Institute for Health and Care Excellence (NICE) guidelines to define Long Covid.

d. Return to work for an individual with Long Covid often needs involvement of several stakeholders: the recovering worker, employer, line manager, and health or occupational health professionals.

e. Established good practice for return to work for other illnesses with similar symptoms is that the primary goal should be progressive, adaptive, and appropriate return to work and support at work (job retention), as working is generally good for health.

436. HSE is currently completing a study as part of the National Core Study which has collected data from 5,886 participants asking questions about Covid-19 and work. The first output from this study will be a paper regarding Long Covid and this is being peer reviewed for publication.

Submissions to DHSC or NHS

437. HSE had no formal consultations nor made formal submissions to the DHSC or NHS outside what I have already referenced above.

438. The EMG paper 'Masks for healthcare workers to mitigate airborne transmission of SARS-CoV-2' (exhibit ref RGB/77- **INQ000075022**) included a reference to HSE's spot inspections of hospitals in late 2020 and early 2021, the standards of compliance found in these inspections and the recommendations made by HSE to Boards and NHS Trusts following the inspections (detailed above at paras 103 - 110).

'HSE and Covid at work: a case of regulatory failure'

439. In February 2021 the Institute of Employment Rights (IER) published a report titled 'HSE and Covid at work: a case of regulatory failure'. Disappointingly the IER did not engage with HSE to discuss and understand our approach to what was a fast-moving response to a public health risk and our broader role in supporting the government's

effort. IER have written previously in negative terms about HSE given their perception of how a regulator should achieve outcomes. HSE was of the view that any comment at the time of the publication of the report would have been unhelpful.

440. HSE takes pride in the work we do as a regulator. HSE strives to achieve the best outcomes possible and will always look for opportunities to do better where they exist. Regardless of HSE's views on its own performance of its regulatory functions, it is the public's opinion, and the findings of the Inquiry that HSE is now focussed on. If HSE has fallen short in any areas, HSE will look to how we can continue to improve. We have no detailed comment to make in respect of the report.

Lessons Learned

'The Effect of Covid-19 in the Workplace'

441. HSE recognised the importance of considering the effect of the pandemic in the workplace, reviewing the measures that employers had put in place to manage workplace risks and any learnings that might assist employers to manage future risks. In July 2020, the HSE Board agreed the terms of reference for a report potentially under s14(2) of HSWA on the effect of the Covid-19 pandemic in the workplace (exhibit RGB/202 - INQ000269723 and RGB/203 - INQ000269692).

442. The report was to provide an interim analysis and evaluation of the impact of Covid-19 on employers, the workforce and the regulatory environment. The report aims to identify and enable HSE to communicate any further recommendations for the (then) continuing response to the pandemic, enabling future resilience, learning and effective health and safety risk management.. The report focused on sectors identified as being significantly impacted by the pandemic, in particular health and social care.

443. In order to prepare the report, analysis was undertaken of early HSE activity between April and September 2020 addressing 4 regulatory themes, specifically:

a. Personal protective equipment (PPE)

b. Guidance, Freedom of Information and Correspondence

c. The Health and Social Care response

d. The regulatory framework

444. The report was finalised in January 2021 (exhibit RGB/204 - INQ000269707). The report was presented to the HSE Board on 27 January 2021 (exhibit RGB/205 - INQ000269702). It was agreed by the Board that the HSE's ExCo would decide on any proposed actions following on from the report's findings. Following further engagement

with the Board, the finalised response to the report was presented to the Board on 28 September 2021 (exhibit RGB/206 - INQ000269698). ExCo's response to the report was set out in a table, detailing the findings, observations from the ExCo and actions.

Summary of Findings and Actions

445. Within the report, the observations and findings were set out under three separate headings:

a. Findings from HSE activity

b. Initial Implications for the HSE

c. Wider implications for the health and safety system

446. The findings from HSE activity highlighted the importance of effective risk management by dutyholders. It was noted that approaches to risk management needed to keep pace with increased knowledge regarding Covid-19 and the importance of communication and the provision of updated information and guidance was acknowledged. Lessons learnt in respect of communication were to feed into HSE's on-going work in this area.

447. The findings highlighted challenges that had been experienced across the health and social care sector in relation to the application of the control hierarchy and PPE. Actions agreed in respect of these findings were to form part of wider business as usual activities across HSE. The findings also highlighted the role of HSE's product safety and surveillance team in enabling the supply of PPE to the required standard to the health and social care sector.

448. The findings noted areas for consideration in relation to the nature of HSE activity during the Covid-19 pandemic, acknowledging the novel situation presented by Covid-19. Learnings highlighted by the report were to be factored into future intervention planning. Lessons learnt in relation to methods of engagement during Covid-19 were to be fed into future work on interventions and in responding to incidents. Targeting poorly managed workplaces and employers was highlighted as a continued area of focus from HSE.

449. Finally in relation to HSE activity, the findings highlighted the impact of the Covid-19 pandemic (as a public health issue) on the wider regulatory framework for the health and social care sector, noting the regulatory responsibilities held by HSE and Local Authorities as well as other agencies and the parallel between management of infection control and worker safety in the health and social care context. Separate actions were

agreed to address these matters in future engagement with health and social care regulators and local authorities.

Initial Implications for HSE

450. The report highlighted the importance of the changing science and evidence base, along with the need for this to be reflected in information and guidance provided to dutyholders. Existing work in this area was highlighted, recognising that this would continue to feed into future actions.

451. The report presented a number of findings which focused on HSE's regulatory activity in response to Covid-19 as a workplace risk. When considering these findings, the steps already taken by HSE to explain its role in relation to the pandemic and its approach to enforcement activity were noted by ExCo. The actions acknowledged the importance of HSE continuing to review and if necessary, adapt its approach as the pandemic continued to evolve. It was also acknowledged that further communications would assist to ensure that stakeholders, dutyholders and the wider public understood HSE's role during the pandemic and the work that HSE was doing in response to the pandemic.

452. The importance of intelligence and information sharing was also highlighted in the report. Again, work done by the HSE in this area was noted by the ExCo and the actions reflected the on-going activity in respect of this matter.

Wider Implications for health and safety system

453. This section of the report considered implications in respect of employees, employers, intervention choices by HSE, legislative framework and other regulators.

454. In relation to employees, it was agreed that findings in respect of the importance of the tone of employee focused communications would feed into HSE's broader communications work. The importance of ensuring that all employees could easily contact HSE if they had concerns was highlighted by the findings. In response it was noted that an on-going pilot in Yorkshire and the Humber focused on channels for messaging to low paid workers was relevant to this issue.

455. The report highlighted that behaviours spanning the workplace and beyond raised challenges for targeted public messaging to different groups and individuals. It was agreed that this would be picked up as part of work between HSE, public health bodies and other workplace regulators.

456. In relation to enforcement, the report highlighted that the healthy worker concept had been the subject of scrutiny. In the response to the report, ExCo noted that this issue had already been addressed in the review of enforcement during the Covid-19 pandemic.

457. In relation to employers, the findings highlighted the importance of clear advice, particularly in respect of risk assessment. The report also highlighted potential difficulties in maintaining effective risk control and the importance of the "always on" aspect of good risk management. It was agreed that there would be further consideration of messaging as part of risk management and control.

458. There was separate consideration of matters arising in connection with PPE procurement, in particular how HSE might better address the question of the "intelligent customer" and show the value of interventions at the right point in the supply chain to enable employers to make good risk management decisions. It was agreed that this would be considered as part of developing HSE's strategy and future iterations of sector/ health and work plans.

459. With regard to intervention choices, it was agreed that HSE's concept of operations should be reviewed as part of lessons learned for future novel workplace risks. It was also acknowledged that learnings from the pandemic may be relevant to future priorities, in particular areas that span the work/public health boundary.

460. The benefits of product oversight were highlighted and it was agreed that the importance of product safety as an effective route for worker protection should be factored into future communications and HSE's broader role in product safety. The benefits of regulator led quality assurance under market surveillance arrangements were also highlighted and it was agreed that this would feed into further work focused on joined up working with other regulators.

461. The report considered factors in relation to targeting, both in relation to targeting workplaces with nominally higher risks of employee outbreaks and targeting interventions on the basis of workplace activity and workforce characteristics. It was agreed that risks in relation to employee outbreaks would continue to be monitored in light of evidence from the National Core Studies on the transmission of the Covid-19. Consideration of targeting based on activity and workforce characteristics was to feed into on-going strategy work.

462. Finally in respect of intervention choices, the report highlighted matters relevant to the application of performance measures and data recording to inform future interventions. It was noted that both issues would be addressed by an on-going workstream.

463. With regard to the legislative framework, the findings considered the boundary between workplace health and safety and public health oversight and the application of relevant legislation. It was agreed that further consideration would need to be given to whether amendments in legislation were needed and further engagement would need to take place between HSE and public health bodies. The report also highlighted questions around the application of RIDDOR. In response, ExCo noted that RIDDOR had not been drafted with a pandemic in mind, resulting in challenges around interpretation. The actions agreed acknowledged on-going work to address this including providing further clarification to NHS Trusts in line with HSE's RIDDOR/Covid-19 guidance. It was also to be addressed as part of lessons learnt work between HSE, public health bodies and other agencies.

464. In relation to other regulators, the findings noted the importance of joined up working with other healthcare regulators and engagement with labour market agencies in shaping future workplace health and safety regulatory strategy. Both findings were agreed and actions set for further consideration by relevant HSE teams.

Implementation of actions and lessons learned

465. As is highlighted in the summary above, a significant number of the actions agreed by ExCo were focused on ensuring that the learnings from the report were fed into on-going and future work during the pandemic and / or wider HSE strategy planning as well engagement with fellow regulators and stakeholders. HSE continued to review and where appropriate, adapt its approach throughout the pandemic, particularly as knowledge of the virus increased. The lessons learned continued to evolve throughout the pandemic.

Lessons Learned across Operations and Policy Divisions

466. In addition to the special report which focused on the health and social care sector, HSE's Operations and Policy Divisions conducted their own lessons learned exercises to consider what had worked well in their Divisions, what challenges they had encountered and what learnings could be taken forward in future work (example at RGB/207 - INQ000269689). These reviews (conducted during the pandemic) were operational in nature, reflecting on how Divisions had adapted work activities in light of the pandemic. The reviews also reflected on the delivery of some of the additional work activities being undertaken across the Divisions in response to the pandemic.

Lessons Learned in respect of HSE's Scientific Response to Covid-19 Pandemic

467. In addition to the lessons learned exercises carried out by operational and policy divisions, HSE's Chief Scientific Adviser commissioned the Workplace Health Expert Committee ["WHEC"] to prepare a report providing HSE with an independent perspective on HSE's scientific response to the pandemic (RGB/208 - INQ000269711). The terms of the commission are set out at page 5 of the report. The report was to assist the Chief Scientific Adviser in preparing for an appearance before the Science and Technology Committee.

468. WHEC is an independent scientific advisory committee governed by CoPSAC principles (exhibit RGB/209 - INQ000269717). In particular para. 6.17 highlights that "The sponsoring organisation should respect the independence of the SAC, and the SAC must bear in mind that policy decisions are based on a range of factors in addition to its own advice". The report from WHEC also highlights that the report and its contents (including any opinions or conclusions) are that of the Committee members alone.

469. The report provided a helpful review of HSE's scientific response and some useful advice that fed into the National Core Studies. It also assisted HSE in its thinking on the interface between HSE and other departments and agencies. However parts of the report went beyond the role of HSE, addressing the wider "system" and certain parts of the report misunderstood HSE's remit. In its review of the report, HSE also identified that there were instances where the report (and its recommendations) did not reflect the work that HSE had done or was in the process of doing at the time the report was prepared.

Statement of Truth

470. I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Richard Gregory Brunt

Dated: 17 November 2023