Witness Name: Richard Gregory Brunt
Statement No.: 3
Exhibits: RGB/210 – RGB/435
Dated: 22 January 2025

UK COVID-19 INQUIRY

WITNESS STATEMENT OF RICHARD GREGORY BRUNT

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

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's regulatory role and to provide details of HSE's regulatory activity prior to and during the pandemic in relation to the regulation of use and supply of Personal Protective Equipment ["PPE"].

The Health and Safety Executive, its regulatory role and the legislative framework

2. HSE is a non-departmental public body, 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's general powers are set out in s13 HSWA. This includes the power to do anything which is calculated to facilitate, or is conducive or incidental to, the performance of its functions (s13(1)). s16 HSWA sets out HSE's power to issue approved codes of practice ["ACOPs"] to provide guidance to dutyholders with regard to their legal obligations under HSWA and the associated regulations.

5. HSE is governed by a Non-Executive Board led by the Chair of the Board, Sarah Newton, and an Executive Committee ["ExCo"] led by HSE's Chief Executive Officer, Sarah Albon. ExCo is HSE's strategic decision-making body comprising HSE's Senior Leadership Team. ExCo supports HSE's Board in carrying out its legislative, policy, operational and administrative functions. In addition to ExCo, HSE has a number of governance and operational committees including the Audit and Risk Committee and the Operations and Regulation Committee.

6. Operationally, HSE is divided into Divisions focusing on areas of regulatory activity, for example, Engagement and Policy Division, Science Division and HSE's Inspection and Investigation Divisions which fall under the Director of Regulation's Office.

The role of HSE in England, Scotland and Wales

7. 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, for example office activities and accommodation provision such as hotels and residential care homes. 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.

8. 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
c. ensuring compliance with health and safety laws through targeted inspections and investigation;
d. enforcement action;
e. providing advice, guidance and information,
f. operating permissioning and licensing activities in major hazard industries and
g. raising awareness in the workplace by influencing and engagement.

9. Throughout the Covid-19 pandemic, HSE retained its role as the enforcement body for health and safety in the workplace under HSWA, however, HSE 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.

The role of HSE in Northern Ireland

10. In Northern Ireland, regulation of workplace health and safety lies with the Health and Safety Executive for Northern Ireland ["HSENI"]. HSENI is a Northern Ireland non-departmental public body sponsored by the Department for the Economy. It is responsible for the encouragement, regulation and enforcement of occupational health and safety in Northern Ireland. Its functions are similar to those of the HSE in the rest of the United Kingdom.

11. Memorandums of Understanding ["MOUs"] exist as between the HSE and HSENI, for example "*Provision of support in respect of Northern Irish Market Surveillance and Product Safety for Workplace Goods*" (exhibit RGB/210 - INQQ000529807) which provides a framework for joint-cooperation and the provision of support by

HSE to HSENI in respect of Northern Irish market surveillance and product safety for workplace goods.

HSE's regulatory role in relation to the healthcare and social care sectors in England, Scotland and Wales

12. HSE is not the primary regulator for healthcare and social care in Great Britain. Healthcare and social care 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 and social care. 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. Social Care and Social Work Improvement Scotland ["SCSWIS"], also referred to as the "Care Inspectorate" regulate, inspect and support improvement of care services in Scotland and provides public assurance on service quality. The Healthcare Inspectorate Wales ["HIW"] is responsible for reviewing and inspecting NHS and independent healthcare organisations in Wales. Care Inspectorate Wales ["CIW"] regulate social care and includes registration, inspection, responding to concerns about regulated services, compliance support and enforcement.

13. HSE's role in relation to regulating healthcare and social care 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).

14. In respect of healthcare, 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)* (exhibit RGB/3 - INQ000101585), HIS "*Memorandum of Understanding between Health and Safety Executive and Healthcare Improvement Scotland" (April 2019* (exhibit RGB/67- INQ000269835) and HIW "*Memorandum of Understand (MOU) Healthcare Inspectorate Wales (HIW) and Health and Safety Executive (HSE)"* (exhibits 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.

15. In respect of social care, HSE has a liaison agreement with Scottish Local Authorities and the Care Inspectorate, *"Liaison Agreement between the Health and Safety Executive, Scottish Local Authorities and Social Care and Social Work Improvement Scotland ('Care Inspectorate')"* (exhibit RGB/211 – INQ000529423) and an MOU with CIW and Local Authorities in Wales, *"Memorandum of Understanding with Care Inspectorate Wales and Local Authorities in Wales"* (exhibits RGB/212 - INQ000529808 (July 2019) and exhibit RGB/213 - INQ000529802 (July 2022)).

16. 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 as explained in our guidance on priorities for enforcement under s3 HSWA (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. In respect of social care, the CQC regulates the providers of social care services for adults in care homes (where nursing or personal care is provided), in the community and in people's own homes. In general, CQC, rather than HSE, will deal with the majority of patient and service user serious health and safety incidents.

17. 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 as detailed in the MOU with HIW (exhibit RGB/68(a) - INQ000269848 at paragraphs 19 – 20). In respect of social care, areas where CIW may have a primary role include incidents arising from failures in the quality of care of people being looked after. Areas where the HSE or the Local Authority may have a primary role include incidents involving service users, staff or others (e.g. visitors) who are injured by the work being

carried out at the premises or activities of contractors; or incidents involving installed plant for the use of anyone.

18. 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 RGB/67 - INQ000269835 at para. 17). In respect of social care, HSE or the Local Authority will lead on the health and safety of employees. However, they may also consider investigation of patient or service user deaths or serious injuries, where there is an indication that a breach of health and safety law was a probable cause or a significant contributory factor. The Care Inspectorate may investigate the quality of care provided to people who use a care service if an accident/incident or a series of accidents/incidents appears to warrant it.

19. 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).

The division of responsibilities between HSE and Local Authorities in relation to social care settings

20. Where HSE or Local Authorities are responsible for regulation in social care sector, the Appendix to the EA Regulations published by HSE on its website (RGB/214 - INQ000529822) sets out the division of regulatory responsibilities between HSE and LA for different types of social care settings. Local Authorities are responsible

for the regulation of premises where the main activity is the provision of residential accommodation ("residential care homes") unless the home is owned or run by the Local Authority, when responsibility sits with HSE. HSE is responsible for the regulation of other care accommodation, including supported living services, sheltered housing and housing support services. HSE will also be responsible for the regulation of premises which provide nursing care and residential care services, where the main activity is the provision of nursing care.

HSE's regulatory role in relation to PPE – the difference between PPE and medical devices

21. PPE is defined in Regulation 2(1) of the Personal Protective Equipment at Work Regulations 1992 ["PPE(W) Regulations"] and the Personal Protective Equipment (Enforcement) Regulations 2018 ["PPE(E) Regulations"]. The PPE(W) Regulations were amended in 2022 by the PPE at Work (Amendment) Regulations 2022. However, during the relevant period, the definition of PPE was:

"*All equipment (including clothing affording protection against the weather) which is intended to be worn or held by a person at work and which protects him against one or more risks to his health or safety, and any addition or accessory designed to meet that objective*".

22. Medical devices are defined by the Medical Devices Regulations 2002 as:

"*Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application which is intended to be used for human beings for the purpose of:*

(i) *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
(ii) *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*

(iii) investigation, replacement or modification of the anatomy or of a physiological process, or

(iv) *control of conception; and*

does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means; and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device".

23. In practical terms, 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.

24. HSE applies the definition of PPE as set out in the PPE(W) and PPE(E) Regulations as detailed in paragraph 21 as it is responsible for enforcing this legislation. This is also the definition that should be applied by employers such as NHS Trusts when complying with their legal obligations under the relevant regulations.

25. International organisations may adopt different ways of explaining the meaning of PPE. HSE can not provide a definitive explanation regarding the approach taken by other organisations to how they define PPE. There may be variations in the definition because organisations adopt what is workable for them, taking into account their circumstances. The World Health Organisation defines PPE on its website page entitled "Health products policy and standards" as being equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards.

HSE's role in the regulation of the use of PPE in England, Scotland and Wales and the legislative framework

26. HSE is responsible for enforcing the provisions of HSWA and the relevant Regulations in relation to the use of PPE in England, Scotland and Wales.

27. 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 health and social care setting to look after the health, safety and welfare of its staff.

28. 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 who may be affected by it, are not exposed to risks to their health and safety arising from, or in connection with the employer's activities. (s3 HSWA). In the health and social care sectors the general duty extends to those who are not health or social care staff employees but who nevertheless are involved with the provision of healthcare services, for example, patients and contractors.

29. The Management of Health and Safety at Work Regulations 1999 ["MHSW Regulations"] require every employer to 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 (Regulation 3). The assessment is for the purpose of identifying the control measures needed to control the risk. In making that decision dutyholders should apply the hierarchy of control which provides that elimination is the most effective form of control and the use of PPE, the least effective.

30. During the relevant period employers in healthcare and social care settings were required to ensure that the risk of contracting Covid-19 was addressed in a risk assessment to ensure adequate controls were in place to protect for those that would come into contact with the virus due to their work activity.

31. The PPE(W) Regulations provide that an employer must ensure that suitable PPE is provided to employees who may be exposed to risks to their health and safety, except where the risks has been adequately controlled by other means (Reg 4). Employers also have other obligations, including to undertake an assessment is determine whether PPE is suitable (Reg 6). This includes an obligation to ensure that PPE has an appropriate conformity marking. Employers must ensure that PPE is appropriately maintained and replaced (Reg 7) and that appropriate information, instruction and training is provided to employees in relation to the use of, and action required to maintain the effective working of PPE (Reg 9).

32. The Control of Substances Hazardous to Health Regulations 2002 ["COSHH"] 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, which cause ill health. The Regulations are supplemented by an ACOP, *"The Control of Substances Hazardous to Health Regulations 2002 (as amended) Approved Code of Practice and guidance L5 (Sixth edition; Published 2013)"* (exhibit RGB/132 - INQ 000269676).

33. Under COSHH all employers within healthcare or social care settings must protect workers who come into contact with the virus that causes 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 do a risk assessment and implement control measures following the hierarchy of control. Employers are responsible for providing, replacing and paying for PPE for use by its workers.

34. 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.

Face Fit Testing Requirements

35. 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 control measures may be required, and providing respiratory protective equipment (RPE) will be the last line of defence for the individual.

36. Where RPE is used 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 the L5 ACOP.

37. HSE is responsible for enforcing the COSHH Regulations and ensuring that dutyholders implement appropriate control measures to manage work-related risks. In relation to face fit testing, it is part of HSE's role to provide advice and guidance on face fit testing to encourage compliance with the requirements. Where appropriate (in line with HSE's EPS and EMM), HSE will also take enforcement action to secure a dutyholders' compliance with the requirements.

38. 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. 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. Portacount machines are used for quantitative fit testing.

39. Face fit tests are necessary to ensure the suitability of a facepiece. 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.

40. A face fit test is to be distinguished from fit checks, the latter being used as a daily pre-use check for a facepiece already matched to the wearer by use of a fit testing method. 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. 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.

41. 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. Without a face fit test, it is not possible to determine whether there is good contact between the wearer's skin and the face seal, thus providing protection to the wearer. If an item fails a face fit test, this indicates that the product is an inadequate fit, reducing the protection afforded by the RPE and giving rise to risks to the wearer's health.

42. HSE guidance states that fit testers should be competent. This can be demonstrated through accreditation, although this is not the only way for competence to be demonstrated. The British Safety Industry Federation ["BSIF"], the trade association for industry, provides an accreditation scheme for fit testers which is called *"Fit2Fit RPE Fit Test Providers Accreditation Scheme".* The scheme was developed by BSIF with industry stakeholders and is supported by HSE as a means of demonstrating competence, albeit the accreditation is not mandatory.

HSE's role as a market surveillance authority ("MSA") in relation to the supply of PPE in the United Kingdom and the legislative framework

43. HSE is the UK MSA for PPE intended 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 market surveillance authority for PPE supplied for intended use at work. HSE is responsible for monitoring compliance with relevant conformity requirements by manufacturers, importers and distributors ("economic operators") of PPE supplied for intended use at work and placed on GB market.

44. Up until 30 December 2020 the responsibilities of MSAs were set out in EU Regulation on Accreditation and Market Surveillance (765/ 2008) ("EU RAMS"). The provisions of the EU RAMS were largely incorporated into UK law, with the Regulation on Accreditation and Market Surveillance (765/2008) ("GB RAMS") coming into effect on 1 January 2021.

45. In accordance with Article 16 of GB RAMS, HSE must ensure that any PPE product to be used in the workplace which is liable to compromise the health and safety of users or does not conform to applicable legal requirements is withdrawn from the market or availability of the product is prohibited or restricted.

46. The health and safety requirements for PPE for use at work and the conformity obligations placed on economic operators of PPE supplied for intended use at work and placed on GB market are contained within EU Regulation 2016/425 ("2016 Regulations") and enforced by HSE through the provisions of the PPE(E) Regulations. There are requirements on manufacturers, importers and distributors of PPE to ensure its products are Conformité Européenne ["CE"] marked (now UKCA), approved and safe. It is HSE's role to monitor and enforce compliance with these requirements.

Obligations under s6 HSWA

47. Additionally, under s6 HSWA manufacturers, importers and suppliers of articles intended for use at work have general duties which include duties to ensure, so far

as reasonably practicable, the safe design and construction of such articles and the adequate provision of information about the use for which the article has been designed or tested.

HSE's enforcement powers in relation to regulating the use and supply of PPE

48. 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. HSE takes enforcement action in line with HSE's Enforcement Policy Statement ["EPS"] (exhibit RGB/78 - INQ000269858) and HSE's Enforcement Management Model ["EMM"] (exhibit RGB/79 - INQ000269863). HSE's enforcement powers did not change during the pandemic.

49. HSE inspectors may provide written information and advice regarding breaches following an inspection or investigation. Where such 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 referred to by HSE as a Notice of Contravention ["NOC"]. NOCs derive from the Fee for Intervention framework rather than being a specific enforcement tool.

50. 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.

51. Section 33 of HSWA sets out the various offences for failure to comply with the requirements of HSWA and the associated Regulations. HSE has the power to issue simple cautions for offences in England and Wales. s39 HSWA provides authorised HSE Inspectors with the power to instigate criminal proceedings for

such offences. With specific regard to the regulation of the use of PPE, prosecutions may be instituted for a range of failings including a failure to comply with specific requirements set out in regulations such as Regulations 4 and 10 PPE (W) Regulations or Regulation 7(3) COSHH. PPE failings can also be prosecuted as an element of a failure to comply with a general duty under s2(1) or s3(1) HSWA. Authorised inspectors can also institute proceedings in relation to failings to comply with requirements under the PPE(E) Regulations, for example Regulation 7 PPE (E) Regulations.

52. HSE has additional enforcement powers specifically in respect of the supply of PPE. Schedule 4 of the PPE (E) Regulations provides that HSE can issue a compliance notice (para 1 of Schedule 4) to an economic operator (an importer or distributor) in respect of PPE if HSE has reasonable grounds for believing that there is non-compliance with the relevant legal requirements. HSE can also issue an economic operator in respect of PPE with a withdrawal notice (para 2 of Schedule 4) or recall notice (para 3 of Schedule 4) where there are reasonable grounds for believing that the PPE presents a risk or there is non-compliance with the relevant legal requirements.

53. HSE's enforcement powers in respect of the use of and supply of PPE did not change during the pandemic. HSE was not instructed or requested not to take enforcement action in respect of non-compliant PPE by the DHSC, Cabinet Office or any government department or body of the UK Central Government or any Devolved Administration at any time during the relevant period.

The delineation of regulatory responsibilities between HSE, MHRA and OPSS

54. MHRA is a government agency that is responsible for the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents. For those items classified as being suitable for the protection of *both* medical devices and PPE, such as a medical examination gloves, HSE is the MSA for such items in accordance with Directive 2007/47/EC which states: *'Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC and*

this Directive, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.' Accordingly, user protection would be regulated by HSE whilst patient protection would be regulated by the MHRA.

55. HSE has no responsibilities in relation to the regulation of key healthcare supplies that do not fall within the definition of PPE. However, employers in the healthcare and social care sectors have obligations under health and safety legislation in relation to the use, storage and transportation of oxygen cylinders as there are a number of potential hazards arising from oxygen cylinders. The Dangerous Substances and Explosive Atmospheres Regulations 2002 ["DSEAR Regulations"] require employers to assess the risks of fires and explosions that may be caused by dangerous substances, such as oxygen contained in cylinders, in the workplace. HSE is responsible for enforcing these regulations.

56. OPSS is the UK's national product safety regulator and is responsible for the regulation of most consumer goods excluding food, medicines and vehicles. OPSS has overall responsibility for the product safety regulatory framework, including accreditation (through its appointment of the United Kingdom Accreditation Service) and supporting standards through work with the British Standards Institution ["BSI"]. OPSS is responsible for product safety legislation, strategic and enforcement policy development, and for the production of guidance. It also maintains registers of non-compliant products, including a public facing database. Enforcement of product safety legislation is exercised via a number of regulators, including HSE, as market surveillance authorities.

The role of HSE and BSI in relation to the regulation of PPE and technical specifications for PPE

57. HSE regulates the use of PPE in the workplace and monitors the conformity of PPE intended for use in the workplace through its role as an MSA. As part of its regulatory function as MSA, HSE will undertake an evaluation of a product to determine whether it meets conformity requirements. This role does not involve testing PPE. HSE's role is separate and distinct from the role performed by BSI in assessing the conformity of products.

58. BSI is a designated EU Notified Body which is an organisation designated to assess the conformity of certain products before being placed on the market. Notified bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. BSI can carry out product testing and provides certification for PPE including respiratory, hearing, eyewear, glove, head, footwear, and workwear protection.

59. BSI also develop British Standards ("Standard(s)") which determine the technical specifications for PPE. Following a Standard is not mandatory, but they offer a consistency of approach which manufacturers will follow. Certain Standards, referred to as harmonised European Standards, or designated British Standards offer a presumption of conformity with the EU product supply requirements such that if they are followed in their entirety, the product will be compliant.

60. Standards are determined by a technical committee convened by BSI. Technical committees usually consist of manufacturers, industry bodies and testing organisations but can also include representatives from organisations or bodies with expertise in or an interest in the particular subject matter. HSE has representatives on technical committees such as the BSI RPE Standards Committee, also referred to as PH/4. This committee covers development in RPE standards at a national, European, and international level. HSE has been represented on this Standards committee before, during and after the pandemic.

61. The technical design of most PPE is outlined in the relevant Standard – for example, the BSEN 374 series relates to protective gloves for chemicals and micro-organisms and BSEN166 for personal eye protection.

62. During the pandemic, working with the Decision-Making Committee ["DMC"] (explained in more detail in paragraphs 69 – 72), HSE and MHRA led the development of essential technical specifications guidance ["ETS guidance"] (exhibits RGB/149 – INQ000269668 and RGB/150 – INQ000269667) for PPE and medical devices, in conjunction with BSI and other technical experts. This guidance sought to summarise relevant Standards or equivalent for PPE and medical

devices. Some of the products did not have a relevant Standard or equivalent so technical specifications were developed by HSE, other regulators and bodies including BSI. This is explained in more detail in paragraph 103 below.

63. During the pandemic, BSI also published a number of guidance products relating to PPE and medical devices including the BSI Guide for personal protective equipment (PPE) products from non-PPE manufacturers (exhibit RGB/215 – INQ000529160) and the BSI Guide to Masks and Face Coverings for use in the UK during the COVID-19 pandemic (exhibit RGB/216 – INQ000529794).

Technical specifications for PPE and CE marking

64. The Standards that apply to PPE items that are used in healthcare and social care settings are set out in the Essential Technical Specifications guidance ["ETS guidance"] (exhibit reference RGB/149 – INQ000269668 and RGB/150 – INQ000269667).

65. 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.

66. 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"].

67. 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. 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.

HSE's engagement with other regulators during the pandemic to ensure the effective regulation of the supply of PPE

68. HSE worked collaboratively with OPSS and MHRA throughout the pandemic to ensure an effective regulatory approach was maintained in relation to the regulation of PPE. The period was challenging, with regulators having to act quickly to address a range of new and emerging issues involving the supply of PPE, particularly from abroad. Engagement between HSE, OPSS, MHRA and other government departments, bodies and regulators was through a number of committees, working groups and through direct liaison, both in person at the Daventry PPE hub and via written correspondence. Such engagement was frequent, with discussions between regulators taking place on a daily basis at the height of the pandemic.

The PPE Decision Making Committee ["DMC"]

69. The DMC was initially set up by DHSC as the PPE/Treatment and Supplies Escalation Decision Making Committee in or around May 2020. The Terms of Reference for the Committee are exhibited as RGB/217 – INQ000529236. The group became the DMC in or around July 2020. The group initially met twice weekly, with the group's high-level objective at that time being in circumstances "w*hen the regulator cannot make a decision regarding a specific product in their scope, agree with regulators which information should be provided for a regulatory decision to be made before the NHS can proceed with purchase/manufacture/use. The committee/board has not been delegated authority from regulatory bodies; regulatory remits and accountability reside with the regulators*." An example of the Terms of Reference for the DMC is exhibited as RGB/218 – INQ000529561.

70. The DMC included representatives from a number of regulators and NHS bodies including HSE, MHRA, OPSS, HSENI, PHE, NHS Improvement, NHS England, NHS Scotland and NHS Wales. It also included representatives from the IPC Cell.

71. The Terms of Reference for the DMC were amended during the relevant period to reflect changing demands presented by the pandemic, including the frequency of the meetings. Terms of Reference dated 15 July 2021 evidence that at that time the group was meeting on a weekly basis (exhibit RGB/219 – INQ000529726).

72. The DMC enabled HSE to work with other regulators and bodies including MHRA and OPSS to address matters relating to the supply of PPE and medical devices quickly and effectively. Examples of this work include on 14 May 2020 at a DMC meeting the OPSS, HSE and MHRA agreeing to work on a Quality Management System (QMS) minimum specification to provide guidance to testing houses on what evidence and testing would be needed to demonstrate an effective QMS system (exhibit RGB/220 - INQ000529309). HSE and the MHRA worked together to produce a list of approved PPE products, including a meeting between the MHRA, OPSS and HSE being arranged through DMC to consolidate approvals data (exhibit RGB/221 - INQ000529437). The DMC also enabled issues in relation to the procurement of PPE to be raised and resolved effectively. This is detailed further in paragraphs 118 to 139 below.

The Regulatory Co-Ordination Cell ["RCC"]

73. HSE was one of a number of regulators who were part of the RCC. The group consisted of representatives from HSE, OPSS, MHRA, ONR and HSENI. The number of attendees changed over time to include Trading Standards, Border Force and others. The RCC was chaired by OPSS and they held the secretariat function. The Terms of Reference for the RCC (exhibit RGB/222 – INQ000529052) reflect that the group represented a coordination function for UK regulators at a strategic and tactical level.

74. The aim of the group was to rapidly and efficiently address and overcome regulatory issues resulting from the unprecedented and immediate demand for

PPE and medical devices; specifically in regard of the safety and effectiveness of PPE for the NHS supply chain, but also considering safety of non-NHS and public supply issues in respect of advice on standards, specifications, testing and market surveillance activities. The group's membership had some overlap with the DMC, allowing for a coordinated approach to provide specialist advice to the Committee and Cabinet Office.

75. HSE's role as a member of the RCC was as the market surveillance authority for PPE intended for use at work. The meetings allowed for routine liaison and discussion between HSE and OPSS about the delivery of PPE legislation and easements under PPE legislation. It also provided MHRA with the opportunity to discuss derogations in respect of medical devices.

76. The RCC provided an opportunity to discuss emerging issues concerning any challenges in relation to non-compliant PPE coming onto the market, including PPE not destined for use in healthcare (not CE marked and where an easement could not be granted) and the need for enforcement action by the relevant bodies. It also allowed HSE to coordinate its publication of the KN95 Safety Alert with other regulators and allowed for discussions around Chinese masks marked, "not for medical use". It also provided a rapid route to single points of contact within MHRA which allowed for the redirection of assessments for medical devices which had come into HSE.

77. Through the RCC, HSE was able to provide updates on the volume and nature of easements being dealt with by HSE, for example, *"RCC meeting notes 19 November 2020"*, (exhibit RGB/223 – INQ000529640) which detail an update from me on reduced volume of easements. It also provided HSE with an opportunity to update the other participants on any relevant engagement with government bodies or agencies, for example, *"RCC meeting notes 18 February 2021",* (exhibit RGB/224 – INQ000529676) which detail an update I provided on HSE engagement with DHSC regarding selling easement products beyond the UK.

78. The RCC also provided an opportunity for health and safety related queries to be raised with HSE. During a meeting on 29 April 2021 a question arose about

whether employees could wash their own PPE at home if it is likely to be contaminated with a substance hazardous to health. HSE advised on requirements pursuant to PPE(W) and COSHH. The relevant email chain is exhibited as RGB/225 - INQ000529693.

79. As highlighted in the examples above, generally RCC meetings provided the members of the cell with an opportunity to discuss issues, rather than provide a forum for decisions to be made. I do not recall any decisions that were taken by RCC that had a direct impact on HSE's performance of its regulatory functions. When HSE discussed concerns about KN95 ear looped respirators at the RCC and its intention to publish a safety alert in June 2020, the purpose was to share information with the RCC rather than to seek a decision to approve this course of action.

80. Following the publication of recommendations from the Boardman Review the implications of Recommendation 26 *"Regulation in the health sector needs a clear structure and the Government should encourage the National Health Service and regulator community to consider appointing a 'lead regulator' with clear definitions around the roles of regulators to make final decisions regarding products in times of crisis",* was discussed at the RCC. The group was satisfied there were already clear structures in place which defined the roles of regulators and did not agree that a lead regulator should be appointed, given the specific and differing remits of each body and that there was an established regulator forum through the RCC that could be stood up in times of crises. This is reflected in the emerging finding of the GIAA in December 2021. A note of the comments recorded by Angela Richardson, Senior Commercial Auditor, GIAA is exhibited as RGB/226 – INQ000529764.

Working with OPSS

81. HSE worked with OPSS on a range of issues arising in relation to particular products or types of products to ensure that appropriate standards were applied. For example, in May 2020 it decided that thumb loop and sleeveless aprons were medical devices (minutes of DMC meeting are exhibited as RGB/227 –

INQ000529264). However, during the pandemic, the NHS approach to these products changed. HSE prepared a paper *"Aprons - are they PPE?" (*exhibit RGB/228 - INQ000529545) and sought a view from OPSS on its position. In August 2020, both HSE and OPSS agreed that thumb loop and sleeveless aprons were PPE (exhibit RGB/229 - INQ000529550). Subsequently DMC were invited to agree that aprons could be added to the ETS guidance (exhibit RGB/230 - INQ000529556).

82. OPSS and HSE worked in collaboration to resolve issues and queries arising in relation to the application of the easement provisions, for example in June 2020 HSE worked with OPSS in relation to queries regarding visors to be used in healthcare settings (exhibit RGB/231 - INQ000529460). This included providing advice in relation to the submission of an application for an easement when the paperwork was partially complete, documents required to assess the safety of a visor, whether there would be a limit on the quantity of items that could be manufactured and using multiple manufacturers for productions of the items. Similarly, on 22 July 2020 HSE and OPSS representatives discussed the response to a query as to whether it was possible to check products and attain an easement if the product was not purchased as part of the national procurement (exhibit RGB/232- INQ000529525).

83. HSE worked alongside OPSS and MHRA at the Daventry PPE hub to undertake assessments of PPE products that had been procured by the Government or donated from other sources. HSE performed this task as part of its role as MSA for PPE intended for use in the workplace. This is explained in more detail in paragraphs 92 - 98 below.

84. HSE also worked alongside OPSS and MHRA to provide advice, guidance and training to DHSC and other government departments and agencies involved in the procurement of PPE and medical devices. This is explained in more detail in paragraphs 108 -117.

85. HSE provided OPSS with information on PPE that we had deemed to be non-compliant or fraudulent. This information was also shared on the Information and

Communication System for Market Surveillance (ICSMS) database so that it could be accessed by other EU member states.

Working with MHRA

86. HSE worked closely with MHRA throughout the relevant period in relation to the regulation of dual products and when questions arose in relation to whether a product was PPE or a medical device. The division of responsibilities between HSE and MHRA in relation to the regulation of PPE and key healthcare equipment and supplies existed prior to the pandemic so there was a well-established relationship in place between both organisations and a clear understanding of our respective roles. During the pandemic, the division of responsibilities helped each organisation to work efficiently. It enabled decisions to be made promptly and effectively at a time when both HSE and MHRA were working at pace.

87. HSE and MHRA worked collaboratively with DHSC and other members of DMC to resolve queries where there was a question over who the MSA for a particular product was. For example, at the DMC meeting on 14 May 2020 members discussed complaints which had been received from users of Cardinal masks, including that the masks had been disintegrating during use (exhibit RGB/220 - INQ000529309). Days later, on 20 May 2020, the Royal Wolverhampton NHS Trust emailed HSE highlighting an additional concern, drawing HSE's attention to its experience of testers of Cardinal masks experiencing a sense of breathlessness, and respiratory tract irritation, after approximately 5 minutes of wearing the mask (exhibit RGB/233 - INQ000529325). The regulatory position was complex as the product had been placed on the market as a medical device, although the mask may also have been PPE due to the splash protection provided. Discussions took place between HSE, MHRA and OPSS and it was agreed that MHRA was the MSA due to the fact that the product had been approved as a medical device.

88. Discussions regarding the Cardinal mask took place at DMC on 22 May 2020 (exhibit RGB/234 - INQ000529355), and it was agreed that an Important Customer Alert ["ICA"] would be issued (exhibit RGB/235 - INQ000529512). The situation in

respect of the masks continued to be monitored post the 22 May 2020 alert being issued. A report dated 23 June 2020 was prepared, recommending that the masks ought to be recalled or destroyed (exhibit RGB/236 - INQ000529465). The matter was subsequently discussed at DMC on 24 June 2020, the meeting minutes noting that "*it is suggested, based on MHRA advice, that we now go out with an alert to recall or destroy all stock of the product*" (exhibit RGB/237 – INQ000529480). A further ICA in respect of the masks dated 26 June 2020 was duly issued, stating "*MHRA has recommended that all lots of this product* (Cardinal Type IIR Masks) *are disposed of locally"* (exhibit RGB/238 – INQ000529496).

89. In addition to addressing issues through the DMC and RCC, HSE liaised directly with MHRA on issues relating to the use of products that required input from both regulators. For example, on 4 June HSE attended a meeting regarding the manufacture of gowns with MHRA, OPSS and BEIS PPE Make Team. The draft notes of the meeting (exhibit RGB/239 - INQ000529430) reflect that that the PPE Make team was making contracts with UK manufacturers to produce 12 types of PPE/medical devices, including gowns. The joint MHRA/HSE Essential Technical Specifications document sets out the tests that each type needs to meet to be eligible for central NHS procurement during the covid-19 crisis, under the appropriate regulatory easement. These specifications refer to both UK manufactured equipment and equipment purchased from overseas. MHRA and HSE were working on a specification to assist manufacturers with the regulatory process. It was agreed by HSE and MHRA that the specification needed to be prescriptive as regards the degree of protection afforded (e.g. fluid resistance, strength etc.) but not prescriptive as regards the garment construction.

90. During the pandemic HSE and MHRA were also required to consider issues in relation to the potential use of new products that had not previously been categorised as PPE or a medical device. These issues were often novel in nature. For example, in April 2020, the designer and Co-owner of AerosolShield (a tent placed over patient's head) sought clarity from MHRA on whether it was regarded as a medical device. The email reflects that clinicians and hospitals were asking to use AerosolShield. MHRA did not consider it to be a medical device and sought input from HSE in respect of our view in relation to whether the product was PPE

(exhibit RGB/240 - INQ000529148). Following email correspondence between MHRA, HSE and NHS England and Improvement (exhibit RGB/241 - INQ000529189) the matter was discussed at DMC on 22 April 2020 (exhibit RGB/242 – INQ000529198) and it was agreed that the product was neither PPE nor a medical device so would fall to be regulated under general product safety regulations and s6 HSWA.

91. HSE and MHRA recognised the importance of ensuring that decisions on dual purpose products were dealt with efficiently. For example, in May 2020 HSE agreed with MHRA that MHRA would take the lead in the relation to the regulation of FRSM's where manufacturers were applying for CE markings covering both FRSMs and RPE (EN149) (exhibit RGB/243 - INQ000529373). Based on this agreement, HSE did not consider applications for easements in circumstances where MHRA had already granted a derogation, allowing for approvals to be actioned, and approved products moved into the supply chain as quickly as possible. A similar approach was adopted in respect of other dual-purpose products. Later in the pandemic, the approach to the regulation of dual-purpose products was considered further, as evidenced in email correspondence between HSE and MHRA in December 2021 regarding the approach to assessments by HSE when MHRA had granted a derogation (exhibit RGB/244 - INQ000529658).

92. HSE worked closely with MHRA to ensure that up to date and accurate guidance on essential technical specifications for PPE and medical devices was available for Government departments and organisations involved in the procurement of PPE and medical devices ["ETS guidance"]. This is explained in more detail in paragraphs 108 – 113 below.

Engagement with OPSS and MHRA at PPE Hub in Daventry

93. In April 2020, following a request from DHSC, HSE attended the PPE hub in Daventry, a large warehouse being used as a distribution depot for PPE, operated by Clipper. HSE was asked to assist the MOD with the assessment of PPE procured by the Government through SCCL or donated via various sources. During the first few days on-site it became apparent that MOD also needed

assistance with the assessment of medical devices. HSE advised MOD that MHRA should be in attendance, and it was agreed that the MOD would facilitate this. It was also agreed that OPSS should have a presence on-site due to their role as the national regulator for product safety.

94. A working group was established at the PPE hub in Daventry which included representatives from HSE, OPSS, MHRA, MOD, Hatmill and later SCCL. The aim of the group was to rapidly assess products arriving for the NHS supply chain to address the immediate demand for personal protective equipment and medical devices, relating to Covid-19.

95. On-site representatives from OPSS, MHRA and HSE agreed roles and responsibilities including allocation of products for assessment. We developed a process map (exhibit RGB/245 - INQ000529234) to identify actions to be taken upon receipt of goods into Daventry and supporting guidance (exhibit RGB/246 - INQ000529233). The ETS guidance was used to assist in allocation of PPE and medical devices and on-site decision making. HSE also assisted to develop a draft Terms of Reference (exhibit RGB/247 - INQ000529421) for the team that was based at Daventry. This was to be approved by RCC (exhibit RGB/248 - INQ000529415).

96. OPSS provided technical and policy support to HSE and MHRA to inform regulatory decisions. Policy support was also provided to clarify the terms of regulation and regulatory easements, as applied to PPE by OPSS and HSE as the MSA.

97. OPSS, using BEIS servers, owned and hosted a SharePoint site which was accessed by a number of external organisations including HSE, MHRA, MoD and NHS. The SharePoint site hosted a master spreadsheet (exhibit RGB/249 - INQ000529806) which logged and tracked all products requiring regulatory clearance at the Daventry distribution centre. Correspondence containing any evidence (including photographs and documentation) were also uploaded to SharePoint. The SharePoint site also hosted the data reports and statistics from the Daventry distribution centre.

98. HSE were also involved in ongoing discussions with MHRA, OPSS and NHS regarding the management and movement of stock in Daventry including discussions about disposal options for items that did not meet regulatory standards. I exhibit an email dated 21 May 2021 (exhibit RGB/250-INQ000529340) inviting HSE, BEIS and MHRA to attend a meeting to discuss the development of a decision-making process for the movement of quarantined stock.

99. There was consultation between HSE and OPSS about the exit strategy for HSE's Supply Team from Daventry. This helped to inform the OPSS Handover Plan for the Covid-19 NHS PPE and medical devices regulatory clearance process, which I exhibit as RGB/251 - INQ000529456.

Trading Standards

100. Trading Standards are the co-regulators of the Product Safety PPE Regulations 2016/425, and the enforcing authority where the item in question is considered to be a consumer product. As part of the performance of our regulatory functions we monitor the compliance of economic operators based in the United Kingdom. We are not able to take enforcement action against foreign based manufacturers or suppliers to prevent non-compliant products from being sold to organisations in the UK but we can take action to prevent non-compliant items entering the national supply chain once they arrive in the UK.

101. Due to the nature of our regulatory roles, HSE works closely with Trading Standards colleagues as there is the potential for significant crossover or queries relating to investigation or enforcement and determining whether a piece of PPE is intended for use at work or by a consumer is not always straightforward. During the pandemic, members of HSE's PPE Unit built on good existing regulatory relationships and worked closely with Trading Standards colleagues, particularly the lead Trading Standards officer for the PPE Regulations. This was invaluable for the sharing of intelligence, especially around suspect suppliers, certificates and test bodies. It also allowed HSE to gain insight into activity at ports and borders, regulated by Trading Standards officers. HSE also worked with Trading Standards

at a regional level, for example in the East of England, HSE and Trading Standards colleagues corresponded and liaised via TEAMS meetings on a regular basis throughout the pandemic which was invaluable in terms of discussions relating to sharing regulatory experience and competence. This work enabled the organisations to better co-ordinate on investigations, producing guidance and developing consistent positions on matters of enforcement.

102. HSE also liaised with Trading Standards through the RCC, sharing information that was relevant to each organisation in the discharge of its regulatory functions.

BSI

103. HSE engaged directly with BSI during the development of the ETS guidance. Through discussion with PPE and Microbiology technical experts from the DMC and BSI, HSE determined what were essential requirements (denoted by the word 'MUST' in the guidance) and those which were highly desirable (denoted by 'SHOULD' in the guidance). For items such as FFP3 respirators and coveralls the technical specifications included most of the requirements set out in the relevant Standard. Items such as visors had a higher degree of regulator discretion because HSE were aware of the work environments which the PPE would be used, meaning some requirements were highly desirable but not essential. Some test requirements e.g. flammability was considered not necessary for the situation of use, these were set out in the essential technical specifications.

104. As the pandemic evolved, new products were added to the list contained within the guidance. In some instances, these products did not have a relevant Standard or equivalent. HSE led the development of technical specifications for PPE products where there was no Standard or equivalent. An example of this was the non-surgical (non-sterile) isolation gown (disposable and re-usable). We needed to develop a technical specification for this item of PPE as the only Standards that existed were for surgical gowns and protective coveralls (suitable for biological contamination). A technical group involving representatives from HSE, MHRA, BSI and PHE was set up to develop the technical specification. HSE compiled an information sheet setting out the background and the Standards for existing

products which was shared with the technical group (exhibit RGB/252 - INQ000529837). The email exchanges exhibited as RGB/253 - INQ000529223 and RGB/254 - INQ000529224 is evidence of the collaboration between technical group members in the development of the specification.

105. In addition to the development of the guidance, during the early stages of the pandemic HSE worked with BSI to fully understand the role of a notified body in the certification processes and the detailed elements of testing included in Standards. HSE also worked with BSI in relation to PPE that had been through BSI's certification process for supply into healthcare settings.

106. As BSI were also involved with the certification of new products during the pandemic, whilst carrying out its assessments, if HSE's Technical Team had questions about tests undertaken by BSI they would raise queries directly with BSI, usually by email. I exhibit an example of such correspondence at RGB/255 - INQ000529579.

HSE's engagement with DHSC on the procurement of PPE and other key medical supplies

107. HSE was not directly involved in the procurement of PPE during the pandemic but HSE was involved in providing advice and guidance to DHSC and other NHS bodies in relation to the procurement of PPE for healthcare workers. This was either through direct liaison with DHSC and other NHS bodies or through the DMC. HSE recognised that purchasers were buying non-compliant PPE that could not be used when it got to UK, so we worked with Government procurement routes to help them make better purchase decisions.

108. HSE was not involved in assisting DHSC in relation to the procurement of ventilators, lateral flow tests or PCR tests.

The development of the ETS and other guidance to assist the procurement of PPE

109. Early in the pandemic, through the DMC, HSE and MHRA led the development of the ETS intended to assist DHSC and other Government departments involved in the procurement of PPE. The guidance was also to be used by new manufacturers of PPE and medical devices to understand the technical specifications that were required. Minutes from DMC meetings in April (exhibit RGB/256 - INQ000529173) and May (exhibits RGB/257 - INQ000529298 and RGB/234 - INQ000529355) refer to the development of this guidance.

110. The first version of the guidance was published by the Cabinet Office in May 2020 (exhibit RGB/149 - INQ000269668). 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 SARS-CoV-2 when the item did not have a CE marking. The guidance detailed the minimum design, performance and labelling requirements for medical devices and PPE to ensure that the products were capable of providing healthcare workers with appropriate protection against SARS-CoV-2. The document also detailed the relevant Standards and other reference documents for each product. Products detailed in the guidance included face, eye, body and respiratory protection.

111. The guidance evolved over the course of the pandemic as more information and technical evidence became available, for example, in respect of PPE products that were designed in a way not typically seen in the UK market prior to the pandemic. Appropriate amendments were discussed and agreed at the DMC with revised versions published in August and October (the October guidance is exhibited as RGB/150 - INQ000269667).

112. The ETS guidance also highlighted where a product did not meet the technical requirements for PPE or medical devices. An example of this was in relation to ear looped respirators which did not meet the technical requirements as they did not meet face fit testing requirements and they could not be properly secured.

113. HSE and MHRA developed a list of approved PPE products, as discussed at the DMC in June 2020 (exhibit RGB/221 - INQ000529437). I exhibit a copy of the approved products list as RGB/ (exhibit RGB/258 - INQ00052927).

114. HSE and MHRA also assisted DHSC to produce an FAQ document (exhibits RGB/259 - INQ000529368 (Version 1) and RGB/260 - INQ000529518 (Version 2)) regarding the technical requirements for PPE and medical devices. This was intended to be sent to all manufacturers and suppliers of PPE and medical devices into the NHS. The FAQs were updated in line with changes made to the ETS guidance.

115. In addition to the ETS guidance, HSE produced product specific guidance sheets in conjunction with the DMC which set out the evidence that would be required by regulators when considering whether a product could be granted an easement or derogation. These were developed to assist manufacturers to design and manufacture products that would meet the technical requirements. The guidance documents to be produced were discussed at DMC, as shown in the minutes to the meeting that took place on 26 June 2020 (exhibit RGB/261 - INQ000529485). The guidance documents were provided to BEIS on 7 August 2020. I produce the guidance documents as exhibit RGB/152 - INQ000269647 (FFP3 and FFP2), exhibit RGB/153 - INQ000269655 (face visors and googles), exhibit RGB/154 - INQ000269636 (re-usable isolation gowns) and exhibit RGB/ - 155 INQ000269642 (disposable non-sterile isolation gowns).

Developing and delivering training to assist the procurement of PPE

116. In April 2020, HSE prepared and delivered training with colleagues from OPSS and MHRA to staff from a range of organisations including DHSC, SCCL and NHS bodies who were involved in the procurement of PPE and medical devices (exhibit RGB/262 - INQ000529220). This included DHSC staff who were going to be based at manufacturers' sites in China to quality assure products before they were shipped to the UK who were known as the "China Buy Team". The aim of the training was to provide information and insight to help those involved in the procurement process avoid unsuitable or counterfeit PPE and medical devices.

Minutes from DMC meetings in April (exhibit RGB/263 - INQ000529190) and May (exhibit RGB/264 - INQ000529317) refer to the development of this training.

117. The training package was updated in May 2020 (exhibit RGB/265 - INQ000529249) and June 2020 (exhibit RGB/266 - INQ000529425) with substantial additions provided by MHRA regarding medical devices. Over 130 delegates accessed the training across 5 live on-line sessions facilitated by HSE's Commercial Training Team.

118. HSE also provided training to DHSC's Quality Assurance Team on 4 August 2020 as part of the exit strategy from the Daventry PPE Hub. This training included delivery of the training materials put together by OPSS, MHRA and OPSS, the ETS, the assurance process and additional training on the procurement of coveralls and gowns (exhibit RGB/267 - INQ000529809).

Advice and guidance provided by HSE in relation to procurement issues at DMC

119. Issues relating to the procurement of PPE were frequently discussed at the DMC during relevant period. During the early stages of the pandemic, DMC were meeting on a daily basis and issues relating to the procurement of PPE were often being considered by the committee. From the minutes of DMC meetings that have been reviewed by HSE to compile this statement, we have identified the following examples of relevant discussions. They are presented in chronological order and I have exhibited the relevant DMC meeting notes.

120. On 16 April 2020 it was confirmed that HSE had sent an investigations team to Daventry to test stock which had arrived and been quarantined due to inadequate paperwork so that checks could be carried out potentially allowing the items to be distributed (exhibit RGB/268 - INQ000529139).

121. On 17 April 2020 the potential procurement of Kingsmoor visors was discussed. It was agreed that HSE would need to check that the minimum specifications were met for the product to be placed on the market (exhibit RGB/269 - INQ000529153).

122. On 5 May 2020 the minutes note that HSE had received a number of enquiries, including from Nissan, on the requirements for aprons, and that the Chair of DMC was to send minimum specifications, approved by HSE and including apron specifications, to the DHSC, so that all the changes made by both DHSC and HSE could be incorporated into the final version of the minimum specification for publication (exhibit RGB/270 - INQ000529256).

123. On 7 May 2020 HSE informed DMC that it had decided that Tiger goggles did not offer suitable protection against SARS-CoV-2. DMC agreed with HSE's assessment and that this decision should be communicated to suppliers of that PPE; and that in response to a query from the Scottish Government HSE agreed to provide a list of approved and non-approved suppliers to the buying team (exhibit RGB/217 - INQ000529236).

124. On 8 May 2020, and in readiness for the imminent arrival of Apple visors at Daventry, a letter intended to be released with the products should be checked to confirm it reflected the exact wording that HSE had previously provided (exhibit RBG/271 - INQ000529267).

125. On 11 May 2020 the minutes note that HSE had become aware of two buying portals which the Scottish and Welsh governments had been using for PPE procurement. It was agreed that HSE would circulate a link to the portals so as to ascertain compliance with the minimum technical specifications (exhibit RGB/272 - INQ000529283).

126. On 15 May 2020 it was agreed that HSE would provide comments on Apple masks (exhibit RGB/264 - INQ000529317).

127. On 19 May 2020 it was confirmed that HSE input had enabled a draft to be completed letter for Apple stating that the masks had been assessed as fit for purpose for use against Covid-19 in health and social care and could be used as part of the PPE ensemble (exhibit RGB/273 - INQ000529324).

128. On 21 May 2020 HSE reported that it had identified an example of a £10 million purchase of KN95 masks that were not usable and as to share the details of that purchase as well as commenting on FAQs, the target audience for those questions being "*external parties*" that wanted to produce PPE against the essential specification, specifically for UK health and social care organisations (exhibit RGB/274 – INQ000529337).

129. On 27 May 2020 HSE stated it had been sent a question from Daventry regarding coveralls, to which HSE had stated that although the coveralls met the US standard for coveralls (AATCC 127) (hydrostatic pressure of 20cm H20), that was not the equivalent of the standard(s) used in the UK, and could not therefore be used in a COVID-19 setting (exhibit RGB/275 – INQ000529366).

130. On 29 May 2020 HSE confirmed it would be sending information to Lord Deighton's team. HSE was asked to put this in front of potential manufacturers to "*get feedback to ensure it is as useful as it can be*" (exhibit RGB/276 – INQ000529418).

131. On 4 June 2020 it was agreed that a call should be held between HSE and SSCL to explore alternative uses for PPE which had been procured but did not meet the relevant standards for its original stated use (exhibit RGB/277 – INQ000549445).

132. On 8 June 2020 HSE presented a paper on ear looped masks to DMC following which it was suggested that recommendations could be made to manufacturers "*not to make the masks and buying teams not to buy them*". (exhibit RGB/278 – INQ000529450).

133. On 10 June 2020 it was noted that HSE had deemed Burberry gowns safe to use; that HSE would provide information on the relevant standards for safely buying products that were CE marked; and that in respect of ear looped respirators following an HSE presentation it was decided that DMC guidance would reflect that manufacturers of ear looped respirators would not be sought, and nor are would "*the buy team*" be seeking to buy those types of respirators (exhibit RGB/279-INQ000529454).

134. On 22 June 2020 there was an action for the DHSC to organise a small working group, including HSE, to review Annex 2 of the DHSC paper on PPE products which had "*not met the required standard*" (exhibit RGB/280 – INQ000529469).

135. On 10 July 2020 HSE participated in discussions regarding (1) a conversation with the FCO to be opened to fully understand the then FFP2/3 export requirements in China, commenting that some products had already arrived in Daventry; and (2) the wording of letters to be sent out with aprons held at Daventry (exhibit RGB/281 – INQ000529500).

136. On 13 July 2020 it was confirmed that HSE had already agreed wording in respect of Arco products marked "not for medical use" (exhibit RGB/282 – INQ000529503).

137. On 15 July 2020 HSE were involved in discussions regarding the altering of labelling to contain wording around "*non-medical use in China but for medical use in UK and Europe*". It was highlighted that millions of products were either in production or in supply chain with "*not for medical use*" labelling (exhibit RGB/283 – INQ000529533).

138. On 22 July 2022 HSE prompted a discussion about whether isolation gown labels ought to explicitly say for COVID-19 use, as they were very specific. Gowns from China that were delivered to Daventry were used as an example by HSE. The gowns had passed hydrostatic and tensile tests but failed all others, so they were able to be used as isolation gowns but were not labelled as such. Discussion was had around the need for correct communications to accompany such products (exhibit RGB/232 - INQ000529525).

139. On 20 November 2020 the DMC agreed an action for discussions to be opened with the FCO to fully understand the then current FFP2/3 export requirements in China in respect of items marked "*not for medical use*". HSE stated that if a product was not CE marked it would need to "go forward for easement" (exhibit RGB/284 – INQ000529646).

140. HSE provided advice to DHSC and other agencies involved in the procurement of PPE to ensure that they understood HSE's regulatory position in relation to specific issues that would impact on the use and supply of PPE products, for example the use and supply of PPE subject to an easement following the expiry of the temporary legislative provisions and extending the shelf life of products, as shown in exhibit RGB/285 – INQ000529694. HSE also provided advice directly to NHS bodies on the suitability of PPE for procurement purposes, for example in April 2020 HSE was asked by NHS England and Improvement whether gowns accredited to the US standard were a suitable purchase. HSE advised that if purchased and imported, that these would need to go through a screening process and that they would need to be sent to a PPE Notified Body to demonstrate that these meet the relevant Essential Health and Safety requirements (exhibit RGB/286 – INQ000529125).

Regulation of the supply of PPE during the pandemic

Easements – Legislative Provisions

141. As a result of the emergence of the pandemic, the EU introduced provisions (EU Commission Recommendation 2020/403 of 13 March 2020) that enabled MSA's to grant regulatory easements that allowed PPE that had been shown to be suitably protective for protection against SARS-CoV-2 to be placed onto the market, even if not yet fully CE marked.

142. Domestic legislation came into force on 1 January 2021 implementing similar arrangements in England (the *Personal Protective Equipment (Temporary Arrangements) (Coronavirus)(England) Regulations 2020*) ("England Regulations") and Scotland and Wales ((the *Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Scotland) / Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020*) ("Scotland and Wales Regulations").

143. In relation to HSE's role in England, Regulation 2 of the England Regulations 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. HSE could grant applications under Regulation 2 from 1 January 2021 to 31 March 2021.

144. 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 the 2016 Regulations. Once the conditions were met, the obligations in the 2016 Regulations were treated as satisfied for the purposes of the PPE(E) Regulations. This provision applied from 1 January 2021 – 30 June 2021.

145. In respect of PPE for healthcare workers and other frontline workers, HSE would not require a conformity assessment to be completed after an easement had been granted. This was solely in cases where the conformity assessment procedure had not been completed and the conformity mark had not been affixed due to reliance on regulation 3 of these Regulations.

146. In relation to HSE's role in Scotland and Wales, Regulation 2 of the Scotland and Wales Regulations 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.

Recommendations for use ("RFUs")

147. In July 2020 the European Commission produced 2 RFUs to be used by Notified Bodies in certifying products in line with the EU easement. These specified a reduced list of requirements/tests that Notified Bodies could use, but which the European Commission still considered provided adequate safety in line with the easement. One of the RFUs was for eye & face protection and the second was for

respiratory protection. Both recommendations provide lower protections, in particular the RFU for respiratory protection omitted the total inward leakage test.

148. OPSS and HSE discussed the position in relation to RPE and both organisations had concerns that the list of testing requirements would not meet the essential technical requirements for the purpose of Regulation 2016/ 425. HSE subsequently prepared a letter to notify UK notified bodies that it would not accept RPE that had been tested to the reduced standards because they failed to meet the essential technical requirements set out in Regulation 2016/425. The draft letter is exhibited at RGB/287 – INQ000529680.

HSE's application of the easement provisions

149. Early in the pandemic it was recognised that there would be a need to source more PPE due to shortages across the NHS. There were products available from countries such as China that had not previously been accredited or assessed to be used in GB market, so could not be legally imported. The ability to grant regulatory easements widened the ability to find PPE from alternative sources, assess its suitability and allow it to be used if it provided the appropriate level of protection for healthcare workers.

150. On 25 March 2020, the Deputy Chief Executive of OPSS 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.

151. In order to implement the changes in relation to regulatory easements, HSE set up a decision making group ["the DMG"] comprising of Professor Andrew Curran (HSE's Chief Scientific Advisor), David Fishwick (HSE's Chief Medical Advisor) and myself. The DMG was supported technical experts ["the PPE Technical Team"] who would provide advice on a products conformity with the required technical specifications.

152. Under normal circumstances a company supplying PPE would send representative samples to a certified testing house to perform the necessary tests and, if passed, the results report would lead to the issue of CE / UKCA certification.

153. Instead of the above, for easements, scrutiny was undertaken by the PPE Technical Team which comprised of HSE staff with expertise and knowledge of PPE, including research and regulatory microbiologists with experience in infection control, RPE research topic leads and occupational hygienists.

154. As reflected in Review of SARS-CoV-2 PPE Unit Data: Internal report dated November 2022 (exhibited at RGB/288 – INQ000529804), documentation required by the PPE Technical Team to undertake an assessment included:

- Test reports;
- Photographs of the product and the packaging;
- A "EU Type Examination Certificate" from a recognised PPE Notified Body (NB);
- A Declaration of Conformity (DoC); and
- Evidence of conformity / quality assurance, usually in the form of a Module C2 or D certificate, or an ISO (International Organization for Standardization) quality management system certificate.

155. If there were concerns about the test results or if the laboratory was not one that had been accredited by a recognised authority, the product would be rejected, or an easement refused. The European Commission, Notified Bodies ("NANDO") website was useful in determining if a NB was recognised and accredited for that product category. If the product already had a verifiable CE mark with a recognised PPE NB, and had a (signed and dated) DoC, then the product could be technically assured.

156. Details of the assessment were recorded on a template form known as a "DMG form". The template was updated during the relevant period. I produce the most recent version of the template and user instructions (dated January 2021) as exhibit RBG/289- INQ000529671. I also produce a copy of an email to users of

the template dated 25 January 2021 explaining changes as exhibit RGB/290 - INQ000529664.

157. HSE's overarching aim was that PPE granted a regulatory easement must protect the end user. For each application, the PPE Technical Team would address the following risks as part of their assessment:

- Are instructions provided?
- Are they correct?
- Are there any caveats?
- Are labelling concerns addressed? e.g. "non-medical / not for medical issues".
- Has the intended use of the product been set out / explained?
- Has the correct testing been carried out by the test lab or notified body?
- Is the testing in accordance with that set out in the Essential Technical Requirements document?
- Are you satisfied that the test results meet or exceed the requirements of the relevant Standard?
- Does the Notified Body check out?
- Are there any concerns about the authenticity of the test data / or any other
- information submitted?
- Has the correct paperwork been supplied by the Notified Body and are there any concerns about its authenticity?

158. When a member of the PPE Technical Team concluded that there was sufficient information available to enable a decision to be made by DMG, the DMG form would be reviewed. Firstly, this was done by other PPE Technical Team members and then the team leader. Once fully checked the DMG form was sent to DMG. DMG members would ask for clarification on points made on the form if required. Easement approvals needed to be unanimous. Where there were different points of view, the DMG met virtually with the relevant PPE Technical Team members also present to provide additional clarification or information.

159. Following a decision by the DMG, the Triage team sent the decision detailed on the form to the enquirer via email.

160. Between April 2020 and June 2021, HSE granted 147 easements and refused a total of 128 applications. This information is contained within the HSE's Review of SARS-CoV-2 PPE Unit Data: Internal report dated November 2022 at exhibit RGB/288 – INQ000529804. We have compiled a schedule that provides details of the easement applications that were considered. I exhibit this schedule as exhibit RGB/291 – INQ000529843.

161. During the pandemic, Cabinet Office provided a daily dashboard to HSE and OGDs of the numbers of PPE and key healthcare equipment and supplies in the NHS. For example, the dashboard may have indicated that the NHS was running low on surgical gowns, and this helped those involved in sourcing PPE to understand what items needed to be prioritised. From HSE's perspective, the information reaffirmed the importance of regulatory easements process in accelerating the provision of appropriate PPE to end users to ensure they were adequately protected. I produce a copy of slide pack, *"PPE PMO Update 24 June 2020 London"* exhibited at RGB/292 – INQ000529462 that reflects the top 3 airfreight and buying priorities for DHSC were for gloves, FFP2 and FFP3 masks.

162. Data in relation to applications for easements that had been considered by HSE, (both those granted and those rejected) was collated and sent to OPSS. During the relevant period, HSE identified anomalies in the data being reconciled for OPSS due to the fact that a number of products were being referred back to HSE for further consideration after an initial application had been refused. HSE sought to address this, but the issue proved quite challenging, due to the dynamic nature of the environment that HSE was operating in. HSE undertook a review of all of its easement related activity as part of the preparation of the PPE Unit report to ensure that it had a robust and accurate dataset. It worked with OPSS and Clipper to ensure that the issue was resolved. This is reflected in the evaluation of easements that OPSS undertook, which is explained in more detail in paragraphs 401 - 403.

163. Whilst HSE's easement assessment process primarily focussed on PPE performance against technical specifications, consideration of the impact on end users did inform decision making. For example, assessment of surgical gowns included consideration of thermal comfort. I produce copy completed "*DMG form*", dated 10 April 2020 recommending approval for use of 200,000 coveralls for healthcare workers as exhibit RGB/293 – INQ000529013.

164. During the pandemic HSE did see new manufacturers emerging who were producing PPE for the first time. In these cases, it was recognised that there may be additional risks in relation to the manufacturer's ability to consistently maintain the required product standards. When making decisions on granting easements for new manufacturers, the DMG would need to be confident that the manufacturer or supplier had the appropriate quality assurance in place to continually meet PPE requirements and ensure that all items produced were of the same quality as the item tested and assessed by the Technical Team for regulatory easement.

165. HSE does not hold reliable data relating to the number of complaints received in relation to PPE that was subject to an easement. This is in part due to the fact that complainants would not necessarily know that the product that was the subject of the complaint had been granted a regulatory easement. However, HSE did observe an increase in the number of complaints received about some products that had been granted an easement, including:

- ClearMask – this was a transparent face covering that was given an easement for when communicating with deaf patients that could lip read. It didn't provide the same prevention of transmission as a surgical mask but did provide droplet protection for the wearer. This easement was issued based on the premise that users could undertake a local risk assessment to decide on where and when it could be used, based on the risk of lack of communication balanced against the risk of asymptomatic transmission. However, this generated issues due to the inability to perform local risk assessments.

- Not for Medical Use – this was a manufacturer's marking on Chinese exported PPE for customs purposes. Easement was granted for use as PPE in health and social care. However, concerns were raised about the marking.

- Lack of CE marking – easements were granted as an alternative to obtaining a CE marking and completing a full conformity assessment. However, concerns were raised about the lack of marking.

166. The technical specifications for PPE did not change as a result of any of the easements considered by HSE.

167. HSE engaged directly with a number of healthcare bodies regarding the changes to the product safety regulations, particularly NHS England and NHS Improvement. The steps taken to provide advice and guidance to organisations involved in the procurement process is outlined in paragraphs 106 to 139 above.

168. To the best of my knowledge and recollection, HSE did not communicate the changes in legislation directly to NHS employers or representative bodies. This is due to the nature of the role undertaken by HSE as MSA. OPSS are responsible for the legislative framework for the regulation of product safety. HSE's role in to monitor conformance with the essential technical requirements. As part of this role, HSE would not engage directly with the end user of the product, unless this was necessary in response to a concern or report regarding a product. The implementation of the easement provisions did not alter the scope of HSE's role, they amended HSE's approach to determining conformity with the legal requirements.

169. HSE did take steps to assist other departments and agencies where a communications plan was necessary in relation to a particular product or type of products that had been granted an easement. For example, in October 2020 HSE drafted an advice paper for consideration by DHSC and DMC on how products imported from China that were labelled "not for medical use" could be used in the UK (exhibit RGB/188 – INQ000269755). As part of this advice paper, HSE commented on the importance of a communications plan to assist dutyholders to

understand the status of the products. HSE also drafted suggested template letters which are contained at Annex 3 of exhibit RGB/188- INQ000269755.

Assessment of PPE intended for supply in healthcare at PPE Hub in Daventry

170. As highlighted in paragraphs 92 – 98, from April 2020 HSE set up a Supply Team based in Daventry to assist the MOD with conformity assessment of government procured PPE. The Supply Team remained at the Daventry site undertaking assessments of PPE until September 2020.

171. If following the assessment by the HSE Supply Team, it was deemed that a product did not meet the requirements, it was marked either as "not fit for any use", "not fit for C-19 use" or "referred to TA" (HSE's Technical Assurance Team). HSE would notify other members of the working group at Daventry (including MOD, OPSS and MHRA) of the outcome of its assessment of products. However, HSE was not responsible for making the decision about whether products were subsequently released into the supply chain.

172. There were a number of issues which led to products being deemed unfit for their intended use, including:

- Documents provided found not to be bonafide (such as test houses confirming they had not tested the products in question and had not issued any certification)
- No documents or incomplete documents (such as no test data or user instructions)
- Incorrect iteration of relevant / correct standards
- Products not tested to the relevant / correct standards
- Missing components

173. Details relating to the quantity of items assessed as "not fit for any purpose", including were captured on a database maintained by the OPSS which I produce as exhibit RGB/249 - INQ000529806, a database maintained by Clipper which I

produce as exhibit RGB/294 – INQ000529498 and a database maintained by NHS Supply Chain which I produce as exhibit RGB/295- INQ000529805.

174. Additionally, a summary of HSE's interventions at Daventry was prepared and presented as part of the report presented to HSE's ExCo and Board, "*the Effect of Covid in the Workplace*" (RGB/204 – INQ000269707). This highlights that between April 2020 and December 2020, the Supply Team undertook 727 assessments of PPE products that had been procured for supply, covering approximately 245 million items of PPE. Of these, 70 product lines were deemed not fit for any use, 67 product lines were deemed not fit for healthcare, 24 product lines were deemed not to be PPE and 66 product lines were referred to the Technical Team as there was insufficient information available to assess whether the product was suitable for an easement.

175. HSE did have concerns about operations as it transitioned away from having a presence at Daventry, which is reflected in an email chain dated between 20 and 23 July 2020 that I produce as exhibit RGB/296 – INQ000529521. HSE became concerned that PPE was being released by Clipper from Daventry to NHS Trusts without the necessary assurance checks having been completed. Examples of this included:

- Guardian Visors sent out before checks were completed;
- Valmy masks assessed as 'Not Fit For any Use' being labelled as a Type IIR surgical masks and then distributed as a FFP3 respirators; and
- GVS FFP3 CE marked respirators being sent out after the product was locked due to a known defect.

176. HSE explained to NHS England and NHS Improvement staff that this was a serious matter amounting to a material breach of the law and that work needed to be managed through robust technical and quality assurance management systems, including the necessary resources, supervision, monitoring and review to avoid these mistakes and errors happening. As shown in exhibit RGB/296 – INQ000529521, HSE requested a meeting to discuss our concerns.

177. In August 2020, HSE raised similar concerns regarding multiple gowns held in Daventry warehouse that required testing. HSE made it clear to DHSC, MOD, and NHS that once test data for the gowns was received, dependent upon their intended use, either as PPE or a MD, they would need to approach the relevant MSA to request an easement/derogation. HSE emphasised that the items should not be released into the supply chain until confirmation of compliance with the minimum legal requirements had been received from the relevant authority (exhibit RGB/297– INQ000529534).

Working with Trading Standards in relation to non-compliant PPE

178. HSE was not involved in seizing items of PPE that were non-compliant with the relevant safety requirements, although HSE was aware of some seizures made by Trading Standards and Border Force through engagement at the RCC.

179. The assessments of products by HSE's Supply Team in Daventry were undertaken to prevent non-compliant PPE that had been centrally procured through SCCL or donated to the UK by other sources being supplied into the healthcare sector. In addition to the team in Daventry, HSE has a Supply Team that was working as part of the PPE Unit that responded to information from other regulators and concerns received from organisations or employees etc, regarding non-compliant PPE. This would include concerns about PPE purchased directly by healthcare and social care organisations and PPE procured centrally.

180. HSE's PPE Supply Team received notifications from Trading Standards about non-compliant PPE for sale on the UK market. For example, on 12 January 2021 a concern was received from Hampshire Trading Standards about KN95 masks being advertised for sale by Get Masked Up Limited. A copy of the email is exhibited as (RGB/298 – INQ000529659). HSE wrote to Get Masked on 15 January 21 advising that FFP2 one type of KN95/N95 must be removed from sale immediately and the second type must be sent to HSE for assessment (exhibit RGB/299 – INQ000529663). On 27 January 2021 HSE chased up the matter and Get Masked Up confirmed the items had been removed from sale (exhibit RGB/300 – INQ000529667). Following further checks, the matter was closed down.

Products tested against the specifications set out in RFUs

181. As highlighted in paragraphs 146 and 147, during the pandemic the European Commission issued RFUs for the conformity testing of PPE. HSE did not adopt the RFU testing standards for RPE as in our view, they were not compliant with the requirements of the 2016 Regulation. As part of its market surveillance activities, HSE identified conformity assessment bodies who were testing and certifying products applying the RFU specifications. HSE wrote to these bodies advising that we were refusing applications for easements where testing had been performed based on the RFU specifications and that we would take steps to remove products in the supply chain from the market. The correspondence also sought confirmation from the organisation of any other products that they had tested to the RFU specification. A copy of a letter sent to a conformity assessment body is exhibited as RGB/301- INQ000529678.

Action in relation to non-compliant or defective products that had entered the supply chain

182. HSE was made aware of concerns regarding non-compliant or defective PPE that had entered the supply chain through a number of different channels, including through concerns received by Clipper or the HSE Supply Team in Daventry and through concerns reported directly to HSE through the PPE Unit.

183. Between March 2020 and December 2020, HSE assisted DHSC to remove 35 product lines from supply where it had been identified that it had been incorrectly released into the supply chain or was found to be defective when used by healthcare workers. This impacted on 281 million items of PPE. This data was presented to ExCo as part of the report looking at the effect of Covid-19 in the workplace (exhibit - RGB/204 – INQ000269707). HSE's role in assisting DHSC was to provide technical input into the product recall notices (Important Customer Alerts). Separately, HSE's Supply Team would determine whether an investigation in relation to compliance with the PPE(W) Regulations was required. HSE also

assisted to develop intelligence to target importers and suppliers of these products outside health and social care settings.

Enforcement action in relation non-compliant PPE

184. HSE has not instituted prosecution proceedings in connection with non-compliant PPE purchased or supplied during the relevant period. However, it did take enforcement action to ensure that non-compliant PPE was withdrawn from the market.

185. Between April 2020 and April 2021 HSE's PPE Supply Team followed up concerns raised against 231 suppliers and importers where non-compliance was identified, 34 of which related to products that were intended for use in healthcare or social care settings.

186. Of the 231 concerns raised, 16 companies could not be contacted or identified. 28 were suppliers of medical products outside HSE's regulatory remit. Nine products were found to be compliant. The remaining products were removed from supply after an email or formal letter or the service of a Notice. The PPE Supply Team served a total of 22 Withdrawal Notices on six suppliers (one for each non-compliant product they were supplying). All Notices were complied with. Suppliers' websites were periodically checked to ensure they continued to comply.

187. Of the 34 matters relating to suppliers of products intended for use in healthcare or social care, HSE served Withdrawal Notices on 2 suppliers. One of these suppliers received 4 Notices in respect of different products.

188. The PPE supply work transferred from the PPE Supply Team to HSE's PSMSU at the end of April 2021. HSE's PSMSU evaluated 27 products and, in the process, engaged with 25 dutyholder 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 evaluations as RGB/302 – INQ000529823.

189. The evaluations have all now been concluded and action has been taken by HSE. In all of the cases, HSE wrote to the dutyholder suppliers requiring either the withdrawal of products, their recall, or other specified actions. In all cases, the requirements have been satisfied without further enforcement action being required.

Fraudulent PPE

190. There was a prevalence of fraud during the pandemic with fraudulent items of PPE emerging for sale on the UK and international market. Some items of fraudulent PPE either centrally or individually procured by NHS Trusts did enter the health and social care supply chain despite a co-ordinated effort by regulators to prevent this from occurring.

191. In March 2020 manufacturers of respirators 3M contacted HSE to report an increase in fraudulent and counterfeit activity in connection with COVID-19. Examples included people fraudulently misrepresenting themselves as being affiliated with 3M and having authentic 3M product to sell or are selling counterfeit 3M products. I produce an email from 3M as exhibit RGB/303 – INQ000529984.

192. To assist in preventing fraudulent PPE from being procured, in April 2020, training prepared and delivered by HSE with colleagues from OPSS and MHRA to staff from a range of organisations including DHSC, SCCL and NHS bodies who were involved in the procurement of PPE and medical devices included slides on what to look out for on CE and none CE marked PPE as well as examples of non-compliant masks and coveralls.

193. In April 2020 DHSC was offered 70,000 KNP5 masks to purchase. OPSS believed that reference to KNP5 was another way of referring to KN95 respirators. DHSC, OPSS and HSE all agreed that a proper assessment was necessary. I exhibit the email chain as RGB/304 – INQ000529157. The completed DMG form dated 20 April 2020, exhibited as RGB/305 – INQ000529159 recorded that *"There is no such thing as a KNP5 mask, if this reference is correct (i.e. not a typo or a genuine*

alternative to denoting KN95) then this would be a red flag for a counterfeit product". The form also went on to record that *"The KN95 standard requirements are broadly the same as the European Standard. However, there is a higher proportion of counterfeit products and as HSE understands they are certified by self-declaration from the manufacturer. As such care is needed when purchasing masks certified to the Chinese standards".*

194. In May 2020 HSE staff working out of Daventry identified fraudulent certificates accompanying a batch of coveralls and were therefore not suitable for release. I exhibit the email chain as RGB/306- INQ000529288.

195. In January 2021 a batch of 3M FFP3 respirators that had been independently sourced by NHS Wales were quarantined after a significant amount of them had obvious faults with the exhalation valve. Wye Valley Trust had also raised concerns about 3M FFP3 respirators having a different appearance (exhibits RGB/307 – INQ000529661 and RGB/308 – INQ000529682). Samples of both respirators were sent for testing and in March 2021 3M confirmed that they masks were not authentic.

196. In or around March 2021 HSE became aware of a large volume of new PPE products, many of which were ear loop respirators, coming to market from China to which Universal Certification had awarded CE marking. HSE examined product documentation, much of which came from a sub-contract test house which Universal Certification were using. The documentation covering different PPE items was so similar so as to raise suspicion. HSE investigated further and concluded internally that it was highly unlikely, if not impossible, that the respirators were being correctly tested to the Total Inward Leakage test method detailed in EN149.

197. HSE conducted an investigation into the test house, which was stated as being located in the USA. A HSE representative rang the test house, and during the call it was admitted that the test house was, in reality, located in Turkey. HSE shared its finding and concerns with the BEIS, who subsequently passed on the information to the OPSS on 21 March 2021 by email, stating "*please be extra*

vigilant with checks carried out on any PPE which has been conformity assessed by the Turkish Notified Body – Universal Certification". This information was then forwarded to relevant bodies, including DHSC, on 22 March 2021 (exhibit RGB/309 – INQ000529683), thereby alerting DHSC to potential non-compliance of PPE items certified by Universal Certification and informing any procurement decisions regarding those items, and other items with which Universal Certification had been involved.

198. In October 2021 DHSC prepared a, "*Root Cause Investigation Report",* exhibited at RGB/310 – INQ000529761. This followed an investigation to review the processes and events that led to the procurement and supply of counterfeit facemasks to frontline NHS employees, namely Fangtian FT045A. The executive summary records *"The facemasks procured by DHSC through SCCL were marked as a model FT045A; in September 2020, just prior to the release in to the wider NHS, Clipper Logistics personnel and a HSE representative raised a concern direct with the DHSC Category Leads and SCCL in respect of the discrepancy between the actual facemask model number and the BSI reports. Even after the challenge was made, pressure in the form of email communications came from DHSC Category Leads and SCCL to Clipper Logistics stating that Polyco and the SCCL Technical Assurance Teams had given assurance that the facemasks were authentic and fit for purpose. These previous technical assurance assessments, however, failed to robustly question or investigate the discrepancies. The product was therefore cleared for frontline NHS use.*

ClearMask

199. HSE issued a regulatory easement in relation to 'ClearMask' on 23 May 2020. This was confirmed to NHS England and NHS Improvement on the same day (exhibit RGB/311 – INQ000529564). At that time, airborne transmission had not been determined as the main route of transmission for Covid-19. The ClearMask offered considerable advantages for certain patients and staff with communication difficulties and the product offered similar splash protection to that of a fluid resistant surgical mask (FRSM) but was not CE marked.

200. A copy of the completed DMG decision proforma for regulatory easement is exhibited as RGB/312 – INQ000529342. ClearMask is described as a transparent product intended to provide equivalent wearer protection to a Type IIR FRSM but allow more of the face to be seen. It was considered PPE due to the splash protection and had been tested to a standard equivalent to EN14683. The regulatory easement decision was to allow the ClearMask product into the NHS supply chain for COVID-19 treatment of hearing impaired or deaf patients and where also deemed necessary, subject to limitations for use being made clear, specifically that the product:

- Was for single use per patient contact;
- Should not be used in high risk or surgical settings;
- Should not be used where there is a risk of excessive splashing or spraying of body fluids;
- It had not been assessed for bacterial efficiency to protect the patient from the worker and should not therefore be used in place of a Type II surgical mask to protect vulnerable asymptomatic patients; and
- It was not an FFP3 respirator to protect the worker during aerosol generating procedures.

201. HSE's position in relation to the easement for the ClearMask did not change during the pandemic, in particular that it provided splash protection for the wearer. However, its usefulness may have lessened as more evidence supporting aerosol transmission of Covid-19 emerged.

202. HSE 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 could not recommend the use of certain items of PPE because the adequacy and suitability of PPE is to be determined by the employer.

HSE's approach to regulating the use of PPE prior to the pandemic

203. As highlighted in paragraph 8, HSE carries out its regulatory functions using a number of methods to influence change and assist dutyholders to manage their work-related risks effectively. These include developing policies and procedures for health and safety, providing advice, guidance and information to dutyholders and taking steps to ensure compliance with health and safety requirements through targeted inspections and investigations following reported incidents. HSE will take enforcement action where this is necessary and proportionate, in line with its Enforcement Policy Statement ("EPS") which I produce as exhibit RGB/78 – INQ000269858.

204. Regulatory functions in relation to the use of PPE were undertaken across a number of HSE's Divisions. Prior to the pandemic policy work related to the use of PPE in healthcare and social care settings was undertaken by a specialist PPE Unit and the Health and Social Care Sector Team. HSE had a generic email address for any PPE related queries which would be received by HSE's Concerns and Advice Team. Enforcement activity relating to the use of PPE was undertaken by the Field Operations Division ["FOD"]. In addition, HSE had a number of specialist teams, including microbiologists, occupational health specialists, occupational hygienists and scientists who provided technical and expert advice to support both policy and operational regulatory activity in relation to the use of PPE.

Guidance and information available for dutyholders on use of PPE

205. HSE publishes a range of guidance on Health and Safety law intended for employers, workers and relevant self-employed persons. In relation to PPE, HSE publishes "*Personal Protective Equipment at Work - Guidance on the Regulations (L25)*. I produce a copy of the 3rd edition of the guidance (published in 2015) which was available prior to and during the pandemic as exhibit RGB/136 - INQ000269664.

206. In addition to this guidance, HSE provides employers with information on their legal obligations to provide suitable PPE on its website. I produce a copy of the

guidance that was available prior to the relevant period as exhibit RGB/313 – INQ000529832. This also includes information on product safety requirements for PPE and the obligations held by employers in relation to ensuring that products meet the relevant conformity requirements. Dutyholders could also access information about COSHH requirements and PPE on our website. I exhibit a copy of the guidance that was available prior to the pandemic as exhibit RGB/314 – INQ000529824.

207. Prior to the relevant period, HSE had additional information on its website regarding RPE. This included both advice and technical information and covered topics such as fit testing. I exhibit examples of relevant pages that were available prior to the relevant period as RGB/315 – INQ000529828, RGB/316 – INQ000529829, RGB – 317 – INQ000529826, RGB/318 – INQ000529827, RGB/319 – INQ000529825, RGB/320 – INQ000529831 and RGB/321 – INQ000529830.

208. HSE has published guidance in relation to the provision of RPE. *RPE at Work – A Practical Guide (HSG 53)* was most recently updated in May 2013 (exhibit RGB/137 - INQ000269685). It also has published guidance in relation to RPE fit testing (*INDG 479*) which I produce as exhibit RGB/138 – INQ000269542. It also had specific guidance on face masks which I exhibit as RGB/322 – INQ000529833.

209. Prior to the pandemic dutyholders, workers and members of the public could contact HSE for advice in relation to use of PPE by using the dedicated email address that was managed by the Concerns and Advice team. Queries would be resolved with assistance from policy and technical staff when required.

Dealing with concerns regarding the use of PPE

210. Workers, members of the public and others can raise 'concerns' about workplace safety via the HSE website or by telephone. This can include concerns regarding the availability, adequacy or quality of PPE provided by an employer. Prior to the pandemic, concerns were considered by the Concerns and Advice team who would review the information provided by the enquirer, gather further information

where this was required (either from the enquirer or the dutyholder) and then determine what further action was required. Concerns would either be resolved by the Concerns and Advice Team or referred to Operations for investigation. In terms of actions taken by the Concerns and Advice team, they would provide informal advice (verbally or by email) to the enquirer or dutyholder or close a matter if it was determined that no further action was required or the complaint could not be followed up.

211. Between 1 April 2018 and 31 December 2019, HSE received 1719 concerns relating to healthcare settings, 89 of which related to PPE. Of these 89, 15 were referred to Operational divisions for investigation. During the same period, HSE received 987 concerns relating to social care settings, 62 of which related to PPE. Of the concerns received that related to PPE, 19 were referred to Operational divisions for investigation.

Regulating compliance with use of PPE requirements – Inspections

212. Inspections are arranged on a case-by-case basis and differ by industry sector but are generally through either prior contact between the inspector and the dutyholder or unannounced. Information is published for dutyholders on the inspection 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.

213. 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 at sites that are subject to permissioning regimes where certain work activities giving rise to significant risk, hazard or public concern can only start or continue where we give permission

214. When planning inspections, HSE targets those sectors and activities with the most serious risks and where the risks are least well-controlled. HSE has undertaken

programmed inspections in healthcare settings to look at issues such as the management of violence and aggression towards employees and manual handling. HSE did not focus on compliance with PPE requirements in healthcare or social care settings as a targeted area for inspection activity prior to the pandemic.

215. Prior to the pandemic, HSE undertook inspections across a range of healthcare and social care settings where it has regulatory responsibility. Between 1 April 20218 – 31 December 2019, HSE conducted 236 inspections (exhibit RGB/ 81a - INQ000269777 and RGB/81b - INQ000269850) in healthcare settings (including nursing homes) including programmed inspections, inspections after investigations and local inspections. During programmed inspections, Inspectors would primarily focus on the relevant high-risk activity. However Inspectors would consider other issues, such as compliance with PPE requirements if they were observed during the inspection. Inspections after investigations and local inspections may include consideration of a dutyholders' compliance with PPE requirements as part of the scope of the inspection.

216. Between 1 April 2018 and 31 December 2019, HSE conducted 60 inspections in social care settings (exhibit RGB/323 – INQ000529839). These inspections focused on a wide range of high-risk work-related activities, from compliance with requirements to manage risks associated with legionella to the safe management and undertaking of construction work at a social care setting. Similar to healthcare settings, whilst PPE compliance would not be the prime focus of the inspection, compliance with PPE requirements would be considered by the Inspector if concerns were identified during the inspection.

Regulating compliance with use of PPE requirements - Investigations

217. HSE carries out investigations into reportable injuries, diseases and dangerous occurrences and concerns referred for investigation. A potential failure to comply with PPE requirements may not be immediately identifiable from the details provided to HSE in a RIDDOR report. Therefore, when considering how HSE regulated the use of PPE prior to the pandemic (in the context of investigations) it

is necessary to consider the number of investigations conducted across the healthcare and social care sectors and how many of these resulted in the identification of a material breach in relation to PPE (including RPE and IPC).

218. Between 1 April 2018 and 31 December 2019, HSE conducted 183 investigations in healthcare settings (exhibit RGB/324 – INQ000529840). In relation to these investigations, NOCs were issued in 8 cases, 3 enforcement notices were served and 2 cases were approved for prosecution. Based on a review of the records available, no material breaches were recorded in relation to PPE requirements.

219. Similarly, between 1 April 2018 and 31 December 2019, the HSE conducted 219 investigations in social care settings (exhibit RGB/325 – INQ000529838). These resulted in a NOC being issued in 13 cases, 2 enforcement notices being served and 5 prosecutions. According to the records available, none of the investigations resulted in material breaches being identified in relation to PPE requirements.

HSE's approach to regulating the use of PPE during the pandemic

220. Early in the pandemic HSE recognised that it would need to alter its operational arrangements to effectively manage regulatory activity relating to Covid-19. Initially HSE set up a Resilience Team whose role was to deal with all Covid-19 related questions, including those on PPE, that could be dealt with using lines take and sources of advice. HSE also set up a Technical Working Group to provide technical advice and respond to queries received in relation to Covid-19.

221. 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).

222. With regard to the regulation of the use of PPE, the teams undertaking key functions were:

- the Resilience Team (explained above)

- the Technical Team who provided expert opinion on all Covid-19 PPE related matters
- the Policy Team who advised PPE Unit (and other policy leads) on implications of decisions and responses
- 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
- Non-healthcare sectors: Advising PPE Unit (and other parts of HSE) on PPE matters for non-healthcare settings.

223. Communications team who developed internal communications material and advised on potential areas for external communications.

224. Other sector teams who responded to routine enquiries with lines to take and advised the Triage team, Concerns and Advice team and Operational teams on the handling of casework.

225. The PPE Unit was operational until July 2021. Following this, until the end of the relevant period, regulatory functions were performed by the Concerns and Advice team, policy and sector teams. Throughout the relevant period, regulatory functions relating to enforcement (inspections and investigations) continued to be undertaken by FOD.

Guidance and information for dutyholders on use of PPE during the pandemic

226. During the pandemic, HSE published additional guidance and information that would assist dutyholders in healthcare and social care sectors when considering how to manage workplace risks related to the transmission of Covid-19, particularly in relation to the use of PPE. At the start of the pandemic, information was published on HSE's website on existing pages, for example the Health and Social Care sector page or news page. However in June 2020, HSE launched a Coronavirus microsite where all relevant updates, information and guidance could be accessed.

227. HSE developed web pages specifically on PPE in healthcare and social care settings which provided information and advice on matters relating to the use of PPE, including links to other relevant information and guidance published by Government departments and other bodies. These were reviewed and updated where necessary throughout the pandemic. I exhibit examples of the webpages from during the relevant period as exhibits RGB/326 - INQ000529821 (June 2020), RGB/327 - INQ000529820) (July 2021) and RGB/328 - INQ000529819 (February 2022). Additional guidance was developed to assist dutyholders, including guidance on the use of face coverings and face masks. I exhibit examples of the guidance from during the relevant period as RGB/329 - INQ000529812 (June 2020), RGB/330 – INQ000529811 (July 2021) and RGB/331- INQ000529810 (February 2022).

228. HSE also had a dedicated web pages on PPE research in healthcare settings and I exhibit examples of the web pages from during the relevant period as exhibits RGB/332 - INQ000529818) (June 2020), RGB/333 - INQ000529816 (July 2021) and RGB/334 - INQ000529815 (February 2022). In relation to RPE and fit testing, HSE's website also contained advice and information for dutyholders in healthcare and social care sectors on fit testing. I exhibit examples of this guidance as RGB/335 - INQ000529815 (June 2020), RGB/336 - INQ000529814 (July 2021) and RGB/337 - INQ000529813 (Feb 2022). HSE also produced other materials, for example news updates on face fit testing which were published on its website. I exhibit an example of a news update published on 26 March 2020 as exhibit RGB/338 - INQ000529836. To promote the proper donning and use of disposable respirators, HSE produced a guidance poster (exhibit RGB/167 - INQ000269684) on how to don RPE correctly and how to perform a user seal check in March 2020.

Providing advice to dutyholders

229. Early in the pandemic, HSE set up a Resilience Team to assist the Concerns and Advice team to manage queries relating to Covid-19. Due to the volume of queries being received by HSE, it prepared, "HSE Briefing and Lines to Take: Wuhan Novel Coronavirus (Covid-19)" from March to September 2020 to assist the Resilience Team deal with queries quickly and effectively. The LTT dated April 2020 (exhibit

RGB/339 – INQ000529211) and September 2020 (exhibit RGB/340 – INQ000529623) provided advice across a wide range of issues, including:

- Shortage of Supply
- Face Fit Testing
- How Long Should Masks Be Worn
- Beards / Facial Hair
- Difference Between Surgical Mask and FFP3

230. Requests for advice from dutyholders or stakeholders that were more complex in nature were sent to the Triage team who would then forward them to the relevant team within the PPE Unit, dependent on the nature of the query and the technical or policy input required to resolve the query.

231. The PPE unit responded to hundreds of enquiries from stakeholders, employers, employees and members of the public throughout the pandemic. Lines to take were developed and updated as the pandemic progressed to ensure that HSE was consistent with the advice being provided. The PPE Unit report (exhibit RGB/288- highlights that 1088 queries were dealt with by the Unit between April 2020 and June 2021. The report contains a detailed analysis of the types of queries received, including 423 requests for advice.

HSE's role in relation to the IPC Guidance

232. HSE was not directly involved in the drafting of the IPC guidance. As the regulator for workplace safety, HSE provided advice and comments to PHE, NHS England and NHS Improvement (as members of the IPC cell) when requested to do so. It is important for me to clarify evidence I gave to the Inquiry on 12/09/2024 (transcript page 133, line 22 to page 134, line 11). HSE did not have a representative that was part of the IPC cell. HSE was a consultee.

233. The advice provided by HSE on the IPC guidance and associated documents such as PPE ensemble tables was focused on the duties held by employers in healthcare settings to undertake a suitable and sufficient risk assessment of work

related risks arising from or in connection with transmission of SARS-CoV-2 and the implementation of suitable controls, through the application of the hierarchy of controls.

234. Examples of when HSE's advice was sought in respect of the guidance are as follows; early in the pandemic, HSE was invited to attend a number of meetings focused on the use of PPE in healthcare. This is evidenced by the emails exhibited as RGB/341 - INQ000528979. HSE was also asked to attend a meeting to discuss amendments to the guidance in relation to PPE for cleaners in healthcare settings (exhibit RGB/342 - INQ000528981). It was also asked to comment on revised guidance in relation to care of the deceased (exhibit RGB/343 - INQ000528995). HSE also commented on amendments to the PPE ensemble tables, as shown in an email (and attachments) from HSE to PHE on 31 March 2020 (exhibit RGB/143 – INQ000269546, RGB/144 – INQ000269663 and RGB/145-INQ000269654). Having provided this advice, HSE was asked to assist in reviewing the glossary of terms for the IPC guidance, as shown in the email correspondence exhibited as RGB/344- INQ000529002.

235. HSE continued to engage with NHS England and NHS Improvement during the pandemic on matters relevant to the IPC guidance. For example in November 2021, HSE was asked to provide advice on the IPC's proposed position on the use of PPE by healthcare staff providing care to patients with, or suspected of having Covid-19, following a change in the WHO guidance. I exhibit the request and HSE's response as exhibit RGB/345 – INQ000529754.

236. In or around March 2022, HSE was invited to contribute to the work being undertaken in relation to the IPC Manual. HSE was part of the membership of the IPC Manual Clinical Oversight Group ["CAG"]. I exhibit the terms of reference for this group at RGB/346 - INQ000529801. As is evidenced by the minutes of the CAG meeting on 22 April 2022 (exhibit RGB/347 - INQ000529800). HSE was not involved in drafting the manual but was invited to comment on it. HSE provided comment on a draft of the IPC manual as shown in exhibit RGB/172 – INQ000269686.

237. When providing advice on the IPC Guidance and the IPC Manual, HSE took into account the available scientific evidence and research that was relevant to the assessment of work-related risks arising from and in connection with the transmission of SARS-CoV- 2 and the application of the hierarchy of controls. HSE's Chief Scientific Adviser was a member of SAGE, a co-chair of SAGE EGM and lead the National Core Study on the transmission of SARS – CoV-2. Where it was helpful, HSE engaged in further discussions with NHS England and NHS Improvement about the link between the scientific evidence and the IPC guidance. This is shown in the email correspondence between HSE's Chief Scientific Adviser and NHS England on 25 April 2022 discussing such a meeting, which I exhibit as RGB/348 - INQ000529795. The meeting between HSE and NHS England took place on 24 May 2022.

238. In addition to providing comments on the various iterations of the guidance, HSE was asked to provide advice by the IPC cell that assisted them when considering updates to the guidance. HSE also provided advice to PHE on specific issues with regard to the use of PPE, for example in October 2020 (exhibit RGB/349 – INQ000529777), HSE provided advice to PHE in relation to the use of PPE during medical laser treatments. HSE also raised queries with the Cell in relation to the content of the guidance, as shown in an email exchange in June 2021 (exhibit RGB/350 – INQ000529715).

239. HSE was also involved in discussions regarding the IPC guidance with DHSC and NHS bodies through the DMC. For example, at the DMC meeting on the 4 June 2020, members discussed the appropriateness of the IPC guidance in relation to the use of Type II surgical masks, in particular its classification as a medical device in the PPE ensemble tables of the guidance. I exhibit summary of the discussion and the resulting decision by DMC as exhibit RGB/351 - INQ000529444.

Regulating the use of PPE during the pandemic

HSE's stance on the adequacy of PPE

240. There are no Regulations specific to healthcare workers in relation to IPC. However, COSHH sets out the requirements in relation to the use of PPE when protecting against risks arising from work related exposure to biological agents where other measures, cannot be achieved. It is the responsibility of the dutyholder to undertake a risk assessment to determine the adequacy and suitability of RPE or PPE as a control to protect workers from risks arising from work related exposure to a biological agent, such as SARS– CoV-2, applying the hierarchy of control measures. When undertaking a risk assessment, and therefore determining the adequacy and suitability of RPE or PPE for a particular work activity, it is necessary to consider a wide range of factors including the likelihood, duration and proximity of potential exposure to the virus.

241. Where, following a risk assessment, RPE is deemed a necessary part of the control measures, HSG53 – Respiratory Protective Equipment at Work 2013 (exhibit RGB/137 - INQ000269685) 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.

242. HSE's stance in relation to the adequacy of PPE during the pandemic was based on the scientific evidence that was available to HSE about Covid-19 and its routes of transmission. At the start of the pandemic, when evidence was limited, some assumptions had to made about routes of transmission based on previous experience of influenza and the relative importance of large respiratory droplets containing the virus. As evidence emerged, this was addressed through the New and Emerging Respiratory Virus Threats Advisory Group ["NERVTAG]" and SAGE Environment and Modelling Group papers and reviews, for example the 'Role of Aerosol Transmission in COVID-19, which was endorsed at SAGE 48 on 23 July

2020. I exhibit the paper as RGB/352 - INQ000529538 and the minutes of the meeting as RGB/353 - INQ000529834. A further study looking at masks for healthcare workers was undertaken by SAGE EMG in early 2021, on which HSE's Chief Scientific Adviser was a co-author (exhibit RGB/77 - INQ000075022). HSE continued to engage with Government departments and NHS bodies as new evidence emerged.

243. In addition, HSE took account of practices being implemented across healthcare settings that would impact on an assessment of the risk of exposure to SARS-CoV-2 and the controls required to protect workers from such risks. This included, for example, the implementation of Covid testing and the segregation of Covid-19 patients and those not suffering from the disease. It is important to highlight that knowledge, guidance and practices across healthcare settings continued to evolve throughout the pandemic.

Steps taken by HSE to assist with PPE Shortages

244. HSE would not ordinarily be expected to be notified of a shortage of PPE/RPE in any industry, however during the pandemic HSE was aware of a number of specific examples of shortages in PPE and RPE and it took steps to seek to assist to address these shortages in relation to the re-use of PPE, decontamination, Portacount machines and in relation to the provision and use of FFP3/FFP2/N95 and FRSMs. It also provided advice to NHS on face fit testing requirements, an issue raised by the NHS as a result of shortages in RPE.

Re-use of single use PPE and decontamination

245. 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. I exhibit a note of that meeting as (RGB/354 – INQ000529458). The guidance was intended to assist dutyholders when considering the adequacy and

suitability of single use PPE for extended use. The guidance permits that disposable PPE can be re-used providing that:

- it remains adequate and suitable and is undamaged
- it continues to provide the intended protection, and;
- workers can put it back on without being exposed to risk.

246. 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.

247. 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.

248. 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.

249. 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.

250. HSE 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.

251. 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.

252. In relation to the re-use of single use PPE, the key messages delivered by the paper were:

a. 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.
b. 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.
c. 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.

253. The NHS Improvement cell, led by Paul Chivers, ran a pilot project assessing if single use respiratory protective equipment (RPE) could be decontaminated and

re-used. As part of this PHE and HSE were involved in the design of a two-stage test protocol.

254. Stage 1 focused on a test protocol to explore if the single use RPE could be effectively decontaminated. This was led by experts in PHE including Thomas Pottage. Hydrogen peroxide was the decontamination agent used. HSE provided advice at this stage with regard to adequately controlling worker (and if rolled out, end users) exposure to hydrogen peroxide as a result of it off gassing from the processed RPE.

255. Stage 2 was drafted by HSE. This consisted of a test protocol assessing if repeated wear and cycles of decontamination would affect the performance offered by the RPE.

256. Although stage 2 was drafted, the study was not progressed beyond Stage 1 because certain factors rendered the test no longer viable. I exhibit a report of the outcome of the pilot as shown in exhibit RGB/355 - INQ000529835.

257. 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.

258. Sessional PPE use in some circumstances was agreed by HSE. This included single use long-sleeved gowns, masks and eye protection which could 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 were able to safely carry out their work when they were 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.

Portacount Machines

259. 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. A portacount machine counts ambient particles and therefore provides a quantitative assessment of leakage from the face seal of a respirator.

260. 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.

261. 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).

262. 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.

263. 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.

Use of FFP2, FFP3 and N95 Respirators

264. 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.

265. 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.

266. 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"].

267. 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.

268. 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

269. During the pandemic, 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).

270. NHS Trusts adopted advice provided by WHO that if FFP3 respirators were unavailable, FFP2 respirators were recommended as a safe alternative. In the context of applying the requirements of Regulation 7 COSHH and applying the guidance in HSG 53, whilst FFP3 was the usual recommended control measure, it may not have 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 showed an FFP2 respirator was suitable for the activity being conducted. This was supported by Part One of HSE's Rapid Evidence Review dated 27 March 2020 (exhibit RGB/146 - INQ000269674) where evidence was examined in relation to FFP2 respirators forming part of the PPE ensemble when caring for patients with Covid-19.

271. HSE's advice to NHS bodies and Trusts on the suitability of PPE focused on the importance of an appropriate risk assessment to determine the controls required to protect works from the identified risks, applying the guidance set out in HSG 53 and importantly, the hierarchy of control. If FFP3 masks were not available, the dutyholder would need to assess whether using FFP2 as an alternative would provide an adequate level of protection when conducting the relevant work activity. The Rapid Evidence Review undertaken by HSE in March 2020 was intended to assist to inform decisions made on the use of PPE in healthcare settings during the pandemic.

The Rapid Evidence Review

272. The Rapid Evidence Review was commissioned by the Government Chief Scientific Advisor (GCSA) on 25 March 2020 (exhibit RGB/356- INQ000528996). The request was to consider equivalent standards of protection afforded by RPE. As it was a very specific question concerning standards, HSE convened a group of experts to undertake the review. The comparison of FFP3, FFP2 and N95 was undertaken by considering existing guidance on IPC, RPE, PPE and aerosol generating procedures, guidance published by WHO and the opinions of other Health and Safety Laboratories from across Europe and USA. The group undertook a comparison of respective testing standards and considered relevant technical information in order to reach its conclusions. With regard to the review of the use of gowns, aprons and eye protection, the group considered current guidance, WHO guidance and published literature, in addition to considering the testing standards (exhibit RGB/146 - INQ000269674).

273. A summary of the findings of the review was delivered to the GCSA on the evening of 25 March 2020. I exhibit the email to GCSA as RGB/357 - INQ000528997 and the summary as RGB/358 – INQ000528998. The report was produced on 27 March 2020 as RGB/146 – INQ000269674. 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.

274. The Rapid Evidence Review concluded that FFP2 masks would provide protection against SARS-CoV-2 as long as the wearer was face-fit tested.

275. The evidence review was used to inform decisions made by NHS bodies and Trusts on the selection of PPE for use in healthcare settings, including decisions about whether FFP2 and N95 respirators could be used for healthcare workers undertaking aerosol generating procedures in the event of insufficient availability of FFP3 respirators.

276. The evidence review recognized that what was reasonable and practicable in relation to minimizing the risks to healthcare workers of exposure to the virus would change during the pandemic. However the review made it clear that the duty to control the risk would still be based upon applying protective measures appropriate to the activity and consistent with the risk assessment. This remained HSE's position throughout the pandemic (page 2 of exhibit RGB/146 – INQ000269674).

N95 masks

277. N95 is a standard used in the United States. Part of the purpose of the evidence review was to establish the equivalent UK standard. WHO adopted the 'N95' terminology early in the pandemic. The N95 was only produced in the US.

278. 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.

279. In terms of applying the hierarchy of control, the N95 respirator was assessed by HSE as providing protection equivalent to that of an FFP2 disposable respirator, as long as a face fit test had been carried out to ensure a good seal to the wearer's face. N95's were only agreed for use in a healthcare setting where there was a shortage of FFP3 and FFP2 respirators. No N95 respirators were procured for national supply in UK healthcare settings.

FFP2 and FRSMs

280. 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.

281. HSE was satisfied that 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. 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. That is because the effectiveness of its filter cannot be guaranteed in the absence of a face fit.

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. HSE did not require a FFP2 over FRSM as the decision on which RPE to use would be determined by the dutyholder's COSHH assessment.

RPE shortages and face fit testing

283. 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 bodies 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.

284. As highlighted in HSE's response (contained within exhibit RGB/160 - INQ000269549), HSE could not 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 had suspended face fit testing or who did not have in place robust arrangements for ensuring that employees are fit tested for their filtering face piece respirators would 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.

285. This position was reiterated and clearly set out in the letter from NHS England and NHS Improvement 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 RGB/161 - INQ000269646).

286. 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 RGB/163 - INQ000269543), where HSE had adopted the same approach.

287. Similarly, 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 RGB 177a - INQ000269631 and 177b - INQ000269661).

288. HSE provided support to increase the availability of fit testing fluid and HSE also provided information about using different salt compounds if the ones described in ISO 16975-3 were no longer available (examples at exhibit RGB/164 - INQ000269541, RGB/165 - INQ000269545 and RGB/166 - INQ000269552).

289. HSE liaised closely with BSIF to support NHS access to qualified fit testers. HSE also provided technical input to PHE in relation to the use of N95/FFP2 respirators through the Rapid Evidence Review report (explained in more detail in paragraphs 271 – 275).

HSE advice on other matters relevant to use of PPE

Alternatives to face fit testing

290. 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 was foreseeable that at times meeting the requirement would be challenging, for example, potentially low stocks of qualitative testing fluid or a different variety of respirator being delivered.

291. Employers needed to have in place contingency arrangements to ensure risks were appropriately managed. During the pandemic, HSE provided advice to dutyholders who raised queries in relation to fit testing requirements that such contingency arrangements required a package of measures: 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.

292. HSE advised that employers could also provide a back-up supply of alternative RPE that did 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. I exhibit an example of where this advice was provided to a dutyholder in response to queries with regard to complying with fit testing requirements as exhibit RGB/359 – INQ000529261.

Advice on alternatives to face fit testing for ethnic and religious minorities

293. HSE's guidance on RPE at Work (HSG 53) which I produce as exhibit RGB/137 - INQ000269685 provides guidance to employers on how to select RPE that is adequate and suitable. It highlights the availability of RPE in different sizes to allow for facial differences (paragraph 12). It emphasises that employers should ensure that RPE selected is of the right size and can correctly fit the wearer and that for tight fitting facepieces, the initial selection should include a fit test (paragraph 28).

The guidance also contains advice to employers on the common factors about a wearer that need to be considered, in addition to factors such as gender, ethnicity and build. These include facial hair or markings that could prevent a good seal between the wearer's face and the PPE, any pre-existing medical conditions and if the wearer uses glasses or contact lenses (paragraph 60). The guidance suggests that if facial hair and markings affect where a face mask seals to the face, a solution would be to consider the use of loose-fitting facepieces.

294. Additionally, HSE's guidance on RPE fit testing *(INDG479)* (exhibit RGB/138 - INQ000269542) provides advice on RPE fit testing for the employer and those conducting fit tests. It also provides information on RPE fit testing methods. It highlights to employers that fit testing is a method for checking that a specific model and size of tight fitting facepiece matches the wearer's facial features and seals adequately to their face. It also highlights that fit testing helps to identify unsuitable facepieces which should not be used.

295. During the pandemic, HSE provided additional guidance to NHS bodies and employers on fit testing and the use of RPE, including considerations for staff from ethnic minorities. For example, HSE attended an NHS England and NHS Improvement's FFP3 Mask Fit Testing Project for BAME staff as part of its Fit Testing Project Steering Group, where fit testing data was shared and wider issues discussed, such as face shape. A copy of presentation slides dated August 2020 is exhibited at RGB/360 - INQ000529537 and slides dated September 2020 exhibited at RGB/361- INQ000529568.

296. HSE received correspondence from the Sikh Council (exhibited at RGB 184a - INQ000269687), which was taken up by NHS England / NHS Improvement, 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. 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 (exhibited at RGB/184b - INQ000269630).

297. HSE also received correspondence from Manchester University NHS Trust exhibit RGB/362 - INQ000529580) advocating the use of a 'Thattha'. Thattha involved an elasticated band being placed and tied tightly round the head to stretch the beard prior to putting a mask on. The suggestion was that application of the band assisted with allowing bearded men to pass face fit tests. Having considered the evidence HSE concluded the bearded wearer would not be adequately protected by use of a 'Thattha' and could not HSE permit this method. A suitable alternative where shaving is not possible would be to use a Powered Air Purifying Respirator (PAPR) with loupes. In coming to this decision, HSE gave due regard to its public sector equality duty, balancing protecting health and ensuring that religious beliefs were positively promoted and respected.

298. HSE responded to a query from the British Safety Industry Federation about whether fit testing could be carried out without requiring a headscarf to be removed i.e. with straps placed over the headscarf. HSE advised that mask straps needed to be worn in contact with the head and not the headscarf. The reason for this was to lessen the chance of the straps slipping, which in turn could lead to a compromise in the face seal. The mask could then be worn with the straps underneath the head scarf. HSE explained that the issue needed be handled sensitively and that there must be a suitable environment for the wearer to don and doff the mask, and the headscarf, in private. A copy of the email request and reply dated between October 2020 is exhibited as RGB/363 - INQ000529780. The same advice had previously been given to NHS England and NHS Improvement. A copy of an email dated October 2020 is exhibited as RGB/364 - INQ000529774.

The extension of shelf life for PPE

299. From February 2020 HSE engaged with DHSC and PHE regarding the possibility of extending the shelf-life of PPE and RPE that had, or was about to, reach its shelf-life as a means by which to address the shortages of suitable PPE and RPE for use in the health and care sectors. There were no specific provisions within the legislation that provided for the extension of the shelf life of PPE. The issue to be determined by the relevant dutyholder was whether the PPE continued to meet the

specified legal requirements. HSE's role in this context was to provide advice on the steps that they should take to ensure that the PPE suitable for use and provided adequate risk control despite having exceeded the manufacturer's shelf life.

300. HSE was asked for any comments, questions, or points of clarification on the first draft of the Four Nations FFP3 respirators strategy, specifically whether HSE were content with PHE's suggested approach for use of expired products in the PIPP stockpile. The document was reviewed by HSE PPE technical experts and the Head of HSE's Emergency Planning Unit. HSE provided PHE with comments and points of clarification on the draft, as shown in exhibits RGB/365 - INQ000528985 and RGB/366 – INQ000528989.

301. HSE's position on shelf-life extension throughout the relevant period was that advice about using any PPE that had passed its marked shelf-life would need, in the first instance, to be sought from the manufacturer. If the relevant manufacturer was unable and/or unwilling to provide such advice, the item in question ought to be passed to a suitable Notified Body such as the BSI, or other technically competent organisation, for testing. HSE was not involved in performing any testing of PPE items in respect of extending shelf-life.

302. An example of this approach is demonstrated by contact HSE had with the DHSC in February and March 2020 in respect of the Pandemic Influenza Preparedness Stockpile (PIPP) which was being managed by Public Health England (PHE) and had been held since 2009. HSE received a request for a meeting with DHSC to discuss the PIPP stockpile and PHE supply chain. Meetings were held on 26 February and 4 March 2020. The meetings focussed on whether the stockpile was fit for purpose, and whether it could still be used, in particular in respect of items of RPE. HSE provided technical advice concerning the testing of RPE, as evidence in emails between HSE and PHE regarding Medline FFP3 masks which I produce as exhibit RGB/367 - INQ000529028. HSE also reviewed the results following the testing of 3M and Medline FFP3s, in order to assist DHSC and PHE determine whether that stock could be used safely. This is recorded in a *"HSE Issues and Action Log"*, exhibited at RGB/368 – INQ000529000. Advice regarding

the use of the 3M FFP3s was captured in a PHE presentation entitled "*Use of 3M respirators in response to COVID-19 as supplied from the Pandemic Influenza Preparedness (PIPP) Stockpile"* which HSE commented on (exhibit RGB/370 – INQ000529409). In May 2020, whilst working in Daventry, HSE identified that some of the 3M FFP3 masks had expiry dates prior to the dates stated for the PIPP stock. It was also identified that when the testing had been carried out, certain tests recommended by HSE had not been completed. DHSC arranged for further tests to be undertaken and HSE's Technical Team reviewed the test results. HSE subsequently confirmed that based on the test results, it was satisfied that the respirators met the required standards (exhibit RGB/369 - INQ000529413).

303. In May 2020, HSE engaged with DHSC regarding Tiger Eye protective goggles and frames that originated from the PIPP Stock purchased in 2009, a quantity of which had been supplied to healthcare settings earlier in the pandemic. At HSE's request, DHSC arranged for tests to be undertaken on the goggles. These were undertaken by BSI. The tests confirmed that the product did not meet the current requirement for splash protection required in BSN 166 (including certain testing requirements documented in BSN 168). HSE reviewed the test results and determined that the goggles did not provide adequate protection against SARS-CoV-2. On 7 May 2020 (exhibit RGB/227- INQ000529264), DMC agreed that the product should not be used in a Covid-19 setting. DHSC subsequently issued a central alert system alert ["CAS alert"] notifying healthcare users that Tiger goggles should not be used in a Covid-19 setting and that they were being removed from the supply chain (exhibit RGB/371 – INQ000529291). HSE engaged with DHSC in relation to the communications and provided advice in relation to responding to queries arising from the CAS alert, both those raised directly with HSE and queries raised through groups such as the IPC cell.

304. Throughout the relevant period HSE did not offer advice regarding how long the shelf-life of PPE items could or should be extended for. That decision lay with the manufacturer and/or relevant Notified Body or similar.

Re-usable PPE

305. HSE's position is that reusable PPE/RPE should provide the same level of protection as single use PPE/RPE. Respirators will have an Assigned Protection Factor (APF). The APF is an estimate of how much protection a respirator provides. An FFP3 respirator and reuseable RPE both have an APF of 20 so in the standards, they offer the same level of protection. The only additional consideration for reusable PPE/RPE is the need to decontaminate properly.

306. HSE does not take issue with the use of reusable provided methods of decontamination and cleaning are carried out in accordance with manufacturer instructions. Where continuity of supply is an issue, reusable PPE/RPE can be more beneficial because, in the case of masks, they will not require repeated face fit testing. A disadvantage of using single use PPE/RPE is assuring a continuity of supply of the same product. In the case if masks, they will require fit testing more regularly.

307. HSE considered the appropriate cleaning methods for reprocessing (cleaning and disinfection) re-usable 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.

308. 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.

309. 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.

310. HSE was commissioned by SAGE to review the decontamination and re-use of PPE. The paper (exhibit RGB/182a - INQ000075024 and RGB/182b - INQ000269671) was endorsed at SAGE on 10 September 2020 (exhibit RGB/183 - INQ000061564). HSE's subsequent Evidence Report ER004 on the decontamination and reuse of PPE published in January 2021 (exhibit RGB/181 - INQ000269677) detailed HSE's position in relation to PPE manufactured for re-use, specifically that:
    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. 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;

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; and

e. 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.

The development of new RPE alternatives that not requiring face fit-testing

311. A number of RPE alternatives that did not require fit testing were developed through the 'Make' cell. New items of reusable powered filtering respirators such as the PeRSo 2, PeRSo 3 and the Morecambe Bay Respirator Hood emerged onto the UK market with new manufacturers or manufacturers from other industries. They sought regulatory easements from HSE for use of their products in healthcare settings.

PeRSo 2 and PeRSo 3 Respirators

312. HSE considered easement applications in respect of two re-usable respirators called PeRSo 2 and PeRSo 3. In respect of the PeRSo 2 respirator, an initial review of the documentation highlighted that the conformity assessment had not been carried out by a Notified Body, test results indicated that the device did not meet the requirements of BS EN1294 and user instructions were very basic.

313. The product was rejected for regulatory easement, but HSE provided the manufacturer with options to make necessary modifications so that it met the necessary performance requirements for use during the pandemic or for the product to be put through a full conformity assessment for use in a non-healthcare setting. I produce the DMG form dated 20 May 2020 as exhibit RGB/ 372 –

INQ000529326. This was communicated to the manufacturer on 23 May 2020 exhibited as RGB/373 – INQ000529339.

314. In respect of the PeRSo3 respirator, whilst the conformity assessment confirmed that the product met the performance requirement of BS EN 12941, there were still significant shortcomings in relation to the cleaning and disinfection requirements. As these types of RPE were more aimed at use with dusty contamination rather than biological agents. Wiping down after use was not enough for biological agents. HSE provided advice on what was required to address the non-compliance issues.

315. Upon more detailed manufacturer instructions as to how to decontaminate the RPE, the PeRSo 3 respirator was granted an easement for use in healthcare during Covid-19. A copy of the DMG form recommending grant of easement dated 9 September 2020 is exhibited as RGB/374 – INQ000529575.

316. Although we recognised the pressure on PPE supplies and the importance of innovation in seeking to mitigate those pressures, HSE maintained our regulatory position that PPE had to be suitable before approval for deployment would be granted. HSE also took action if it became aware that products that had not been approved had been released onto the UK market. This is demonstrated by steps that we took to ensure that PeRSo 3 devices that had been released onto the UK market before the easement had been granted were removed. When HSE became aware that PeRSo 3 devices were on sale, we wrote to the manufacturer requiring immediate withdrawal of the product from the market and the recall of any products if the device was not ultimately brought into conformity requirements. HSE also advised the manufacturer that information displayed on its website regarding an EU declaration of conformity was incorrect and needed to be removed immediately (exhibit RGB/375 - INQ000529541).

Morecambe Bay Respirator Hood

317. The Morecambe Bay Respirator Hood was a similar device to PeRSo3 but with components provided from more than one manufacturer used in the welding

industry and aviation industry. HSE gave advice in respect of regulatory requirements including advice on the need to specify how many times the product required disinfecting, what cleaning products should be used and testing to demonstrate its effectiveness. Once this had been resolved an easement was granted. HSE internal communication dated September and October 2020 exhibited as RGB/376 - INQ000529583 reflect that the following was advice given,

"The active ingredient for Clinell wipes is proven to be efficacious against SARS-CoV-2 when left in situ for the defined contact time, however, the likely of success of this cleaning and disinfection method is related to the complexity of the component part shapes and the various materials of construction, as well as the detail within the instructions provided".

318. In addition to considering applications for regulatory easements, HSE provided advice to organisations who were in the process of developing potential RPE alternatives that did not require fit testing, for example HSE exchanged correspondence with Manchester University NHS Foundation Trust after we identified through a press report that a new device was potentially being trialled in a hospital managed by the Trust. This led to further correspondence with us, within which we provided advice on the easements process. We also took steps to ensure that NHS Make Cell were made aware of the project (exhibit RGB/377 – INQ000529582).

Regulating compliance with provision and use of PPE Requirements during the pandemic

Responding to concerns about the use of PPE in healthcare and social care settings

319. Early in the pandemic, 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. 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 and social care settings. The revised process categorised concerns as green, amber or red. Concerns relating to PPE (where there was an identifiable dutyholder and infringement) were generally categorised as amber (inadequate risk assessment and / or control measures) or red (cases that involved extremely vulnerable and vulnerable people, including the elderly, and work in people's homes). Examples of concerns relating to PPE that were triaged as "red" include:

- *"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".*

- "*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".*

320. The revised process had the effect of routing any concerns from healthcare and social care 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 dealt with the most complex or sensitive issues in person. 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. The VCT was stood down in March 2021.

321. Data from HSE's Concerns and Advice team confirms numbers of concerns raised in healthcare settings (including nursing homes) for the period 1 January 2020 to 28 June 2022 was 2241. Of these, 107 concerns relating to PPE were referred to Operational divisions for investigation.

322. Similar data held by the Concerns and Advice team shows that between 1 January 2020 and 28 June 2022, we received a total of 2677 concerns in relation to social care settings. Of these, 1237 related to PPE. 176 of the concerns regarding PPE were referred to Operational teams for investigation.

323. Concerns received by HSE in relation to PPE covered a range of issues including availability of PPE / shortages, adequacy or suitability of PPE and concerns regarding the quality of PPE provided by employers. From the data available, it is not possible to differentiate between concerns raised by employees or others regarding the adequacy of PPE purchased directly by dutyholders in the healthcare and social care sectors or in connection with government procured PPE.

324. From the data that can be retrieved from HSE's records, it is not possible to carry out an accurate or reliable assessment of the specific number of concerns received about PPE shortages or non-compliant or inadequate PPE. However during the pandemic, the HSCSU contemporaneously monitored all of concerns that were coming in in relation to PPE and social distancing, recording on a weekly basis the types of concerns that were being received. This activity was undertaken throughout the period that HSCSU were in operation (1 March 2020 – 8 March 2021). The Unit produced a qualitative analysis of PPE and social distancing concerns and the regulatory outcomes at the end of this period which I exhibit as RGB/94 - INQ000269849.

325. The analysis shows that the highest number of the concerns received about PPE during this period were regarding PPE provided not being to the PHE guidance (152 – 46.77% of total concerns received). HSE also received 44 concerns regarding inadequate supply to or within healthcare and social care settings and 18 concerns about the quality of PPE. During the specified period, 1 NOC was

issued in relation to compliance with PPE requirements and informal advice (verbal or email) was provided in relation to use of withdrawn PPE.

Inspections

326. 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.

327. Information extracted from HSE's database shows that during the relevant period HSE conducted 242 inspections in healthcare settings (as set out in exhibits RGB 81a - INQ000269777 and 81b – INQ000269850 and RGB/83a - INQ000269810 and 83b- INQ000269776). 104 of the inspections conducted during the relevant period were specifically focused on Covid-19 work arrangements, which included consideration of the provision of PPE and RPE. 38 spot inspections also included consideration of Covid-19 working arrangements.

328. Of the 242 inspections conducted in healthcare settings during the relevant period, 173 of these were undertaken in hospitals across England, Scotland and Wales and 7 were undertaken in nursing homes. Of those conducted in hospitals, 106 inspections were programmed inspections (including spot inspections) and 67 inspections were focused specifically on the management of Covid-19. For those conducted in nursing homes, 3 were programmed inspections and 4 were specifically focused on the management of Covid-19.

329. The data recorded on HSE's database indicates that there were 26 cases where material breaches were identified in relation to RPE, PPE and IPC, resulting in the issuing of a NOC or an enforcement notice.

330. 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. The inspections focused on seven specific areas including PPE. The scope of the inspections is set out in guidance that was compiled for inspectors prior to the commencement of the programme (exhibit RGB/84 – INQ000269820).

331. A summary of the findings was prepared in February 2021 (exhibit RGB/85a - INQ000300380) 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).

332. 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 a NOC. The contraventions of health and safety law identified included 5 contraventions in relation to PPE.

333. 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, including establishing routine monitoring and supervision arrangements to ensure control measures identified in the risk assessment are implemented and are being maintained.

334. 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 - INQ000269862 at pages 3- 9).

335. Based on records from HSE's database, during the relevant period, HSE conducted 117 inspections in social care settings, resulting in the service of 12 enforcement notices and 10 NOCs. One matter was also referred for a decision on prosecution. Based on a review of the case details available, of the inspections conducted, 25 were spot inspections, specifically focused on Covid-19 arrangements including PPE. Of these inspections, 1 resulted in the issue of an enforcement notice in relation to failure to comply with face fit testing requirements. A further inspection resulted in a NOC being issued for matters relating to inadequate Covid019 control measures. A further 9 inspections included consideration of Covid-19 control measures in place. One of these inspections resulted in the service of 2 enforcement notices relating to an insufficient Covid-19 risk assessment and inadequate training for staff on Covid-19 risk control measures. A further inspection resulted in the service of an enforcement notice for inadequate Covid-19 control measures. Four remote inspections were undertaken where an assessment of Covid-19 control measures was carried out. None of these resulted in enforcement action being taken. We also undertook an assurance inspection to a premises where previous material breaches had been identified in relation to Covid-19 controls, including PPE. This resulted in no further action being taken against the dutyholder.

Investigations

336. During the relevant period, 768 investigations (remote and site based) were conducted in healthcare settings which include hospitals and nursing homes (exhibit RGB/86 - INQ000269871, RGB/324 – INQ and RGB/378 - INQ000529841) . With regard to regulatory outcomes, 45 resulted in the issuing of a NOC. HSE also issued 4 enforcement notices, including one in relation to a failure to comply with fit testing requirements. A further enforcement notice was issued because a Trust had failed to ensure that reusable respiratory protective equipment used by

employees was properly stored in a well- defined place, checked at suitable intervals and when defective repaired or replaced before further use.

337. HSE also issued a NOC to a Hospital Trust for use of PeRSo 3 respirators as an alternative to an alternative to a surgical mask when the Trust was aware that the PeRSo 3 respirator had not completed conformity assessment against the relevant technical criteria, nor been approved by HSE as the market surveillance authority for use in a healthcare setting. While it appears to have been recognised by the Trust that the respirator could not be used as an FFP3 device it was still brought into use as PPE for an alternative use without any evidence of its effectiveness for this, or any other purpose. As such, the respirator could not be ensured to protect against the risk of infection at this time. A copy of the NOC is exhibited as RGB/379 – INQ000529552.

338. 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 a NOC or an enforcement notice. However, there are a number of cases where this information cannot be determined from the database records.

339. Similarly, during the relevant period, 502 investigations were conducted in relation to social care settings. As a result of these investigations, HSE took a range of enforcement action. NOCs were issued in 17 cases, 4 enforcement notices were served and 3 cases were approved for prosecution. Of these cases, material breaches in relation to the provision and use of PPE and RPE were recorded in 3 cases where a NOC was issued and in one matter which, following the completion of the investigation, has been reported to Crown Office and Procurator Fiscal Service ["COPFS"] for review.

Enforcement following concerns in relation to PPE shortages, inadequate or non-compliant PPE

340. Of the concerns referred for investigation during the relevant period, a search of HSE's database records using the terms "shortage of PPE" or "shortage of RPE" or similar permutations identifies 11 records that contain the terms in the details

recorded on the database (including details of complaint, case details and details of activities such as telephone attendances and emails). In these cases, NOCs were issued to dutyholders following 2 of the investigations and an Improvement Notice was served on a dutyholder which included requirements in relation to the provision of RPE and face fit testing (as referred to above in paragraph 335).

341. For social care settings, the records in respect of 11 concerns referred for investigation during the relevant period contain reference to PPE shortages or similar. No material breaches in relation to PPE were identified in 10 of the cases. However, one of the concerns is linked to the investigation that has been reported to COPFS for review.

342. With regard to inadequate or non-compliant PPE, a search of the records of concerns referred for investigation using the terms "inadequate" and "non-compliant" or similar permutations identified only 2 matters where the details recorded on the database include such terms. However, the adequacy or conformity of PPE and RPE in relation to the relevant product safety standards would be dealt with by HSE's PSMSU rather than referred for investigation by Operational teams.

343. In relation to our records of concerns received from employees, members of the public or other organisations / bodies, it is not possible to differentiate between concerns raised in relation to PPE purchased directly by NHS Trusts and those raised in relation to government procured PPE.

Enforcement in relation to fit testing

344. As explained previously, it is difficult to accurately identify all investigations that related to (or included consideration of) poor or inadequate face fit testing. However, having applied "face fit testing" and associated permutations to search HSE's investigations records, we have identified 31 investigations conducted in healthcare settings during the relevant period where the term is identified in narrative contained within the database records (either in the details of complaint, case details or details capturing activity undertaken on the file – for example

telephone attendance notes and emails). From these records, we can identify that 6 investigations resulted in NOCs being issued to dutyholders and an improvement notice was issued to an NHS Trust in relation to compliance with face fit testing requirements under Regulation 7 of COSHH. A copy of the Improvement Notice is exhibited as RGB/380 – INQ000529562. As highlighted in paragraph 335, an Improvement Notice was also served in relation to face fit testing requirements. I exhibit a copy of this Notice as RGB/381 – INQ000529842.

345. In relation to social care, a similar search of HSE investigation records suggests that HSE conducted 5 investigations that involved consideration of issues relating to face fit testing requirements. None of those resulted in enforcement action.

Safety Alerts

346. During HSE's normal activities of inspection, investigation and dealing with concerns, we come across information that needed to be passed on either to a wide audience or to a specific group or sector of industry. HSE uses 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.

347. 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.

348. 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. Once HSE determined that ear loop respirators did not meet the essential technical requirements, 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.

349. 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).

350. 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).

HSE engagement with NHS Bodies and Trusts in England, Scotland and Wales during the pandemic

351. HSE's engagement with NHS bodies and Trusts ranged from contact with individual NHS Trusts asking HSE specific PPE issue related questions, to HSE's participation in the DMC and its contribution to NHS linked and/or led working groups and committees across England, Wales and Scotland.

352. A significant amount of liaison between HSE and NHS bodies was through its membership of the DMC. HSE provided advice relating to use of PPE and advice in relation to the IPC guidance. In addition, HSE worked with NHS bodies on communications relevant to the use of PPE. An example of this form of communication is when HSE was consulted by NHS England and NHS Improvement on a letter to be sent out healthcare colleagues regarding the use of ClearMask facemasks (exhibit RGB/382 – INQ000529510). In communication with NHS England and NHS Improvement, HSE emphasised that any communication sent out needed to include wording in relation to the risks to shielding patients (exhibit RGB/383 - INQ000529509).

353. Further, on 27 July 2020 there was discussion at the DMC regarding the steam decontamination of FFP3 masks following an NHS proposal to utilise that form of decontamination (RGB/384 - INQ000529526). The NHS proposal dated 27 July 2020 was titled "*Approval of the Moist Heat Treatment (MHT) as a method for NHS Organisations to decontaminate and re-use FFP3s, subject to HSE's authorisation of the emergency re-use of FFP3s*", highlighting HSE's role within the group (RGB/385 - INQ000529527).

354. In addition to the DMC, HSE was a member of some of the PPE sub-groups and committees, for example the Decontamination and Re-Use Group ("DRU Group") during the relevant period. This group was chaired by MHRA and the secretariat was provided by NHS England and NHS Improvement. Initial meetings took place on 14 and 15 April 2020 (exhibit RGB/386 - INQ000529032). In its early stages the group was referred to as the Rapid Review Sub-Group, before formally becoming the DRU Group. The DRU was on occasion referred to as the PPE Technical Sub-Group and the Emergency PPE Re-Use Sub-Group I exhibit the DRU Group's Terms of Reference as exhibit RGB/387 - INQ000529214. HSE's involvement in the DRU Group was largely providing technical input in respect of RPE as well as advisory work in relation to health and safety legislation. Examples of HSE's contribution are shown in the meeting minutes dated 7 July 2020 (exhibit RGB/388 - INQ000529490) and HSE's representation at a meeting on 23 April 2020 (exhibit RGB/389 - INQ000529193).

355. HSE also liaised with NHS England and NHS Improvement through the IPC cell. Some of the queries received from IPC related specifically to PPE, for example on 22 September 2021 HSE was asked by IPC cell for its comments on updated specific IPC guidance for the forthcoming autumn and winter season (RGB/ 390 - INQ000529751).

356. HSE also provided advice directly to NHS Trusts during the relevant period on the use of PPE, steps that an employer should take to ensure suitability and adequacy of PPE and the content of the IPC guidance. For example:

i) In January 2020 liaising with Leeds Teaching Hospitals NHS Trust (as well as NHS England and NHS Improvement) in respect of face coverings and masks (exhibit RGB/391 - INQ000529660);

ii) On 20 February 2020 HSE liaised with East Sussex NHS Trust following a concern raised by them regarding infection prevention control (exhibit RGB/392 - INQ000528980); and

iii) On 19 April 2020 the Chief Executive Officer of the Sheffield Teaching Hospitals NHS Foundation Trust emailed HSE, inviting HSE's comments, on its work on reviewing options to turn single use PPE into multi-use PPE. HSE's Chief Scientific Advisor reviewed the work, and by way of liaison provided detailed comments and discussion, particularly in respect of cleaning and autoclaving of gowns through detailed email exchanges (exhibit RGB/393 - INQ000529149).

Engagement with professional and representative bodies on the use of PPE

357. HSE was part of a tripartite NHS Health, Safety and Wellbeing Partnership liaison Group ("HSWG"), which included trade unions such Unison and Unite, as well as healthcare professional bodies such as the RCN and the Royal College of Midwives.

358. The HSWG works in partnership to support compliance with health and safety legislation and the raising of standards of workplace health, safety, and wellbeing in NHS organisations across the UK. The group promotes a safer working environment for all healthcare staff by promoting partnership working between employers and trade unions across the NHS and promotes best practice across the NHS and independent sector. Membership included nominated employer and trade union representatives from within the NHS and included a mix of employer's representatives from occupational health, human resources, health and safety backgrounds and every level of healthcare provision, including primary, secondary, mental health and ambulance services. The terms of reference for the HSWG are exhibited as RGB/394 - INQ000529731.

359. During the relevant period HSE attended HSWG meetings, held online every 2-3 months, contributing to meetings and providing updates when required. By way of example, the minutes from the 10 June 2021 meeting show at Item 5 an update on HSE's spot check inspections exhibit RGB/395 – INQ000529719.

360. In addition to liaison through HSWG meetings, from late 2021 onwards, HSE held meetings with RCN and other Trade Unions representing people working in the Social Care sector. The meetings were held every 6 months. This was a new engagement meeting, the purpose of which was to enable HSE to gain insight into the key issues affecting people working in social care, including matters relating to the pandemic.

361. DHSC chaired a Task & Finish Group for PPE to the adult social care sector. The group was attended by the main care sector representative bodies (Care England, ADASS, NCF, CPA, UKHCA) and smaller providers. The Terms of Reference reflect that the aim of the group was,

"to ensure the social care sector is properly prepared, trained and supplied with the personal protective equipment required to keep them and their attendees safe from Covid-19".

362. There was a standing weekly update on guidance and supply routes each week, with the rest of the agenda set according to key issues and stakeholder feedback. HSE was invited to attend on 10 June 2020 to speak about how it was supporting the health and safety of care workers and provided an opportunity for HSE to engage with relevant stakeholders in the sector.

363. During the meeting HSE addressed a request for a simplified guide for care providers to have so they know that they are purchasing compliant PPE was requested. This was because they were concerned about buying the wrong PPE. HSE suggested that the PPE specification table provided for manufacturers might be useful and a starting point.

364. Following this, PHE circulated updated draft guidance, *"Personal protective equipment (PPE) – resource for care workers working in care homes during sustained COVID-19 transmission in England".* HSE contribution to this guidance was to reiterate that the Technical Specification guide would be helpful to care providers purchasing PPE independently, however it was designed for easements from HSE and derogations from MHRA and was aimed at new manufacturers so could not be used as a purchasing guide in its own right but would provide the relevant BS EN Standards for Medical Devices and PPE.

365. HSE continued to attend weekly meetings. Initially, discussions were about the lack of PPE in the care sector and how this challenge might be resolved. Later, draft versions of guidance were discussed and attendance at this group provided a helpful forewarning about forthcoming versions changes to PHE guidance.

366. HSE's Chief Scientific Advisor established a Multi-Disciplinary Occupational Health Group representing a wide range of occupational health professional bodies. The group's purpose was to provide an ongoing and direct liaison between the HSE's technical/scientific specialists and professional bodies associated with occupational health in order to share information and intelligence. This included professional bodies linked to the healthcare and social care sectors including the NHS OH Physicians Network and Faculty of Occupational Medicine. I exhibit the group's Terms of Reference as exhibit RGB/396 - INQ000529634. Meetings of the group continued throughout the relevant period. I attach, as an example of the issues covered by the group copies of meeting minutes from April 2020 (exhibit RGB/397 - INQ000529212) and March 2021 (exhibit RGB/398 – INQ000529687).

Correspondence with BMA, RCN and other representative bodies

367. HSE received and responded to correspondence from the BMA, the RCN and other representative bodies throughout the relevant period. A number of these correspondence raised concerns or queries relating to PPE.

368. On 1 December 2020 Dr Anne Raynal, Chair of the BMA Occupational Medicine Committee, wrote to HSE. I produce a copy as exhibit RGB/399 - INQ000529681.

One of the points raised was in respect of the correct PPE that should be used by health and support staff who were likely to be exposed to patients who were infectious with COVID 19, outside of aerosol generating procedures. The BMA's letter noted that the "*current recommended RPE by Public Health England and HSE is insufficient and that the advice provided by the British Occupational Hygiene Society guidance should be followed. That is, that properly face- fitted, Filtering Face Piece Respirators Respiratory protection of the FFP3 or N95 models should be used by all staff when providing direct care to patients with confirmed or suspected COVID-19*." The letter highlighted BMA's belief that "*aerosol generating procedures"* (AGPs) was a misleading term, because it implied that managing a patient, for example when examining or bed changing, carried out whilst the patient was coughing, talking or even just breathing was not aerosol generating when, in the BMA's view, they almost certainly were. Furthermore, BMA's view was that that all patients should be treated as if they were positive unless or until they are proven to be negative.

369. HSE responded to the BMA's letter on 18 December 2020 (exhibit RGB/400 - INQ000529654). In its response HSE addressed all of the points raised by the BMA, including in respect of using FFP3 masks and aerosol generating procedures. By way of summary HSE stated:

i) HSE was unable to comment on the list of aerosol generating procedures (AGPs) as it was not within HSE's remit to do so. The list of AGPs was set out in the Four Nations Guidance ("IPC Guidance").

ii) That the IPC Guidance set out the standard of PPE that should be worn, including the level of RPE.

iii) HSE research referred to in the BMA's letter was in fact HSE Research Report 619 (RR619) "*Evaluating the protection afforded by surgical masks against influenza bioaerosols",* a copy of which I exhibit as RGB/193 - INQ000101591 produced in 2008, which addressed a specific research question – '*what level of protection is afforded to the wearer by surgical masks when exposed to an influenza virus aerosol*?'

iv) That the overall findings of "*Evaluating the protection afforded by surgical masks against influenza bioaerosols*" were not inconsistent with contemporaneous IPC Guidance.

v) That the contemporaneous WHO guidance "*Mask use in the context of COVID-19 – Interim guidance*" dated 1 December 2020 specified the use of tight-fitting respirators, but only when AGPs were being performed, a position which was consistent with the IPC Guidance.

370. HSE received a further letter from BMA on 1 December 2020 which raised questions in relation to the reporting of cases of, or deaths from Covid-19. It also raised questions regarding the use of PPE for healthcare and support staff who who were likely to be exposed to patients with Covid-19 (RGB/401 - INQ000529642). HSE's response is exhibited as RGB/402 - INQ000529691 and RGB/403 - INQ000529692. In our response we highlighted the guidance that was available on HSE's website regarding the reporting of dangerous occurrences, cases of disease and deaths due to occupational exposure to SARs-CoV-2. We also explained the role of the employer in determining the need for RPE as part of the risk assessment process and the HSE guidance available to assist the employer determine the type of RPE that was required. We sought to explain HSE's role as the regulator and why it was not within the remit of our role to undertake such a risk assessment to determine when, and what type of RPE was required.

371. HSE received a joint letter from the BMA and RCN dated 21 January 2021 (INQ000097909) in which two specific issues were raised; (1) infection prevention control guidance following the identification of the SARS-Co-V2 variant; and (2) ventilation across the health and care estate in light of the identification of the SARS-Co-V2 variant.

372. HSE responded by letter dated 29 January 2021 (exhibit RGB/404 – INQ000529669). In its response, HSE reiterated that COVID-19 was primarily a public health issue, and overall responsibility for developing and publishing the infection prevention control guidance lay with the DHSC working closely with PHE

and the devolved administrations. HSE stated that whilst HSE would not be conducting its own review of the IPC guidance given those bodies had already conducted such a review and published revised guidance on 21 January 2021, HSE would continue to work closely with the DHSC and other government departments in providing advice on workplace and workforce issues " *to support the UK response, particularly in the provision of technical advice to protect health and care workers, and others, providing care to people who have been diagnosed as having the virus.*"

373. In respect of ventilation, HSE's response stated that relevant guidance had recently been updated on the HSE website and contained specific advice on measures that could be taken to improve ventilation, as well as directing employers to seek further advice on complex ventilation systems from the Chartered Institute of Building Engineers (CIBSE) website.

374. HSE's response also addressed a more general point made by the BMA and the RCN in their letter of 21 January 2021 regarding the need for employers to be aware of their legal obligations and to carry out sufficiently robust risk assessments. HSE's response noted that "*work on this is well underway and, during December and January we inspected the arrangements of thirteen NHS trusts and four health boards across England, Scotland and Wales for managing risks arising from Covid -19*" and that "*at a national level we will also be sharing our findings with NHS England and Improvement and the devolved nation equivalents...*". HSE's response concluded by stating that it would update the tripartite Health, Safety and Wellbeing Partnership Group (which included the RCN) on the outcomes of the inspections at its next meeting on 25 February 2021. The meeting would offer the opportunity to discuss any issues arising from the inspections, and HSE would separately update the relevant care providers across the four nations.

375. HSE's Chief Executive, Sarah Albon, was cc'd into a letter dated 6 July 2020 sent by the BMA to the Chief Executive of NHS England, Sir Simon Stevens (INQ000097855). The letter raised questions relating to Cardinal FFP3 and surgical masks. Given the letter was sent to HSE for information only, no formal

response was commissioned within HSE. As detailed in paragraphs 86 and 87, the issues in relation to Cardinal surgical masks were considered by DMC.

376. The RCN wrote to HSE by letter dated 30 March 2020 (INQ000328917) raising, amongst other things, concerns that some NHS and social care employers were failing to follow statutory obligations in relation to the provision of PPE, and asked HSE to "*issue instructions to all providers of care where patients are being treated for, or are suspected of COVID -19 infection.*" HSE does not note any express reference to fit testing in the RCNs' letters. The RCN Wales and RCN Scotland also wrote to HSE, on 1 and 9 April 2020 respectively, raising similar issues (exhibits RGB/405 - INQ000529006 and RGB/406 - INQ000529011).

377. HSE responded to the RCN and RCN Wales letters on 2 April 2020, and to the RCN Scotland letter on 15 April 2020 (exhibits RGB/407 - INQ000529001, RGB/408 - INQ000529008 and RGB/409 - INQ000529047). HSE's responses set out the steps it had taken to ensure that both healthcare workers were adequately protected, and that the government had facilitated, and was continuing to facilitate, a sufficient supply of appropriate PPE. HSE confirmed that there had been no change in providing PPE and RPE to protect people at work as reflected in HSE guidance.

378. The HSE response set out the activity in which it was involved to ensure a continuing supply of (adequate) PPE, through working with DHSC, PHE and other government departments to address supply chain issues which were affecting the supply of PPE. HSE activity set out in the response included:

i) advising on appropriate re-use of PPE;
ii) liaising with PHE and the NHS regarding fit testing and the regulatory requirements for FFP3 respirators;
iii) attending regular meetings with DHSC supply chain leads to discuss the PPE/RPE stockpile;
iv) working with PHE to review evidence for the comparability of FFP3 and N95 respirators and aprons and gowns; and

v) involvement in the temporary suspension of specific regulations in order to fast track PPE to the marketplace.

379. In its response HSE emphasised how seriously it was taking the issue of PPE, and the view of HSE was commensurate with fulfilling its duties as regulator.

380. In addition to the issues raised by the BMA and RCN in specific pieces of correspondence set out above, HSE received correspondence, either by email or letter, from RCN covering a range of issues at various times during the relevant period. Those included issues such as the availability and suitability of PPE; fit testing and fit checking; decontamination and reuse of PPE; clarification on RIDDOR reporting including the reporting of Long Covid; Portacount machine settings; infection prevention in light of new Covid-19 variants and FFP3 masks and surgical masks. I have set out examples of correspondence received and HSE's responses below:

381. On 16 April 2020 the RCN enquired by email as to the type of protective coveralls that were suitable and asking for HSE's views on whether type 3B coveralls complied with the most recent PHE guidance (exhibit RGB/176c - INQ000269551).

382. On 17 April 2020 the RCN wrote to HSE stating its view that there was a failure in providing health and care staff with adequate and sufficient PPE, as well as requesting that HSE provided advice on PPE to employers and asking HSE for information on any advice that HSE may have provided in respect of infection control and alternatives to PPE should PPE items not be available (exhibit RGB/410 - INQ000529146). The RCN attached the results of a PPE survey it had conducted (RGB/411 - INQ000529147). HSE's response on 24 April 2020 (exhibit RGB/412 - INQ000529218) set out the comprehensive steps that HSE was taking which were directly relevant to the RCN's concerns.

383. On 29 April 2020 the RCN wrote to HSE regarding (i) the reuse and decontamination of PPE and (ii) highlighting HSE's apparent acknowledgment in its 24 April 2020 letter of the disproportionate impact of Covid-19 on Black Asian and Minority Ethnic (BAME) workers (exhibit RGB/413 – INQ000529222). HSE

responded on 3 June 2020 (exhibit RGB/414 - INQ000529427) stating that its comment regarding BAME workers had been a conclusion drawn from data from the Office of National Statistics, and on the date of response PHE had published their review of disparities of risks and outcomes of COVID 19 which included further data on BAME outcomes, which HSE would be reviewing. HSE also confirmed, amongst other things, that the use of PPE had been extended following consultation with PHE.

384. On 4 May 2020 the RCN sent an email raising concerns over fit testing (exhibit RGB/415 - INQ000529251). HSE had been consulted previously on a PHE letter dated 24 April 2020 sent to all NHS Chief Executives, Chief Nurses and Medical Directors, which emphasised the importance of proper fit testing of disposable sessional PPE face masks (including FFP3 masks). The letter stressed that fit checking should be performed every time a mask was donned, albeit fit checking was not a substitute for the fit testing of different masks (exhibit RGB/416 – INQ000529227). The PHE provided a link to HSE guidance on fit testing. HSE's stance was that the PHE letter represented an accurate reflection of HSE's position on fit testing. HSE's response is exhibited at RGB/417 – INQ000529262).

385. On 27 May 2020 the RCN wrote to HSE seeking clarification on (i) the definition of responsible person for the purposes of RIDDOR; and (ii) an explanation of the process for recording occupational deaths of health and care staff as a result of Covid-19 (exhibit RGB/418 - INQ000529362). HSE responded to both points on 3 June 2020 (exhibit RGB/419 - INQ000529713). On 5th August 2021 the RCN's Chief Executive and Chair of the RCN's Trade Union Committee wrote again on the same issues, seeking clarification on RIDDOR terminology as well as asking that HSE acted to ensure that all frontline staff deaths related to COVID-19 were reported to HSE as occupational fatalities as a precaution (exhibit RGB/420 - INQ000529742). A letter raising similar points was subsequently received days later from RCN Wales on 9 August 2021 (exhibit RGB/421 - INQ000529744). HSE responded to the RCN on 15 August 2021, clarifying RIDDOR reporting requirements, as well as confirming that the condition known as "Long Covid" (ongoing symptomatic Covid-19 and post Covid-19 syndrome) was not reportable under RIDDOR. HSE provided advice on responsibilities should a diagnosis of

Long Covid be made (exhibit RGB/422 - INQ000529749). A similar response to RCN Wales' letter was sent on 17 August 2021 (exhibit RGB/423 - INQ000529747).

386. On 20 July 2020 the RCN raised with HSE concerns about the Portacount machine at the Alder Hey Children's NHS Foundation Trust being set to US instead of UK test protocols for face fit testing (exhibit RGB/424 - INQ000529508). HSE confirmed that an alert had been drafted and would be sent to all NHS Trusts and other health and social care sector providers, highlighting the need to ensure all quantitative face fit testing machines were set to the UK test protocols. HSE confirmed that a reminder of the importance of fit testing and the need for competent persons to carry them out would also be included (exhibit RGB/425 - INQ000529703).

387. On 23 December 2020 HSE was copied into a letter sent jointly by the BMA and RCN to the government's Chief Scientific Advisor (exhibit RGB/426 - INQ000529656). The BMA and RCN sought further clarification following the identification of a new variant of the SARS-Cov-2 virus, and whether it is necessary to increase levels of protection for nursing, midwifery staff and doctors caring for patients in all settings with suspected or confirmed Covid. As HSE was not the direct addressee, no response was provided by HSE to the BMA and/or the RCN.

388. On 28 January 2021 the RCN requested that research undertaken in 2008 by HSE was revisited and repeated as a matter of urgency utilising SARS-CoV2 as the live virus in place of influenza (exhibit RGB/427 - INQ000529668). HSE responded on 9 February 2021 stating that the Four Nations COVID-19 infection prevention and control guidance had recently been reviewed in light of the new variants of COVID-19, recommending the use of FFP3 respirators when providing direct patient care and undertaking aerosol generating procedures to possible or confirmed cases of COVID-19 (exhibit RGB/428 - INQ000529674).

389. HSE also received and responded to questions and points raised in correspondence by other representative bodies for health and social care throughout the pandemic. For example, on 25 November 2021 HSE received a

letter jointly sent by individuals from a number of healthcare bodies, including the RCN's Professional Lead Infection Prevention Control representative and the Chief Executive of the British Occupational Hygiene Society (exhibit RGB/429 - INQ000529755). The letter requested HSE to take action in a number of areas, including enforcement action and inspections with a particular emphasis on the availability and capability to supply, fit and support respiratory protection equipment. HSE responded on 15 December 2021, summarising the obligations of employers, including those under COSHH, as well as confirming that HSE would not be conducting a review of the contemporaneous Four Nations Guidance because that had already been completed by the DHSC, working closely with UK Health Security Agency and the devolved administrations (RGB/430 - INQ000529757).

390. Another example is HSE's liaison with the National Ambulance Resilience Unit following an enquiry HSE received regarding ambulance coveralls on 23 March 2020 and subsequently responded to by HSE on 24 March 2020 (INQ00026954).

391. Further, on 12 March 2021 HSE received correspondence from the Society of Occupational Medicine (SOM), in which SOM raised a number of points including SOM's concerns over a lack of understanding of risk and how to manage it in healthcare settings and workplaces. HSE responded on 29 March 2021, stressing that if an employer was following updated guidance to control exposure to Covid-19, they would be taking, under health and safety legislation, reasonably practicable precautions to control the risk. HSE confirmed it would continue to work closely with the DHSC and other government departments to provide information and advice on workplace and workforce issues, particularly in the provision of technical advice to protect health and care workers, and others, providing care to people who have been diagnosed as having Covid-19 (exhibit RGB/431 – INQ000529685).

392. In addition to receiving, considering and responding to direct communication, monitored media and website pages for points raised by organisations such as the BMA. For example, in or around January 2022 the BMA published an article titled *"Looking ahead in 2022 reporting staffing pressures".* HSE was concerned by the

BMA's comments in respect of forgoing fit testing for FFP2 masks. The article stated *"given that Omicron is readily transmissible in air and there is now enough evidence that there is community circulation – with the ONS estimating that one in 15 people in England had COVID-19 in the most recent week – we must take a more precautionary approach. And in the absence of readily available fit testing, there is a growing consensus that we should use non fit tested FFP2 masks as a default when seeing patients. A well-fitting FFP2 with a decent seal will provide better protection than a FRSM."* HSE considered that approach would be incorrect, and as such the BMA's suggestion ought to be challenged, however before the HSE responded formally to the BMA the article was removed (exhibit RGB/432 - INQ000529792).

Lessons Learned

393. 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 – INQ00026973 and RGB/203 – INQ000269692).

394. 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.

395. 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

396. 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.

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

e. Findings from HSE activity

f. Initial Implications for the HSE

g. Wider implications for the health and safety system

398. The findings 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. 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.

399. 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.

400. 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.

401. In relation to the procurement of PPE and the HSE's role in market surveillance, the report identified that market surveillance is potentially a very powerful route to risk elimination and control if it prevents unsafe products entering the market and avoids wasteful spend. However, the report acknowledged that the resource allocation in HSE's Science Division to carry out both proactive market surveillance and reactive investigation was not large. Whilst allocation of resource had increased due to demands related to the Exit from the EU, the report acknowledged that both market surveillance and regulatory activity focused solely on PPE were a small part of HSE's wider functions prior to the pandemic. It also highlighted that HSE had no role in monitoring the availability of PPE more generally.

A review of regulatory easements

402. In September 2021, OPSS undertook an evaluation of the use of regulatory easements which was informed by data received from HSE and BSI. The summary of the evaluation was set out in a PowerPoint slide pack which HSE was invited to comment on. The evaluation made reference to gaps in data that was held by OPSS in relation to easements issued by HSE. As highlighted at paragraph 161 above, this was something that HSE had been aware of and was trying to resolve. Steps were taken by HSE that resulted in the data being reconciled.

403. HSE provided feedback to OPSS on the draft slides, to which OPSS responded as detailed in RGB/433 - INQ000529760. OPSS also made amendments to the slides to incorporate some of the feedback HSE had provided (exhibit RGB/434 – INQ000529759). However HSE remained concerned about the approach to the evaluation, in particular the scope of the evaluation and whether it sufficiently

captured the complexities of the pandemic and the work that was undertaken by OPSS, MHRA and HSE throughout the pandemic. HSE's observations on the scope and approach to the evaluation are contained in an email to OPSS which I exhibit as RGB/435 - INQ000529758.

404. Subsequently HSE prepared its PPE Unit report and in doing so undertook a comprehensive review of the easements data to ensure that reliable statistics were available (exhibit RGB/288 – INQ000529804).

HSE's Internal Operations during the pandemic

405. As highlighted in paragraphs 219 - 224 above, early in the pandemic HSE set up a dedicated PPE Unit to seek to ensure the effective management and delivery of regulatory activity arising in connection with the pandemic. The review of the PPE Unit (exhibit RGB/288 – INQ000529804) which was published in November 2022 provided HSE with an opportunity to reflect on its internal operations and how the steps taken during the pandemic may be relevant to the HSE's management of a similar Annex B of the PPE Unit Report provides a guide to setting up a virtual team in HSE and this will assist HSE in the future should the need arise to rapidly set up an internal team to deal with a future pandemic or other emergency.

Statement of Truth

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.

Personal Data

Signed: Richard Brunt

Dated: 22 January 2025