Witness Name: Louis Burns
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UK COVID-19 INQUIRY (Module 3)

WRITTEN STATEMENT OF LOUIS BURNS ON BEHALF OF HEALTH AND SAFETY EXECUTIVE NORTHERN IRELAND

I provide this statement in response to a request under Rule 9(1) and (2) of the Inquiry Rules 2006.

I, Louis Burns, will say as follows: -

1. I am one of four deputy chief executives (DCE) in The Health and Safety Executive for Northern Ireland (HSENI). I joined HSENI in 2000 as a trainee inspector, became an inspector in 2002, a principal inspector in 2005 and Deputy Chief Executive (DCE) in 2016. I am responsible for Services Division. When the pandemic started in March 2020 I was Head of Services Division until 1 June 2020 when I was temporarily moved to a role of overseeing HSENI's EU Exit preparations. I was replaced as Head of Services Division by my colleague, Kevin Neeson. I returned to being Head of Services Division on 1 November 2021.

2. HSENI is a non-Departmental Public Body of the Department for the Economy (DfE) with Crown status. HSENI has an independent board made up of non-executives. Given our statutory role as a regulator, our relationship with government in Northern Ireland is characterised by the term 'independence'. HSENI does not get involved in the development of government policy in Northern Ireland.

3. HSENI's work focuses on helping ensure that everyone stays safe and well 'at work' which is defined in Health and Safety at Work (Northern Ireland) Order 1978 [*The Order*] as, "*work as an employee or as a self-employed person*". It is further defines that, "*an employee is at work throughout the time when he is in the course of his employment, but not otherwise*".

4. The remit of HSENI is set in legislation and extends to a range of sectors including manufacturing; schools and universities; chemical plants; hospitals and nursing homes; construction; disciplined services; transport; district councils; gas supply and distribution; government departments; agriculture; fairgrounds; market compliance in respect of chemicals and products used at work; mines and quarries. HSENI does not have any enforcement responsibility in respect of premises such as residential homes, retail, entertainment & leisure, offices activities etc. Enforcement for these premises falls to local authorities.

5. During the pandemic, HSENI had a staff complement of approximately 100 staff of which around 10 were principal inspectors, 30 were inspectors. Principal Inspectors and Inspectors are recruited as trainee inspectors with relevant primary degrees and industrial experience. On recruitment they all must achieve the same postgraduate regulatory qualifications. Principal Inspectors is the more senior grade and will carry a range of administrative and management duties. Inspectors work within sectoral teams (e.g. manufacturing / construction etc.) and each of these teams will be managed by a Principal inspector. In addition we had four other front line staff (compliance officers). For various reasons such as health / shielding / caring responsibilities etc. only circa 25 of these inspectorate staff could be deployed to fieldwork.

6. The staffing complement set out above is broadly in keeping with the numbers we had in the five years before the pandemic. In some years the numbers would have been a little lower. This was because we traditionally only recruited to fill vacancies.

7. The number of premises which are physically inspected is limited by the number of available inspectors and other work pressures. In order to increase our reach to dutyholders we use a mixture of inspections, website, events, media etc. Prior to

the pandemic, we prioritised our limited resources more in the high-risk industries and activities known to be associated with serious injuries and fatalities. These would include agriculture, construction, extractive industries and manufacturing, work at height, workplace transport, machinery safety etc. In addition we deployed staff to cover all work sectors and meet our statutory duties. Our work would have been a mix of proactive (inspections, education etc.) and reactive (complaints, investigations etc.).

8. HSENI is not statutorily required to carry out inspections in any sector. Its functions are set out in Article 13 of the Order. Article 22 to 27 of the Order provide inspectors with enforcement powers which would include carrying out inspections and examinations etc. In normal circumstances, depending on resources and other priorities, proactive inspections may be carried out in any and all sectors including healthcare. Reactive work would also be carried out in all sectors where, for example, an accident report of a complaint was received. Fatalities, major injuries, occupational diseases, incidents likely to give rise to serious public concern, serious breaches of the law may be subject to inquiry or investigation subject to disqualifying criteria which are: Inadequate resources / other priorities / impracticability of investigation (e.g. unavailability of witnesses or evidence or disproportionate effort would be required) / or no reasonably practicable precautions available for risk reduction.

9. When the pandemic started HSENI was inundated with an unprecedented increase in complaints and requests for advice on managing covid-19 in workplaces (see Table One below).

Table One:

Total interactions recorded by HSENI during the pandemic.

Table One - Covid Related Interactions			
Year	**2020**	**2021**	**2022**
Inspections	2069 (926)	1758 (508)	170 (164)
Advisory Contact	961 (25)	162 (5)	27 (4)
Complaints	3153 (295)	585 (99)	14 (6)

(Interactions include emails / letters / site visits / telephone calls)

10. To put this in context, in the years before the pandemic, we would expect to receive approximately 800 to 850 complaints. In 2020 we received 3,153. The volume of complaints and requests for advice resulted in us prioritising our resources to meet this demand. Our entire staff complement moved immediately to home-based working. In the period 25/03 to 05/05 2020 HSENI suspended site visit inspections for all but serious and fatal incidents to reduce the risk of staff contracting and spreading Covid. For the duration of the period, typically a serious incident would have been a fatality. Our inspectorate staff were tasked with responding, mostly by telephone and email to the increased number of complaints and requests for information. Given the number of requests, the novel nature of the subject and that the available guidance was public health guidance, meeting this demand engaged all our available inspectorate staff. Due to this and the risk to HSENI staff, alternative methods for dealing with them were developed. These included remote inspection methods where confirmation of any required actions was obtained by video, photographic or documentary validation and where possible corroboration by the complainant or Trade Union Officials. Staff would have used these methods to a lesser extent before the pandemic. The move to using these methods on a much greater scale was due to the volume of complaints and requests for information received and also to protect our own staff as much as possible from the risks of Covid-19 by maximising opportunities to adopt a home-working model. These methods allowed for the handling of a large volume of work in relative safety for our staff and was useful for issues where verification was somewhat more straightforward (e.g. was a guard on a machine / was a worker trained etc. It was less effective for making judgements about safety behaviour in the workplace such as employee compliance with safety processes and procedures. These issues will always be easier to assess with a site visit but even site visits have limitations insofar as the presence of an inspector will have an immediate positive behavioural effect.

11. Part of HSENI's role is to ensure compliance with relevant health and safety at work legislation to protect workers' health. The need for this came into sharp focus as a result of the Covid pandemic, albeit the increased risk could have been the result of non-work interactions rather than the work activity itself. HSENI did not have the public health competence to develop Covid-19 guidance or best practice,

so the organisation's work in the period was to provide / signpost advice and assist organisations to operate in compliance with the available public health guidance, particularly in working environments. The basic guidance issued and promoted by the UK Government both in and out of the workplace was predicated around maintaining two metres distance which then became "Hands, Face, Space" circa September 2020. This work was underpinned by the duty under law, for "every employer to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all his employees".

12. HSENI has never had the capacity to develop health and safety guidance for industry. The policy and research functions necessary to develop health and safety guidance rest within HSE and BSI etc. HSENI adopts approved codes of practice and guidance issued by HSE for use in N. Ireland.

13. The health and safety legislation applies in equal measure to all situations where there is an 'at work' (defined as work as an employee or self-employed person throughout the time he in the course of his employment but not otherwise).

14. The key legislation used by HSENI is (and was) the Health and Safety at Work Order (NI) 1978, The Management of Health and Safety at Work Regulations (NI) 2000 and the Workplace (Health, Safety and Welfare) Regulations (Northern Ireland) 1993. It should however be noted that these regulations were drafted to protect workers and members of the public from risks to their health and safety created as a result of a work activity. They were not designed to address a pandemic where the hazard is at large within the community. It was reasonable to assume that workers should be afforded the same level of protection in the workplace as they would have in wider society in terms of a pandemic. The application of public health guidelines to workplaces (under health and safety legislation) was assumed to be based on the legal test "so far as is reasonably practicable".

15. A collection of secondary legislation provides greater detail for dutyholders but none of this is specifically drafted for healthcare settings. This would include: the Personal Protective Equipment at Work Regulations (Northern Ireland) 1993; the Workplace (Health, Safety and Welfare) Regulations (Northern Ireland) 1993; the

Provision and Use of Work Equipment Regulations (Northern Ireland) 1999; the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003; and the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997. This list is not exhaustive

16. HSENI inspectors (as appointed under Article 21 of the Health and Safety at Work Order (NI) 1978 [the Order]) have powers as set out in Articles 22 to 24 of the Order. Where an inspector believes a dutyholder is contravening one or more of the relevant statutory provision he may serve an improvement notice which gives the dutyholder a specified period of time to bring the matter into compliance. Where an inspector believes a dutyholder is carrying on an activity which the involves a risk of serious personal injury he may serve a prohibition notice which generally requires the dutyholder to stop the activity immediately and until the prohibition notice is complied with.

17. The enforcement guidelines followed by HSENI are exhibited as LB/7 **INQ000400932** The document's overall aim is to ensure that duty holders take action to deal immediately with serious risks and promote and achieve sustained compliance with the law. They provide the rationale that duty holders who breach health and safety requirements, and directors or managers who fail in their responsibilities, may be held to account, which may include bringing alleged offenders before the courts in Northern Ireland in a manner which is demonstrably proportionate, targeted, consistent and transparent.

18. In the period before 1 March 2020, inspections of healthcare settings were generally done on a reactive basis in response to an incident or accident. In the preceding year there were 18 interactions associated with healthcare which would have been arranged through Trust Health and Safety teams mainly because of the nature of the undertakings. These 18 interactions included a mixture of complaints, inspections, investigations, provision of advice and the discussion of machinery defects (after statutory insurance company inspections). Complaints ranged from perceived poor treatment from staff / high environmental temperatures / potential chemical exposures / electrical equipment / building safety in specific working areas / to issues with promised PPE supply for staff (pre-Covid pandemic); and

workplace transport issues around sites. Inspections also took place in Trust sites as part of HSENI's statutory requirement to inspect ionizing radiation equipment in workplaces.

19. HSENI dealt with approximately 30 complaints from the NI Health Trusts in the period and also received 5,479 NI2508's (statutory notifications) categorised as "Disease" from the Health and Social Care Trusts. These covid complaints related to: concerns over risk assessments; non-isolation; social distancing in the workplace; PPE provided; employees not being allowed to work from home; potential spread via Health teams going around the community; and lack of testing. Twelve of these were upheld / partially upheld. Thirteen not upheld and four passed to another organisation as they were not within HSENI's enforcement remit.

20. HSENI has no vires in respect of the Health Protection (Coronavirus) Regulations, however each workplace was contacted to ensure these regulations and PHA advice was being followed as far as was reasonably practicable.

21. NI2508 is a report of injuries, diseases and dangerous occurrences in a workplace made to the to the relevant enforcing authority. There is a statutory requirement to report certain specified occurrences under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR). COVID-19 is classified as a biological agent as defined in regulation 2(1) of the Control of Substances Hazardous to Health Regulations (NI) 2003. For a report of Coronavirus to be reportable under RIDDOR there must be reasonable evidence that someone clinically diagnosed with the disease was likely exposed because of their work. Guidance was issued on HSENI's website on the conditions to be met before reporting a case of Covid as a disease under RIDDOR Report an incident | Health and Safety Executive Northern Ireland (hseni.gov.uk).

22. Due to the number of notifications being so large these were closed off except for those which fell under 'formal investigation'. In the period (1 March 2020 to 28 June 2022) HSENI reviewed the circumstances surrounding the deaths, as a result of Covid-19, of four Health and Social Care Trust employees: Shirley Lucey BHSCT; Tony Doherty BHSCT; Peter Henry Vayro SEHSCT; and Glenda Scott SEHSCT.

23. HSENI's formal investigation policy involved making contact with the relevant Health and Social Care Trust to determine whether Covid Risk Assessments were in place for the relevant section where the deceased staff member worked; identifying whether suitable control measures were in place and whether there were any Covid positive cases both within the deceased's work colleagues and in their immediate family circle. A decision was then made based on the relevant evidence whether the death could be directly attributed to the workplace. The four cases above were reviewed in line with HSENI's "formal investigation policy in relation to Covid" and it was determined that a clear workplace link could not be established in any case.

24. In the period after March 2020, there was no official suspension of site visits. Rather HSENI followed PHA / GOV advice and carried out its work remotely where possible. The coronavirus Regulations took precedence to Health and Safety legislation in terms of prescriptive Infection Control Procedures. RQIA normally carry out routine inspections in healthcare settings. In determining when to attend a premises HSENI uses Enforcement Guidelines which set out the general principles and approach which all health and safety enforcing authority staff are expected to follow. In addition, HSENI staff also followed the current advice from PHA.

25. Interactions with duty holders were mostly by remote contact (phone / email etc.). This was in order to protect our own staff, to operate within the public health guidelines and also to avoid bringing covid-19 into and / or out of healthcare settings where there were unprecedented pressures. This was a pragmatic approach in extraordinary circumstances. HSENI liaised with all the Health and Social Care Trusts to discuss the provision of appropriate PPE across the health and social care sector. As part of the ongoing actions around the sourcing of relevant PPE during the early stages of the Covid pandemic, HSENI placed information from HSEGB (known as "safety alerts") with regards to mask suitability and purchasing arrangements on its website to inform all local dutyholders of the UK-wide guidance. Following this, there was a later meeting between HSENI, PHA and BHSCT in May 2020 after concerns were raised by an employee regarding the use of "Tiger Masks" in the Belfast Trust (i.e. the same surgical masks with ear

loops that the general public would have been wearing). Following this complaint, all Health Trusts were subsequently contacted to ask if they had enough PPE stock for staff including front line staff (such as those in ICU). This e-mail also included questions on stock levels for tight fitting (FFP3) masks and its prioritization; as well as ("Face Fit") testing for staff wearing both these masks and other FFP2 / N95 masks (depending on existing stock supply / distribution chains at that time in the pandemic).

26. HSENI did not identify any themes from healthcare inspections during the relevant period. This role is not within HSENI specific enforcement remit and our only involvement (from the perspective of Covid) was to review locations where there had been clusters of positive cases identified and to evaluate the control measures which were in place (against the relevant guidance at that time).

27. All Trusts had at least one HSENI visit within the cited March 2020 – June 2022 date range and the reasons for these inspections varied – from HSENI's ongoing statutory requirement for completing Ionisation Radiation inspections, to asbestos checks, to following up on PHA reported Covid clusters.

28. There was only one PHA reported Covid cluster for a Health Trust (out of the approximately 621 received in total across all sectors enforced by HSENI during this time frame of 1 March 2020 to 28 June 2022) and it was found that all controls had been put in place to prevent the risk of transmission.

29. HSENI does not have the competence to inspect healthcare settings with regard to clinical matters. HSENI cannot comment on whether Infection Control Procedures were adequate.

30. In and around May 2020 HSENI did start site visits to a number of key industry sectors. These were mainly the meat processing and some factories. Meat plants were inspected as they had been identified as high risk as a result of a number of well documented outbreaks worldwide at the time. Meat processing factories remained operational to produce food and also to prevent a backlog in the slaughtering and processing of animals. Other site visits were happening in construction as the locations were generally outdoor. HSENI staff used a mixture of precautions such as respiratory protective equipment, maintaining distance and

observing hand hygiene to mitigate the risks as much as it was possible to do so and these were developed in line with public health guidance to address situations where covid may be encountered. These precautions could not guarantee total safety from the virus and as such it would not have been appropriate to have deployed staff in healthcare settings where there were large numbers of confirmed covid cases. As outlined, the risks associated with entering healthcare settings both for our staff and for users meant that no site visits were conducted in that sector. The number of site visits conducted can be seen in Table One in paragraph nine.

31. In the majority of site visits it was not necessary to use formal enforcement as employers engaged positively with HSENI's efforts to make changes to layouts / improvements etc. to move towards compliance with public health advice as far as it was possible to do so.

32. HSENI adopted existing HSE guidance on infection prevention and control ("IPC") and the use of PPE and RPE. HSE guidance covered healthcare and other settings and was also supplemented by PHA advice current at the time. HSENI did not have the competence to interpret or amend this so we made it available on our website at that time. Essentially nothing changed with HSENI's approach.

33. The HCID decision did not affect HSENI's guidance, as any information provided followed public health advice or relevant infection prevention and control guidance for the healthcare sector.

34. The HCID decision did not affect the approach to inspections in healthcare settings, as HSENI at an early stage of the pandemic decided to suspend visits to healthcare establishments to reduce risk of infections to those under care.

35. There was no requirement for categorisation of the risk posed by previous pandemic viruses. Where employees are required to work with such viruses, as part of their working environment, then employers are expected to implement relevant controls to minimise risk to individuals under the Control of Substances Hazardous to Health Regulations.

36. HSENI does not have a formal assessment of the level of risk of contracting COVID-19 in healthcare settings over the course of the relevant period. The expectation of enforcement was directly related to the public health guidance of the time or other relevant standards such as infection prevention control guidance.

37. HSENI did not make an assessment of the level of workplace risk of contracting Covid-19 in healthcare settings or indeed for any work sector. This was outwith HSENI's competence and was a matter for the Department of Health in NI and the NI Public Health Agency. The same would apply to earlier viruses such as SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome). As stated HSENI did not carry out inspections of the healthcare sector.

38. It was HSENI's understanding that all healthcare settings were operating under extreme pressures and doing the best they could to reduce the risk of Covid-19 spread. There were widely reported issues around the availability of protective equipment but there was an unprecedented societal expectation of the healthcare sector and the need to maintain the functions

39. HSENI does not have the competence to inspect healthcare settings with regard to clinical matters. HSENI cannot comment on whether Infection Control Procedures were adequate.

40. HSENI did not provide its own guidance or regulations on infection prevention and control in healthcare settings or specific interpretation of existing regulations or guidance. The NI Health Service would have had access to expertise in these areas which was not available in HSENI. HSENI did not take enforcement action in any healthcare setting in respect of potential breaches of IPC, PPE or RPE regulations during the relevant period. As previously stated, site visits were not undertaken to healthcare settings.

41. The following were issued:

    a. Safety Alert issued to Health Trusts (published on HSENI's website on April 2022) is exhibited as LB/8 **INQ000400959** his document was a HSL report which outlined the limitations of surgical masks in respect of aerosols.

HSENI did not undertake any subsequent research or issue any guidance in response to the research paper;

b. The Use of face masks designated KN95 (published on HSENI's website on 11 June 2020) is exhibited as LB/9 INQ000236249 This document was an alert stating that HSENI had been informed that a substantial number of face masks, claiming to be of KN95 standards, provide an inadequate level of protection and are likely to be poor quality products accompanied by fake or fraudulent paperwork and that HSENI was working to remove them from the supply chain with colleagues in HSE(GB), the Office for Product Safety and Standards (OPSS), Border Force, the Medicines and Healthcare products Regulatory Agency (MHRA) and Trading Standards to identify manufacturers and suppliers of these masks and prevent them entering the UK; and

c. UPDATE: UK Guidance on the Repurposing of Non-Compliant Personal Protective Equipment (PPE) and Medical Devices (published on HSENI's website on 19 June 2022) is exhibited as LB/10 INQ000236256 this document was to alert workplaces that OPSS guidance states, where a product has been designed or manufactured as Personal Protective Equipment (PPE) or as a medical device and is found to be non-compliant, the business in the supply chain that owns the product, can now take on producer responsibility and repurpose the product to sell as a face covering during this time of Covid 19 Pandemic. Any business repurposing products to classify the product as a face covering must demonstrate it meets the requirements under the General Product Safety Regulations (GPSR).

42. During the pandemic, HSENI was involved in ensuring that the PPE ensemble for healthcare in Northern Ireland met the required quality assurance standards, i.e. REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on personal protective equipment. During the early stages of the pandemic, the European Union gave member states the opportunity to put easement measures in place in relation to the conformity assessment process for PPE, which the UK as a whole decided to take forward, led by the policy lead OPSS at the then DEPT of BEIS.

43. There are two sets of product safety regulations that govern the placing on the market of equipment used to protect users and patients in the health care setting, the EU Regulation 2016/425 on Personal Protective Equipment (and the Personal Protective Equipment (Enforcement) Regulations 2018) and the Medical Devices Regulations 2002. Whether a product is defined as PPE or a medical device depends on the purpose for which it is designed to be used. If the purpose of the product is to protect the patient, then it is a medical device. If the purpose is to protect the worker, it is PPE. Some products are both PPE and a medical device as they are protecting both the worker and the patient.

44. The Office for Product Safety and Standards (OPSS) is responsible for PPE product safety policy which is enforced in health care settings by the Health and Safety Executive for Northern Ireland (HSENI) in Northern Ireland. The Medical Devices Regulations are 'owned' and enforced by the Medicines and Healthcare Products Regulatory Authority (MHRA) across the UK.

45. Enforcement of these two sets of regulations includes monitoring the market to ensure products on the market meet the applicable essential health and safety and performance requirements of the regulations that govern them. HSENI is the market surveillance authority for workplace PPE in Northern Ireland and MHRA is the market surveillance authority for medical devices across the UK.

46. Outside of the pandemic (in 'normal times') PPE and medical devices placed on the market have to carry a CE mark and HSCNI contracts with suppliers would require all suppliers to ensure that a CE marked product meets the essential health and safety requirements set by the relevant regulations.

47. In Northern Ireland HSCNI, through BSO's usual procurement procedures came under extreme pressure during the pandemic, which was compounded by a massive surge in global demand for PPE as Covid-19 took hold across the world. Unprecedented quantities of PPE were needed quickly to protect health care workers within Northern Ireland. In order to speed up supply of PPE to health care workers, the EU introduced two regulatory easements to the PPE regulations.

48. One easement allowed Member State Governments to procure PPE without a CE mark for use by health care workers. The PPE product had to be approved by the relevant market surveillance authority, and in the case of Northern Ireland, HSENI.

49. The second easement was introduced for manufacturers bringing their products to market. This easement allowed manufacturers and distributers to sell PPE for the purpose of protecting against Covid-19 without completing the CE marking process, provided certain other conditions were met. A manufacturer must have started the CE marking process, contacted a Notified Body and have approval from the market surveillance authority, again HSENI.

50. During the pandemic, HSENI continually discussed with colleagues in HSCNI, BSO on the suitability of PPE being brought into the health care setting, and on a very regular basis, carried out inspections of new PPE assignments brought into HSCNI's central warehouse store in Carrickfergus, Co Antrim.

51. HSENI also worked closely with our colleagues in Border Force at points of entry, to carry out inspections on PPE destined for the health care setting, before they were placed on the market in Northern Ireland.

52. HSENI, became the gateway for quality assessment for PPE donations from both the private and third sector, who responded to public sentiment that everyone should help secure PPE for the Health care setting across the United Kingdom. HSENI ensured that any products being offered to the Healthcare met the required standard as laid down by a guidance paper developed by HSE(GB) and MHRA for manufacturers on the essential technical requirements for non-CE marked PPE being procured directly by Government for the health care setting.

53. As new innovative ideas for PPE where conceived, HSENI worked with manufacturers to ensure that new prototype PPE products did not reach the healthcare setting without meeting the required standards.

54. Throughout the pandemic, HSENI gave Health and Social Care Board Business Services Organisation (HSCNI BSO) guidance, from what OPSS had published,

on a regularly basis, for the various easements / derogations that where in place at any given point.

55. HSENI was a participant in two National Committees, the PPE Regulatory Co-ordination Cell (RCC), led by OPSS and The Personal Protective Equipment Decision Making Committee (DMC) led by the Dept. of Health and Social Care. Both committees remit solely looked at product issues that may enter the Four Nations supply chain, primarily through Daventry. HSENI did not carry out any assessment on the suitability of existing PPE worn by HSC staff but carried out periodic inspections of PPE consignments being purchased by HSCNI (BSO). HSENI did not have a role in relation to testing the adequacy or standard of RPE.

56. HSENI did not have a role in what PPE / RPE was suitable or sufficient for the Health Care Sector, but worked along with colleagues in BSO to ensure that products entering their supply chain met the required standard.

57. As previously highlighted HSENI, under the easement, had the final approval as to whether non-CE marked PPE could be placed on the market, for use within the health care setting. To ensure that quality of PPE was of a suitable standard, HSENI collaborated with colleagues in HSE(GB), OPPS, and through HSENI's membership of the PPE Regulatory Co-ordination Cell (RCC). The main Purpose and function of RCC was to:
    a. Represent a coordination function for UK regulators at a strategic and tactical level;
    b. Provide specialist advice and coordinated support for dealing with national regulatory issues, and standards of PPE within the supply chain; and
    c. Allow members of the group to share intelligence and analysis on market surveillance activities to focus strategic efforts and if necessary, coordinate with Notified Bodies, test houses and government laboratories to support UK testing capability and capacity, and to facilitate the rapid testing of products to inform decision making.

58. The group was invoked during the Covid-19 pandemic to address and overcome regulatory issues resulting from the unprecedented and immediate demand for

personal protective equipment (PPE) and medical devices (MD); specifically in regard of the safety and effectiveness of PPE for the NHS supply chain across the United Kingdom.

59. HSENI also valued the expertise and competence in the group. We valued and relied on the guidance produced jointly by HSE(GB) and MHRA for manufacturers on the essential technical requirements for non-CE marked PPE being procured directly by government for health care workers, when assessing the quality standard of the PPE.

60. Both HSE(GB) and HSENI also worked closely with the British Safety Industry Federation (BSIF), to ensure that PPE standards within the health care setting were being met.

61. HSENI became the conduit to the health care setting of all decisions made across the UK in relation to various easements / derogations etc.., with all policy decisions being made at a National level by the following:

    a. the PPE Regulatory Co-ordination Cell (RCC), which HSENI was a member of;
    b. the Personal Protective Equipment (PPE) Decision Making Committee (DMC) which HSENI was a member of; and
    c. the PPE policy owner in the UK, the Office of Product Safety and Standards (OPSS).

62. HSENI informed HSCNI at every stage of changes to policy / easement etc.., as they occurred, and responded to all queries from HSCNI in a timely manner. Examples exhibited:
    a. Module 3 – Fang Tian Masks (exhibited as LB/11 **INQ000400942**
    b. Module 3 - Novel item of PPE [two attachments – next two lines] (exhibited as LB/12 **INQ000400952**
        i. Novel Item of PPE - Clear Mask Product Specifications Sheet (exhibited as LB/13 **INQ000400950**
        ii. Novel Item of PPE - Face mask MHRA doc. (exhibited as LB/14 **INQ000400951**

c. Guidance on 2020/403 (PPE easement) (exhibited as LB/15 **INQ000400943**
d. Overlabelling of FFP3 boxes (exhibited as); and
e. Revalidation [this one has five attachments – next five lines] (exhibited as LB/16 **INQ000400958**
    i. Revalidation Picture 1 (exhibited as LB/17 **INQ000400953**
    ii. Revalidation Picture 2 (exhibited as LB/18 **INQ000400954**
    iii. Revalidation Picture 3 (exhibited as LB/19 **INQ000400955**
    iv. Revalidation Picture 4 (exhibited as LB/20 **INQ000400956** and
    v. Revalidation Picture 5 (exhibited as LB/21 **INQ000400957**

63. It is my understanding that HSENI did not respond to the APPG's 'Long Covid Report'. HSENI does not have a policy unit. In the main, we adopt policy developed by HSE. HSENI has not given any policy view in respect of Long Covid being recognised as an occupational disease and for a compensation scheme for frontline workers to be launched.

64. HSENI also received correspondence from Pat Cullen of the Royal College of Nursing (31 March 2020) (exhibited as LB/22 **INQ000400948** She was expressing concern about the ongoing lack and adequacy of personal protective equipment [PPE] supplied to our members. She mentioned healthcare settings such as: hospitals; GP surgeries; nursing homes; and for community nurses visiting people in their homes. She raised particular concerns around: FIT testing of FFP3 masks is currently not widely available; In the absence of FIT testing, health and care workers are being asked to wear FFP3 masks which they have not been trained to use, resulting in the wearing of ill-fitting equipment placing them at risk of infection; and that the guidance is being interpreted by employers in response to what they have available, as opposed to what will protect staff.

65. In his response of 6 April 2020 (exhibited as LB/23 **INQ000400947** HSENI's Chief Executive set the context around the global shortages and pressures around PPE supply. He provided an assurance that the matters would be raised with the Department for the Economy (parent department) and the Department and with Health to ensure that all reasonable action is being taken at the most senior level. He also indicated that HSENI inspectors would contact Trusts to ensure that where

stocks of PPE are limited, especially respiratory equipment, that existing stocks are being directed to those engaged in nursing activities at highest risk. In addition, where there are shortages of PPE, HSENI would ask that the Trusts provide assurance that everything possible is being done to reduce risk so far as practicable to all healthcare staff.

66. HSENI received correspondence from Ms Iqbal of the Nursing and Midwifery Council (NMC) (16 April 2020) (exhibited as LB/24 **INQ000422810** in relation to concerns regarding inadequate supply of personal protective equipment (PPE) for front line staff working in the Western Health and Social Care Trust (WHSCT). Ms Iqbal stated, "Staff have been advised by their unions that they should not continue to work in conditions where they do not have adequate PPE protection and have requested the HSC Trust to advise on this".

67. In his response of 5 May 2020 (exhibited as LB/25 **INQ000400946** HSENI's Chief Executive set the context around the global shortages and pressures around PPE supply. He provided an assurance that the matters would be raised with the Department for the Economy (parent department) and the Department and with Health to ensure that all reasonable action is being taken at the most senior level. He also indicated that HSENI inspectors would contact Trusts to ensure that where stocks of PPE are limited, especially respiratory equipment, that existing stocks are being directed to those engaged in nursing activities at highest risk. In addition, where there are shortages of PPE, HSENI would ask that the Trusts provide assurance that everything possible is being done to reduce risk so far as practicable to all healthcare staff.

68. HSENI received correspondence from Dame Kinnair and Dr Black (21 January 2021) (exhibited as LB/26 **INQ000400935** in their respective roles as Chief Executive & General Secretary of the Royal College of Nurses (RCN) and the Northern Ireland Council Chair of the British Medical Association (BMA) in respect of '*concerns about the ongoing threat posed to health and care staff following the identification of the SARS-Co-V2 variant (VOC 2020/2101) and in particular the risk of aerosol / airborne infection and HSENI's regulator's role in preventing work related ill health, death or injury*'. They asked for a review the Infection, Prevention and Control (IPC) guidance for health and care to reduce transmission, particularly

in respect to aerosol and airborne transmission as a result of coughing, talking, calling out or shouting, as commonly occurs in health and care settings. This must include an assessment of the use of appropriate PPE across settings. They asked for a review of guidance and the provision of ventilation across the health and care estate, to ensure it remains fit for purpose given the emergence of new variants. The letter also touched on their view of the supplies of PPE for staff.

69. HSENI's Chief Executive set out the HSENI position in relation to the same in a letter of (9 February 2021) (exhibited as LB/27 **INQ000400944** He stated that in respect of Prevention and Control (IPC) Guidance, the content of these clinical care standards is not within the powers of HSENI to direct. He stated that review of the Infection, Prevention and Control (IPC) guidance has now been published and that the revised guidance has considered the UK VOC 202012/01, lineage B1.1.7, first identified in Kent on 20/09/2020 and lineage B1.351 or 501Y.V2 first identified in South Africa in October 2020. The guidance on page 2 confirms that, "following a clinical and scientific review, no changes to the recommendations, including PPE, have been made in response to the new variant strains at this stage, however this position will remain under constant review. He stated that HSENI would ask for assurance from the Trusts in Northern Ireland that they are fulfilling their "Governance and responsibilities" roles as detailed in Section 3 of the IPC Guidance. HSENI would also seek reassurance of compliance with the standards for PPE detailed within the reviewed IPC Guidance, including information being appropriately communicated to staff. The standards also require the implementation of adequate ventilation as a risk control.

70. HSENI had contact with the Trusts about the supply of PPE at the start of the pandemic on foot of the complaint was raised by the RCN. Following this contact was made with the Trusts. These included:

    a. Summary of Evaluating the protection afforded by surgical masks against influenza bioaerosols by HSL (exhibited as LB/8 **INQ000400959**
    b. SHSCT – Complaint from doctor about mask wearing (exhibited as LB/28 **INQ000400939**

c. SHSCT – Correspondence about Tiger Brand Surgical Masks (exhibited as LB/29 INQ000400940
d. BHSCT – correspondence about safety of masks – (exhibited as LB/26 INQ000400935
e. NIAS – correspondence about Ear Looped Type II R Fluid Shield Mask (exhibited as LB/31 INQ000400937
f. WHSCT – correspondence about Tiger Brand Surgical Masks (exhibited as LB/32 INQ000400941 and
g. SEHSCT - correspondence about Tiger Brand Surgical Masks (exhibited as LB/33 INQ000400938

71. HSENI did not have direct contact with the CMO and did not seek to engage with the CMO about IPC in healthcare settings. As set out above in HSENI's chief executive's response of 9 February 2021to Kinnair and Black - Prevention and Control (IPC) Guidance, the content of these clinical care standards is not within the powers of HSENI to direct.

72. HSENI provided advice and guidance to the Trusts in relation to the reporting of cases of Covid-19. Guidance was placed on HSENI's website and was in line with the guidance provided by HSEGB. Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) (exhibited as LB/34 INQ000422811

80. RIDDOR reports do not raise concerns but HSENI received some 5,487 NI2508 reports categorized as "Disease" received during reference period from the Health and Social Care Trusts (Belfast 618 / S Eastern 865 / Southern 2,306 / Western 812). It is HSENI's understanding that the Trusts are still in the process of reviewing cases.

81. RIDDOR is the law that requires employers, and other people in charge of work premises, to report and keep records of:
    a. work-related accidents which cause deaths

b. work-related accidents which cause certain serious injuries (reportable injuries)
c. diagnosed cases of certain industrial diseases; and
d. certain 'dangerous occurrences' (incidents with the potential to cause harm).

82. HSENI reviewed the circumstances surrounding the deaths, as a result of Covid-19, of four Health and Social Care Trust employees:
    a. DS202012-0562 Shirley Lucey BHSCT;
    b. DS202012-0513 Tony Doherty BHSCT;
    c. DS202011-0162 Peter Henry Vayro SEHSCT; and
    d. DS202011-0149 Glenda Scott SEHSCT.

83. Each case was reviewed in line with HSENI's "formal investigation policy in relation to Covid" and it was determined that HSENI were "unable to establish a clear workplace link."

84. No RIDDOR reports were received in respect of members of the public.

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.

Signed: Personal Data

Dated: 12 January 2024