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UK COVID-19 INQUIRY

WITNESS STATEMENT OF ALAN MURRAY ON BEHALF OF THE BRITISH SAFETY INDUSTRY FEDERATION

I, Alan Murray, will say as follows: -

Introductory

1. The British Safety Industry Federation (BSIF) is the UK Trade Association for the Safety Industry. The BSIF membership includes manufacturers, importers, distributors and specialist service providers in personal protective equipment (PPE) and associated safety apparatus. Our membership also includes all of the official Approval Bodies, scoped for PPE product approval decisions and appointed by The Department for Business and Trade (DB&T). BSIF brings together the expertise of the supply chain and the approval bodies in order that PPE regulations are applied and adhered to effectively in the UK.

2. BSIF was established in 1994 and since that time has been providing leadership and authoritative information on PPE and on a wide range of workplace safety issues. In the UK there are a number of bodies involved in health and safety, but BSIF of all the stakeholders in the UK safety and health environment, is the body focused on safety and personal protective equipment. We work closely with the Health and Safety Executive (HSE) and Trading Standards (TS) with whom we have a Primary Authority agreement, (Hertfordshire Trading Standards). BSIF are the UK's leading association for the Personal Protective Equipment Regulation (EU) 2016/425 and it's subsequent UK assimilated version. All PPE placed on the UK market must comply with this regulation.

3. BSIF administer (supported by HSE) the Fit2Fit face fitting competency scheme for individuals providing face fitting services to wearers of tight fitting respiratory protective equipment (RPE) which are often referred to as masks or respirators. BSIF also manage the Registered Safety Supplier Scheme which seeks to verify the competence of PPE suppliers and the compliance of the PPE they market. BSIF provide independent information and guidance for employers and duty holders on a wide range of issues relating to PPE.

In addition to working with HSE and TS, BSIF also work closely with Regulators such as the DB&T and the Office for Product Safety and Standards (OPSS).

4. BSIF engages with our membership through a series of Special Interest Groups (SIGs) who debate PPE issues as they relate to their area of interest in PPE, from head to toe, safety headwear to safety footwear and all points between. One of the SIGs is the Test and Certification Association, whose membership includes all of the Approved Bodies appointed by DB&T to provide approval decisions for PPE within the scope of Regulation 2016/425. This forum is also attended by the Regulators, HSE, TS and OPSS. This in normal times this facilitates the consistent application of regulation and product standards as they apply to PPE. During the pandemic this forum proved invaluable in working through the easement to PPE regulation and applying them in a uniform manner.

5. Organisationally, BSIF is led by its' CEO supported by functions managing membership services, marketing, membership and product auditing, finance and administration of the federation and the Fit2Fit Respiratory face fitting competency scheme. The board of BSIF is made up of 2 executive and up to 18 non-executive directors, drawn from member companies.

6. BSIF members may specialise in certain types of PPE, and some may not have any direct involvement in the sort of PPE that was required to protect healthcare workers during the pandemic. However, a significant portion of the BSIF membership were, to a greater or lesser extent, involved in supplying PPE to the health and care sector during the pandemic, where they were able to, given the disruption in supply.

7. BSIF's central competence relates to PPE that is regulated and defined under PPE Regulation (EU) 2016/425 and subsequent UK assimilated versions, as equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety. In the context of the pandemic these products would include respiratory protective masks, (FFP and repeat use masks) designed to protect the wearer, hand protection (gloves) eye and face protection and personal protective clothing, typically limited life chemically resistant coveralls. We would be considered as an authority on face- fitting and I will comment accordingly.
Other items referred to in the request for evidence may sit outside of the main expertise of BSIF and are not, in regulatory terms PPE, these include Type II masks (medical devices designed to protect other than the wearer) aprons, gowns, scrubs and shoe protectors. These items which were included generically as PPE in the pandemic conversation, and indeed also included within the scope of this request for evidence, are not PPE. They are items outside of the expertise of BSIF and my response relates only to PPE as defined and controlled under the PPE Regulation.

8. BSIF members involved in PPE supply will have different business models some manufacture PPE, some import 3rd party manufactured items and many distribute varied ranges to end users. We have manufacturers, many of whom are multi-national, with multiple manufacturing sites, and while some manufacturing may take place in the UK, they will be subject to/dependent upon an international or global supply chain for components and materials. Many will also be dependent

upon international logistics and warehousing, meaning that product which may be sold in the UK can be stored outside of the country. We also have many members who import PPE either as proprietary brands or brands in their own name, and again they would be subject to impacts and interruptions on the international market.

9. It is important that the Inquiry has a view into the PPE supply chain and the effect that the outbreak of the pandemic had upon it. It is believed that the Covid-19 pandemic began around December 2019 in Wuhan, China and had reached Europe by early 2020. Wuhan, as it happens, has historically been a manufacturing centre for limited life PPE including respiratory protective equipment, protective suits, and other relevant items such as medical masks. Wuhan was not just an important centre for finished goods it was a significant area for componentry for these products. Many PPE items, while absolutely safety critical, can be high volume but sometimes relatively low unit value, (e.g. FFP masks) and much of their manufacturing has long been off-shored to China. Single use gloves (whether approved as medical devices or PPE) are not manufactured in the UK but are produced on a mass scale in eastern Asia from China to Malaysia.

10. By late February of 2020 BSIF began hearing of interruptions in PPE supply chains and reports of the Chinese Government taking control of (joint venture) PPE manufacturing and directing product exclusively for domestic use. At that time BSIF, concerned about supply to "industry" where the majority of PPE was used, advised the Health and Safety Executive (HSE) in the normal course of our communications of concerns. Our alert to the HSE was driven by fears that PPE stocks for the industrial safety and health market would be significantly affected. However, given the incredible scale of what very quickly unfolded, this concern for the industrial market, was misplaced. From March 2020 industrial consumption was vastly reduced due to lockdowns and the demand, on an unprecedented scale, came from the healthcare sector. Historically, infection control apparel and Type II medical masks, as opposed to PPE (such as FFP masks) would have been more commonplace and familiar to the healthcare sector. Perhaps it does not need to be said but, it is important in the context of PPE (with a global supply chain), that it is appreciated that the incredible levels of demand created by the pandemic, were on a global scale.

11. By March 2020 with Italy in lockdown and their health service overwhelmed, the demand for Covid-19 related PPE in healthcare increased dramatically, first across Europe and then globally. This we must remember was at the same point that the supply chain was collapsing. At that point BSIF was attempting to support the UK authorities who were scouring for immediate supplies of PPE, primarily FFP masks, for front-line healthcare staff. We were able to connect an international BSIF member with NHS sourcing and their UK production was then entirely dedicated to NHS requirements.

12. BSIF are members of the European Safety Federation (ESF) the European umbrella organisation for national bodies (such as BSIF) operating in the PPE market. At that time, I was the President of ESF and while BSIF were supporting the UK, ESF was engaging with the EU to assist PPE supply efforts through the EU Commission and the member states. ESF's efforts with the Commission

reflected what BSIF were doing in the UK, but at the European level. The engagement was often around challenging Recommendation 2020/402 and interpreting Recommendation 2020/403. The challenges the UK faced were mirrored across the EU.

13. During this time BSIF were providing constant support and information on PPE sources to the Cabinet Office, the Crown Commercial Agencies and the various structures supporting the NHS and the public health agencies across the devolved nations. We supplied all the senior contact information for legitimate PPE manufacturers and suppliers in the UK and across Europe, in order that the authorities could communicate directly with the right people. In addition, along with the European Safety Federation (ESF) we did the same for the EU Commission, who were seeking to source communally on behalf of member states. While this was happening the UK's strategic pandemic PPE stocks were being audited and very often found to be beyond their useful life.

14. In response to the shortages certain EU states unilaterally prohibited the export and free movement of PPE with ranges of conditions applied by the various member states. The ensuing confusion of this action led to the EU publishing "Recommendation 2020/402" which required any exporting of PPE to undergo an "authorisation" process. BSIF and ESF were very active in engaging with the Commission and other authorities on the damage that such a poorly designed protectionist process could do. In the first place PPE and Covid related PPE do not have identifiable tariff codes and furthermore many international PPE manufacturers who warehoused centrally in EU states, including the UK, could have difficulties moving product to legitimate priority markets. The pandemic and this recommendation was creating unhelpful reactive protectionism which was not helping supply. In the UK, Her Majesty's Revenue and Customs (HMRC) took the lead in providing authorisation for the movement of relevant products.

15. There was a growing media outcry as the essential services clearly did not have sufficient PPE and often what PPE they had was not of the appropriate quality or suitability.

16. Subsequently the EU Commission produced their "Recommendation" (2020/403) on allowing PPE for covid facing healthcare workers, to be placed on the market without it having to go through the full product approval process. BSIF began to work closely with the Department of Business Energy and Industrial Strategy (BEIS) and the Office for Product Safety and Standards (OPSS) on supporting how the EU Recommendation 2020/403 could be employed in the UK. For direct government purchases on behalf of healthcare workers we suggested a triage system of receipt and testing of PPE, recommending appropriate laboratories with easy access to and from Heathrow (the original planned port of arrival for emergency PPE supplies for healthcare). In the end a different system was set up, led by a dedicated OPSS/HSE technical team. This team were charged with "accepting and releasing, fit for purpose PPE" sourced directly by the Government on behalf of healthcare workers.

17. By April 2020, and with the active participation of BSIF, BEIS/OPSS produced the first Guidance on how Recommendation 2020/403 could be applied in the UK. This recommendation was often referred to as "easement" against the

established conformity assessment process for placing safe and compliant PPE on the market. The "Recommendation" changed the process by which PPE would be allowed to be placed on the UK market and along with the consultations we provided to BEIS/OPSS on creating the Recommendation Guidance, once published, the guidance required to be interpreted and communicated to the BSIF membership and the wider market including end users.

18. The first "Guidance" produced in April 2020 was followed by many subsequent revisions as the circumstances developed. By September 2020 multiple versions of the Recommendation Guidance had been published and as each update was produced BSIF reviewed and cascaded the information to the stakeholders and the market. Recommendation 2020/403 was to be applied by member states (including the UK) as they each saw appropriate for their own specific needs. Confusion, over what the "Recommendation" actually allowed and how it should be applied, as well as who could receive the PPE under "easement" (initially healthcare only) was significant. Part of the confusion or difficulty in comprehending and conveying onward Guidance stemmed from frequency of new guidance documents coming out and also that some were aimed at supporting businesses and users and some were supporting manufacturers who had the potential to make PPE. There was then some separate guidance for "high volume manufacturers". The guidance was intended to describe how it would be acceptable to place PPE on the market without going through the complete regulatory process. The impact was that it was often difficult to know what compliance now looked like and that applied to producers, consumers and market surveillance authorities.

19. The UK government, around this time, had put out the "call" for UK based manufacturers to convert production to Covid appropriate PPE. In my experience, we had many businesses, well-intentioned, but lacking in the appropriate knowledge, or regulatory requirements making PPE and attempting to have it certified under the temporary easement (Recommendation 2020/403). The results were very mixed. At this time the BSIF Test and Certification Association, the group of UK Notified Bodies (after EU exit termed as Approved Bodies), were constantly meeting (remotely) and debating the actions necessary to apply the Recommendation consistently in the UK. This unique collaboration through the BSIF Test and Certification group, was extremely valuable to BEIS/OPSS, even if ultimately the process was imperfect.

20. Coinciding with the soaring demand and fracturing of traditional supply chains came an eruption of other opportunist businesses attempting to supply PPE into the UK. It appeared that anyone with international trade connections, in any product category most often unrelated to PPE, was now supplying or attempting to supply PPE. They were doing this without understanding the critical nature of the products and with little attention paid to compliance or product provenance. Internet portals and online marketplaces were promoting significant quantities of non-conforming and potentially unsafe PPE. It was not just the traditional online platforms selling these products, they were also being sold in increasing numbers by individuals on their personal social media accounts, and at hugely inflated prices. Once again, when alerted, BSIF staff would engage and encourage these (non- BSIF members) sellers to desist. This engagement with these sellers was often a fraught and unpleasant experience. The market surveillance authorities

appeared unable to stem this tide, as evidenced by the continuing availability of non-compliant potentially unsafe PPE being offered for sale.
Note, that while we use the term "PPE" within this text, the priority focus at this point, was around the supply of filtering facepieces FFPs (disposable masks) and to a lesser extent face shields. However, as the months of the crisis wore on, the supply of other PPE items such as face shields, limited life garments and gloves were also added to the list of products in desperately short supply and subject to the same abuses as were experienced with respiratory protective equipment.
End users, the vast majority in healthcare and essential services, were absolutely desperate to find supply, but very often did not know how to recognise legitimate product.

21. The BSIF staff, mostly working remotely since the end of March, were completely occupied and utterly absorbed in supporting members, non-members, end users and the authorities, constantly reacting to their PPE questions and concerns. At this time, we began to see the arrival of FFP masks constructed with "ear loops" instead of the "adjustable head harnesses" to secure to the wearer's face. In most cases the FFPs being supplied were "KN95", a classification of respirator defined under the Chinese domestic standard GB2626. The KN95 is not compliant with the UK or European PPE standards. Many of the products were not even legitimate KN95 certified respirators. Yet despite it clearly being outside of the Regulation the products were flooding the market. In April 2020 a UK Google search for KN95 resulted in some 16 million hits. The ubiquitous KN95 was being commonly marketed as KN95/FFP2, but they are not the same thing, they perform differently with testing and quality assurance requirements less stringent than an FFP2 under PPE Regulation 2016/425. In addition masks secured to the wearers face with ear loops will struggle to "face fit" properly, failing to provide a seal with the face leaving the wearer unprotected. When tight fitting masks are deployed, they must be face fitted to the wearer to provide protection. The HSE and the NHS refused to allow the wearing of FFPs which had ear loops for just this reason. At this juncture it is important to appreciate that HSE maintained their insistence on the need for face fitting when any tight-fitting respirator such as an FFP was to be worn. HSE are to be commended for maintaining this stance. However, the supply of the same make, model and size of the masks to the healthcare sector was not reliable, therefore wearers were required to have multiple face fit tests across a range of masks.

22. BSIF administer the Fit2Fit face fitter competency assessment scheme and as such have a database of qualified individuals who could provide face fitting services to the frontline workers in healthcare. It should be recognised that prior to the pandemic the requirement in healthcare and the NHS for respiratory protective masks to be worn was relatively low. The pandemic saw the need for masks and face fitting of those masks increase dramatically. However, there were insufficient competent face fitters available to immediately cover the requirement across healthcare and further the equipment necessary for carrying out face fits was also in desperately short supply. At one point, BSIF were actively supplying the recipe for the manufacture of the test agent used in the "Qualitative" method to potential manufacturers.

23. It should be recognised that Fit2Fit Accredited face fitters performed admirably, carrying out an estimated one million face fits over the period in the NHS Trusts

and in the new Nightingale facilities, under very difficult circumstances. At one point, we were advised that members of the army had been brought in to assist in the coordination of face fitting, but that initiative appeared to peter out as quickly as it began. BSIF and the Fit2Fit community attempted to organise, coordinate and prioritise face fitting through the Cabinet Office, which though well intentioned was ultimately not the best way forward. A confused time was certainly not helped by the fact that contacts within the Cabinet Office with whom we had been in communication were often, not as it turned out Cabinet Office staff, but one of the many consultants working for the Government and subject to very quickly moving on to different pandemic response teams.

24. Many areas of our society were now for the first time confronting the need to wear PPE to mitigate against the risk of Covid-19 including GP and Dental Surgeries. Dentists, closed since late March were by June attempting to re-open but needed the appropriate PPE and face fitting for respirator wearers. Dental practices were regarded as a significant risk due to the treatment often involving aerosol generating procedures and the associated risk of cross infection. Once again with little background in PPE, or respiratory protective equipment or the need for face fitting, the situation in the dental sector was very challenging. During 2020 the BSIF office remained manned at all times, and I can report that, for a 3 month period we answered a phone call from dental practices (it seemed) once every 5 minutes! Dental practices were unfamiliar with PPE of the sort required to protect against covid 19 and they had little understanding of the face fitting processes. Their enquiries and our support and responses was based around this type of PPE and PPE services.

25. Obviously desperate and difficult times with legitimate products (especially respiratory protective equipment) in short supply and unproven potentially unsafe PPE being sold widely by opportunists through any, and all channels that were able to source product. In November 2020 and in support of the market BSIF created a webinar to assist users in identifying safe and compliant PPE. With over 1,200 registrants, the webinar reached and provided advice to end users, market surveillance authorities and other potential PPE suppliers. From the webinar, 200 questions were submitted, and all were answered by BSIF and posted on the website within 5 days. To coincide with the webinar, we produced and published a series of documents to help users and potential suppliers identify genuine PPE amongst all of the non-compliant and illegal product being offered in the market. We also produced a video guide to navigating the EU NANDO (Notified Bodies) database in order to help individuals authenticate products and genuine documentation. (See Annex I) We also created and publicised a series of guidance documents including to illustrate what users and inexperienced suppliers should be looking for when checking PPE documentation. At this time BSIF staff were also responding to queries and concerns around medical masks (Type II) which required BSIF staff to develop at least some working knowledge of Medical Device Regulations, as well as reaching out and creating relationships at the Medicines and Healthcare products Regulatory Agency (MHRA).

26. At every turn, non-compliant PPE was being placed on the market and central to the problem was a huge number of bogus, fraudulent, dishonest and misleading documents offered in support of the product by bad actors, internationally. BSIF

staff were called upon to verify document after document and certificate after certificate. Some of the paperwork was clearly fictional, some wrong, not what was required by legislation, others misleading, and some copies of legitimate paperwork applied to different products. (See Annex II)

27. There was also something of a growing phenomenon whereby several Notified Bodies (not scoped for PPE approvals) were providing certificates purporting to be CE certificates for PPE but which were nothing of the sort. (See Annex III)

28. Along with fake certificates we also saw the emergence of bogus certification bodies offering CE PPE approval decisions. These supposed "certification bodies" were fictional "offering" illegitimate services to the unsuspecting. (See Annex IV)

29. BSIF were at all times, front and centre in the efforts to keep bad PPE from the market and after following up on market intelligence and feedback, we would investigate and establish validity or otherwise, engaging with those involved and ultimately ending up reporting hundreds of examples (we believe that over the period we reported more than 300 examples of either products or traders) of wrong doing to the authorities. We reported to either HSE or Trading Standards authorities, sometimes to both. We did not make reports to the police. I would summarise this descriptive introduction by stating (perhaps the obvious), that the country was ill-prepared to provide the necessary PPE, and the training required to utilise PPE effectively (this was obvious from the many pictures in the media of medical professionals wearing FFPs incorrectly). We as a country were also ill-prepared to provide associated services, such as the face fitting of respiratory protection, at the onset and during the height of the pandemic.

30. The UK however, was not alone the majority of countries had failed to create or manage PPE stocks strategically for when, where and at the volume, the products, services and training would be required. The international PPE market, significantly the supply chain for respiratory protective equipment, gloves and limited life protective clothing was dependent on the efficient working of a long global supply chain which ruptured during the early months of 2020. The reliance on an international supply chain for critical products raises obvious questions around the lack of resilience which needs to be accommodated in future preparations.

During the pandemic

31. The issues, as have been explained in my introduction, were primarily lack of legitimate products and the influx of non-compliant potentially unsafe PPE. We were assisting the market in recognising acceptable PPE. The challenges in supplying healthcare would vary, and apart from scarcity of supply would be different should suppliers have had pre-existing agreements or framework agreements with the healthcare institutions. As became clear healthcare needed to find alternative suppliers often without pre-existing arrangements or experience in PPE. Healthcare authorities themselves did not appear to have adequate knowledge of regulated PPE or the supply chain.

32. Because of our experience and expertise in regulated PPE items required by healthcare, we were in constant communication with the authorities primarily to aid supply and signpost to legitimate, experienced PPE suppliers. Our dealings have already been described in the previous paragraphs. BSIF supported the legitimate supply of PPE and provided contacts to the authorities. The overriding issue was scarcity of supply versus massive and sudden demand!

33. Export bans whether brought in unilaterally or under the EU Recommendation 2020/402, which was also applied in the UK, had a negative impact, it was a blunt instrument with unforeseen consequences as…
i) PPE does not have its own international tariff codes therefore effective restrictions on specific product was not practical.
ii) PPE is subject to an international supply chain and warehousing. For example the commercial supply to the UK could be warehoused in a 3rd country, but due to that country having an export restriction in place PPE could arguably not be sent to a rightful and priority market. There are certainly (anecdotally) examples of multinational PPE manufacturers who warehoused in Belgium and Germany to serve their normal European markets, who when export restrictions came into play found moving product unnecessarily difficult. However, the situation did indeed improve over time and I believe that the EU recommendations (the restrictions) were only in place from March until May of 2020.

34. BSIF had not received formal feedback on the effectiveness of procurement schemes run by the UK Government or the Devolved Administrations. General feedback in this area was most often centered on complaints that the government and other authorities appeared to be sourcing product from irregular suppliers who had little or no experience, expertise or legitimacy in the sector.

Changes to the industry

35. The calls for switching production to PPE was not entirely relevant in that BSIF members were already supplying (whether manufacturing/importing or distributing) PPE, it was, and remains their core business. However, as one would expect where there were opportunities to maximise production for key products in support of healthcare users these taken. Some BSIF members invested (and were encouraged to invest) in extra capacity for key products for healthcare users. BSIF did not play a coordinating role in any of the UK Government or Devolved Administrations initiatives for increasing supply of key production. It was entirely appropriate that these arrangements were responded to directly between the authorities and the potential suppliers. However, BSIF members with resources in Scotland did invest in extra capacity for the production of critical PPE, with encouragement from the Scottish administration. One BSIF member company created new capacity to support HSC in Northern Ireland. One former BSIF member with support from the authorities set up new production of Medical and FFP masks in England. The FFP mask production ceased some time ago.

36. BSIF were not directly involved in the communication or coordination of the UK Government or Devolved Administration initiatives for extra production and supply. Naturally these initiatives, were, in the main, aimed at businesses, not in the PPE sector who could feasibly transfer production or assembly to making

PPE items, as opposed to their normal product ranges where demand due to other factors, including lockdown, meant they had spare capacity and transferable technology. Many of these companies were businesses of scale but with no experience of PPE or applicable regulations. In addition to such companies others potential suppliers were often artisanal or research-based groups. Products such as masks and face shields were produced and all too often, with little or no idea of the regulatory framework supporting these life-preserving products. BSIF's area of competence is in PPE as recognised by the Regulation 2016/425 which is well established and understood by those companies already in the PPE field. However, for a business switching from non-regulated products to regulated products can be a difficult and time-consuming endeavor, even for established manufacturers and even in normal times, regardless of easements in place. BSIF advised these individuals and companies as and when they approached us, which they did frequently. However, in the main It felt like this was a cottage industry response/solution where the volume of product required needed mass production. These comments do not necessarily apply to the manufacture of items such as aprons, but they do apply to PPE products such as respiratory masks and eye and face protection products (Regulated PPE).

37. During the pandemic companies and individuals sought to support the provision of PPE either by expanding or moving into "PPE" but as we came out of the pandemic and the requirement for PPE normalised the "new" manufacturing was no longer needed and that extra capacity has in the main, but not entirely, become redundant. BSIF was not privy to the financial arrangements provided by public authorities to PPE producers or potential PPE producers. However, continued production or otherwise has, following the end of the pandemic supply crisis, been determined by the vastly reduced consumption and the amount of product still available in the market.

Regulation

38. Due to working closely with OPSS, BSIF members were informed at all times of the changes in regulatory requirements and as we were often consulted in the proposed or potential changes and easements to the regulations, we were able to communicate with both members and non-members as soon as changes were published. It was not only regulatory changes that we communicated, we also took the opportunity to share guidance from other authorities such as WHO and PHE. Within our structures we relate with respiratory face fit providers and were able to share changes originating from the HSE in "hygiene" guidance, vital in the close- proximity working of face fitting respirator masks. .

39. With regards to gaining and checking/authenticating product certifications this can be viewed in 2 parts and there were indeed some challenges. Assuming an applicant company (for product approval certification) understood the requirement for certification and the approval body also understood the latest interpretation of easement guidance, the main difficulty was lead time for testing and certification at the Approved Body. Despite best efforts and the fact that there was a lockdown in place lead times and processing times had an impact on capacity and availability. The Approved Bodies did a commendable job in reacting in the circumstances. The cost involved in the approval process was

also a barrier to some who had little experience of the PPE market (note: to new entrants, not BSIF members)
On the other hand the checking of certification of product flooding the market was a monumental, but vital task. Without the correct certification the PPE cannot be assumed to be safe to use against the risk of Covid 19. As previously explained BSIF did a great deal of examining of certification on behalf of the market and at no cost, duly informed the authorities where we saw risk.

40. Other information such as HSE communications, were cascaded by BSIF as well as being available on HSE channels. In addition to BSIF members we also cascaded HSE information to those on our face fitting database as appropriate. HSE are a regulator with whom BSIF works closely in normal times, and during the pandemic this was no different. We had regular and frequent communication with HSE. On the other hand, the MHRA is a regulator with whom, historically, we did not have an everyday relationship, they being the regulator for medical devices and our area of competence being PPE (regulated by HSE and Trading Standards). However, we did find ourselves having to give advice and opinion to the market on product regulated by MHRA, and at our instigation developed contact with MHRA compliance, in order to seek opinion and provide answers to enquirers. BSIF provided the link to the regulators and while our membership understood the difference between PPE and medical devices others did not. The most frequent area of confusion in the wider market were the different product regulations, standards and performance requirements of FFP (PPER – Standards EN149) and Medical Masks (MD – Standard EN14683). BSIF would be the point if interaction as required by our membership, users and often NHS and Healthcare enquirers.

41. The changes in Infection Prevention and Control guidance had a limited direct effect on the BSIF membership. Often the issues surrounded the acceptability and use of different grades of masks FFP2 or FFP3 and in what specific application, for example in procedures where aerosol would be generated. BSIF members would supply what they could against what was required for risk mitigation as understood by the healthcare specifiers, the duty holders. It is my belief that changes were made to guidance in reaction to best available information at any point in time.

Liaison with health and care sector

42. Other than in some specific areas, BSIF did not have a great deal of direct communication or liaison with the sector as a whole. The HSE is the regulator for workers in that sector and our communication on relevant topics would go through or be with HSE.
BSIF and the Fit2Fit structure did attempt to support the NHS on face fitting and face fit training but that did not mature due, in my opinion, to the autonomous nature of NHS Trusts. However, some BSIF members were able to establish bespoke face fit training schemes for PHE/NHS England. Further, we did engage and respond to requests for help and support from trusts and individual units on face fitting and the availability of products and services as well as advising on the legitimacy of PPE that they were being offered. This was reactive and not a coordinated or centralised process.

43. As previously explained, we helped and advised, where we were able, on the legitimacy of PPE being offered to the sector. Healthcare units knew that we were ready, able and willing to examine and opine on the authenticity of documents provided with PPE. We were also challenged on PPE quality and in May 2020 I received a joint communication from the RCN and the BMA on the lack of choice in sizing and fit of FFP masks being made available to the workforce in healthcare. I of course acknowledged the situation and accepted that historically the design and size mix had been based on the industrial worker, which was not representative of the diverse needs of workers in the modern healthcare setting. I did however, point out that BSIF manufacturers (of RPE) believe that for a considerable time they have had sizes and styles available to accommodate a wide range of needs, but had struggled to get these established as mainstream products within the NHS supply chain. BSIF is fully appreciative of the need for PPE to be adequate for the hazard and suitable for the wearer. Unfortunately, at the time of a severe shortage of product, the opportunity to be selective and have supplied the most appropriate product was very significantly restricted. However, the responsibility to provide the right PPE and indeed involve workers in its selection, sits with the employer, the duty holder. The circumstances of the pandemic and the supply crisis clearly did not allow the PPE selection process to run as it should have. Workforce engagement and involvement leading to proper selection and specification should have happened as part of the planning process – it did not.

44. We are currently involved in the creation of a British Standard on the Procurement and Provision PPE which is inclusive and which seeks to provide a good practice guide for employers and duty holders specifying PPE which accommodates all wearers recognising needs in ethnicity, gender and religious beliefs.

45. BSIF members have also participated with standards bodies on the development of a potential new product standard for an Infection Prevention Mask, which seeks to combine the properties of both the PPE mask (EN 149) and the Medical mask (EN 14683). Developments continue. This item could if eventually placed on the market be a "dual use" item and be regulated accordingly.

46. As a consequence of the shortages it was often reported, especially early in the pandemic, that healthcare workers would be supplied with different makes and models of FFPs depending on what was available. The changes in products being supplied to frontline workers necessitated more face fitting as the face fit test matches a make, model and size of a mask to the wearer. Face fitting for FFP masks was a challenge across the healthcare sector and at one point I was asked to be involved in a review of the provision of face fitting in Northern Ireland in reaction to the report of face fitting having been carried out in HSC Trusts, using an inappropriate protocol.

Liaison with government bodies

47. BSIF's liaison with Government bodies was not directly on behalf of the membership. Any specific initiatives or support programmes entered into for PPE supply were between the authorities and the member directly.

Liaison with the health and care sector

48. BSIF as a body did not liaise on behalf of our members with the NHS trusts in relation to PPE supply. The members of BSIF may have had direct relationships with the trusts and attempt to provide them with the PPE they needed at that difficult time. Some BSIF members were already part of the healthcare and NHS supply frameworks while others were not, their experiences vary. The NHS was clearly forced to vary normal purchasing procedures in an effort to acquire PPE, employing emergency non-tendered sourcing which could involve new suppliers.

Lessons learned

49. BSIF, as a trade body, represents the PPE supply chain and has a greater purpose in attempting to ensure that the occupational health of our country is protected, believing that nobody should be unsafe or have their health compromised while they are at work. Our specialist area is Personal Protective Equipment, as defined by the Regulation (EU) 2016/425 and its UK assimilated versions. The pandemic showed this country, and many others, that it is over-reliant on a long supply chain often out of its' own control. PPE will rarely be manufactured commercially for consumption in the UK alone. The lessons learned from the pandemic will surely come from the Covid Inquiry, but clearly the country was not well enough prepared for the volume of, or styles including variants of PPE needed to protect key workers. Nor were we prepared for the training of wearers necessary for effective use of PPE. The scale of specialist services such as face fitting of masks in the NHS was not anticipated in any planning, but I believe this has improved with more NHS staff now engaged in face fit provision.

50. This country was similarly unprepared for the volume of non-compliant, potentially unsafe PPE which came into the country often being offered for sale through digital channels. We at BSIF did not need the experience of the pandemic to show that market surveillance of PPE is wanting and non-compliant PPE in the market remains a problem. The current Product Regulation and Metrology Bill is seeking to address some of the issues, but enforcement will remain a challenge into the future, regardless of having legislation in place. Clearly any future strategy and its' implementation needs to come from the government and BSIF and the PPE manufacturers and suppliers stand ready to support and contribute to the creation of any future plans.

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: PD

Dated: 24/01/2025