

Considerations for PPE reprocessing based on international practices

A commentary from the National Engineering Policy Centre

Executive summary

This paper sets out some of the considerations for personal protective equipment (PPE) reprocessing. It draws on international examples received through our network of national engineering academies and expertise across the UK as part of the National Engineering Policy Centre (NEPC). These considerations have been outlined in consultation with Fellows of the Royal Academy of Engineering, experts from the Institution of Chemical Engineers, the Institute of Healthcare Engineering and Estate Management, the Institution of Engineering Designers, the Institute of Physics and Engineering in Medicine, and the International Society for Pharmaceutical Engineering UK Affiliate, and through our networks of national engineering academies across the globe. Reaching across this diversity of engineering expertise has allowed us to understand the complex considerations of the process. This paper has informed a knowledge summary undertaken by the SAGE Environmental and Modelling sub-group.

Context

The demand for PPE is anticipated to continue: the Academy of Medical Sciences has presented a reasonable worst-case scenario that shows a sustained period of high numbers of daily infections and highlights the need to ensure an adequate and appropriate supply of PPE is provided in advance of any future surge of COVID-19.¹ The UK should now be better equipped, with PPE national manufacturing facilities that account for 70% of anticipated demand (excluding gloves)², stockpiles, distribution capability and robust procurement strategies. However, this may be tested with the strains of winter including sustained periods of high transmission rates and increased hospital admissions or supply disruptions due to adverse weather events and the end of the EU transition period.

Internationally, multiple countries have pursued a dual strategy that creates the opportunity to reprocess single-use PPE. This has relied heavily on the skills of engineers to scale up scientific processes and ensure the material integrity is maintained. This paper presents several different approaches taken to reprocess

¹ Academy of Medical Sciences (2020) '[Preparing for a challenging winter 2020/21](#)'

² Department of Health and Social Care (2020) '[Personal protective equipment \(PPE\) strategy: stabilise and build resilience](#)'

single-use respirator masks to respond to anticipated shortages. This is not an endorsement of these methods.

To reprocess PPE at scale to meet the needs of health and care workers is a complex undertaking with decisions that have implications for the PPE users and those carrying out the reprocessing procedure. This paper approaches this by considering three factors and some of the trade-offs between them:

- A. Risks introduced by PPE reprocessing – implications for material, fit, filtration effectiveness, biocontamination, and viral inactivation.
- B. Selecting an appropriate decontamination approach – a range of decontamination approaches have been assessed against the risks they carry, and some techniques, including hydrogen peroxide vapour, ultraviolet light, moist heat, dry heat, and radiation, have been deployed at scale.
- C. Operational challenges – deploying any of the approaches to decontamination requires consideration of how the wider process can be carried out safely and effectively at scale, including transportation, preparation, facility, quality assurance, and support from health or care workers.

Conclusions and recommendations

The considerations for reprocessing are complex, but have been successfully tackled for respirator masks in certain international contexts, although without full support from health and care professionals.³ Should the NHS, Health and Safety Executive (HSE), and Medicines and Healthcare products Regulatory Agency (MHRA) adjust regulations and guidance to advise on reprocessing of single-use PPE for emergency shortages – or in the longer term, manufacturers produce PPE that is designed for multi-use and reprocessing – these recommendations should inform the approach:

1. International examples have illustrated popular techniques delivered through different mechanisms. These should be drawn on to ensure the learning is transferred. However, any reprocessing solution should be cost-effective and bespoke to the specific requirement of the UK's NHS and wider healthcare sector and regulatory system.
2. NHS England/Improvement should lead the development of appropriate reprocessing facilities in consultation with experts across the delivery pipeline. This will ensure all the component parts, including reprocessing equipment, personal containers, and the provision of skilled personnel, can scale simultaneously to meet potential demand.
3. Choice of decontamination method will inform the details of the approach to deployment, the PPE applicable, necessary validations, potential risks, and the limit on the number of times the PPE can be reprocessed. Standardisation of the approach across the UK would be beneficial.
4. Accompanying procedures for operationalising the use of decontaminated PPE should be developed, such as protocols for the safe collection, transfer and

³ National Nurses United (2020) [Warning » Battelle N95 decontamination system is not safe and may not work](#)

transportation of used PPE, and protocols to identify and return decontaminated PPE to its owner.

5. Quality management records will be critical to ensure good practice, traceability, and auditability alongside robust health and safety protocols to assess and manage risk assessments. Health and care professionals should be consulted to ensure any outstanding risks are fully understood.
6. Any process deployed should be validated locally but remain under review as international scientific evidence continues to emerge.
7. Different PPE designs from different manufacturers should be individually assessed to ensure functionality has not been compromised because of reprocessing. The list of products that can be reprocessed should be kept up to date as new suppliers and designs are sourced. Compliance with international standards should be maintained and where possible manufacturers' guidance should be sought and employed.
8. Emergency reprocessing of single-use PPE is not an alternative to increasing the supply. Investing in significant facilities should be done with a view to their longer-term sustainability. Increasing UK capacity to reprocess PPE safely could support the use of reprocessed multi-use PPE, therefore reducing the cost and waste produced across the whole PPE lifecycle.

National Engineering Policy Centre commentary on considerations for PPE reprocessing based on international examples

Context

PPE is a vital component of the COVID-19 response. It protects healthcare workers and care providers while they carry out a critical role, ensures laboratories can process samples in controlled conditions, enables food to be prepared safely and will be required across new sectors of the economy as greater numbers of people return to work. The recommended PPE for these roles varies depending on exposure. Face masks are categorised as respirator masks, surgical face masks and general masks; other PPE includes gowns, gloves, visors, eye shields, safety glasses, and protective suits/coveralls. This categorisation informs the intended users, who they are designed to protect, what they protect against, the applicable regulations, and the enforcement authority.⁴ Face coverings for public use are not categorised as PPE and are not considered in this paper.

Scale of PPE demand

Between March and July 2020, the Department of Health and Social Care has delivered over two billion items of PPE to the health and social care system in England alone, including over 400 million masks, 300 million aprons, 4 million gowns and half a billion pairs of gloves.⁵ In this period, millions of items of PPE have also been delivered to Northern Ireland, Scotland and Wales.⁶ While delivering this demand has been an unprecedented feat, shortages of PPE have been reported throughout this time period, suggesting the demand was even higher. Additionally, these numbers capture PPE dedicated for medical workers and no other essential workforce. As more restrictions are lifted, there are concerns about a second wave and it is vital the PPE demand in this instance can be met.

Meeting that demand

To sustain the PPE needs, the government has published a UK-wide PPE plan under the leadership of the PPE 'tsar', Lord Deighton. The plan details a three-tier approach to increasing PPE provision including:

- expanding supply from overseas
- increasing manufacturing capability
- expanding and improving the logistics network for delivering to the front line.⁷

These will be important components to ensuring supply. However, global demands on materials and equipment and possible disruptions to supply chain logistics resulting from trade restrictions, varying exchange rates or oil prices, may make delivery challenging. The UK government is scaling domestic PPE manufacturing capability to be able to produce 70% of PPE (excluding gloves) in the UK by the end

⁴ BSI (2020) [Guide to masks and face coverings for use in the UK during the COVID-19 pandemic](#)

⁵ Department of Health and Social Care (2020) [Major milestone hit as 2 billion items of PPE delivered](#)

⁶ Our Plan to Rebuild: [The UK Government's COVID-19 recovery strategy \(2020\)](#)

⁷ Department of Health and Social Care (2020) [Coronavirus \(COVID-19\) – Personal Protective Equipment \(PPE\) Plan](#)

of the year.⁸ Orders of 70 million masks are to be made by Honeywell over the next 18 months⁹ and national supply chains for PPE materials have been established with £15 billion allocated to procure PPE for frontline staff in the Chancellor's Summer Statement.¹⁰

Implications for waste

According to the NHS waste-labelling system, used PPE tends to be labelled as 'infectious' (hazardous, contaminated with bodily fluids) or 'offensive' (non-hazardous, contaminated but non-infectious), which mandates that disposal must prevent transmission of any pathogens to the wider population.¹¹ There are systems in place for safe disposal of single-use protective wear used by the NHS, such as segregation and incineration; the scale of these is unknown.

Case study one: decontamination and disposal of PPE waste in Wuhan, China

Regulatory context: the national environmental authority issued guidance for gasification, pyrolysis and incineration of medical waste, and the Ministry of Ecology and Environment worked directly with the Wuhan local government.

Equipment: a new gasification, pyrolysis and incineration technology was used in the treatment of medical waste at the Leishenshan field hospital in Wuhan. PPE was gasified under oxygen-limited and oxygen-deficient conditions. By controlling the oxygen supply in the gasification and pyrolysis processes, dioxin generation was limited.

Scale: the city of Wuhan increased its treatment capacity from 40-60 tons per day to a peak of 247.3 tons per day. A single gasification-pyrolysis incinerator can treat more than 30 tons of medical waste per day.¹²

Benefits: the new gasification, pyrolysis and incineration technology enabled medical PPE waste disposal to be carried out immediately on site, removing the transportation risks. The new treatment process limited the discharge of smoke, odour, sewage, and tar.

Challenges: scaling up the waste decontamination capacity with the necessary degree of automation to ensure the process was as safe and efficient as possible was the biggest challenge.

⁸ Department of Health and Social Care (2020) [Personal protective equipment \(PPE\) strategy: stabilise and build resilience](#)

⁹ BBC News (2020) [North Lanarkshire tech company to make 70 million face masks](#)

¹⁰ HMT (2020) [A Plan for Jobs 2020](#)

¹¹ Royal College of Nursing (2018) [Freedom of Information Follow up Report on Management of Waste in the NHS](#)

¹² International Solid Waste Association (2020) [Medical Waste Management Experience and Lessons in COVID-19 Outbreak in Wuhan](#)

Enabling PPE reuse

In the UK at present, the Department of Health and Social Care, MHRA and HSE guidance does not recognise or recommend the reprocessing of single-use PPE. However, HSE has issued guidance suggesting PPE may be used throughout a shift (sessional use) or reused in times of acute shortages.¹³

For reuse of medical masks, Public Health England guidance highlighted the following important requirements, which have since been withdrawn:

- The mask should be removed and discarded if soiled, damaged, or hard to breathe through.
- Masks with elastic ear hooks should be re-used (tie-on face masks are less suitable because they are more difficult to remove).
- Hand hygiene should be performed before removing the face mask.
- Face masks should be carefully folded so the outer surface is held inward and against itself to reduce likely contact with the outer surface during storage.
- The folded mask should be stored between uses in a clean sealable bag/box, which is marked with the person's name and is then properly stored in a well-defined place.
- Hand hygiene should be performed after removing the face mask.
- Some models of PPE cannot be physically reused as they deform once being donned and do not go back to their original condition (meaning it would be difficult to re-don and achieve a fit check). Fit checks should be performed each time a respirator is donned if it is reused.

Longer term, some of the strain on the demand for PPE could be relieved with an increase in the provision of reusable PPE and by methods of reprocessing and then reusing single use items.

Reprocessing considers the process of receiving, preparing, cleaning, decontaminating, and storage.

Reprocessing requires a significant scale up of decontamination facilities. Depending on the PPE item the reprocessing steps will vary. Reprocessing includes cleaning and disinfecting¹⁴ the different processes include;

¹³ Public Health England (2020) [Considerations for acute personal protective equipment \(PPE\) shortages](#).

¹⁴ Centers for Disease Control and Prevention (2020) [Emergency Considerations for PPE](#).

- **Cleaning** – a process that removes dirt, dust, large numbers of microorganisms, and organic matter using detergent and warm water. Cleaning is a prerequisite to disinfection or sterilisation.
- **Disinfection** – a process of inactivating pathogenic organisms except for bacterial spores.
- **Sterilisation** – a process of removing or killing all viable organisms including spores. Dead microorganisms, toxins and inactive viral/prion residues may remain.
- **Decontamination** – the destruction or removal of contamination to a level that renders an item or the environment safe. The term decontamination includes cleaning, disinfection and sterilisation.¹⁵

International approval

In response to the pandemic-induced demand, countries such as the US have issued Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices to allow the decontamination of single-use PPE. This is primarily focused on respirators (N-95 masks). Battelle, an applied science and technology not-for-profit organisation, has been awarded a contract from the US federal government to provide N-95 mask reprocessing at 60 sites across America.¹⁶ The supporting Centers for Disease Control and Prevention (CDC) evidence¹⁷ has been circulated in Japan and supplemented by exceptional handling guidance for surgical masks, long-sleeved gowns, goggles, and face shields. In Germany, guidance has been issued for dry heat decontamination.

Considerations for the UK

The complexity of providing the capability to decontaminate PPE at scale requires consideration of three factors and the trade-offs between them:

- A. Risks introduced by PPE reprocessing.
- B. Decontamination approaches.
- C. Operational challenges.

These considerations have been outlined in consultation with Fellows of the Royal Academy of Engineering, experts from the Institution of Chemical Engineers, the Institute of Healthcare Engineering and Estate Management, the Institution of Engineering Designers, the Institute of Physics and Engineering in Medicine, and the International Society for Pharmaceutical Engineering UK Affiliate, and through our networks of national engineering academies across the globe.

This paper draws on international examples to extract some of the considerations for deploying a similar system in the UK. As the international examples have largely been deployed for respirator masks shortages, some risks and limits of decontamination effectiveness are specific to respirator masks.

¹⁵ Black Country NHS Foundation Trust (2019) [Infection Prevention and Control Assurance - Standard Operating Procedure 7 for Decontamination \(Cleaning, Disinfection and Sterilisation\)](#)

¹⁶ Battelle (2020) Press Release: [Battelle CCDS Critical Care Decontamination System™ Services Now Available at No Charge](#)

¹⁷ Centers for Disease Control and Prevention (2020) [Decontamination and Reuse](#).

A. Risks introduced by PPE reprocessing

As much of PPE is designed for single use, reprocessing can introduce questions about the quality and effectiveness of the PPE following the decontamination process. The Institute of Healthcare Engineering and Estate Management has highlighted six ways in which PPE function may be compromised by reprocessing.¹⁸ Before deploying a reprocessing method there must be confidence that the risk that the efficacy of the PPE may be compromised in any of these ways is as low as is reasonably practicable. These factors include:

1. **Material compatibility** – the compatibility of the materials exposed to the decontamination method will depend on the approach taken, type of PPE, brand and even the specific design. For more complex items, such as respirator masks, how its constituent parts respond should also be considered.
2. **Physical damage** – removal of PPE may result in physical damage, creating holes in the fabric or damage to the materials employed to ensure a good fit. Careful inspection before reuse would need to be carried out to ensure no such physical damage had occurred.
3. **Residuals** – the consequences of cleaning and sterilant residuals must be considered for the safety of wearers. Different decontamination approaches and the degree of skin contact will affect this. The process should also be checked for the presence of malodours following treatment.
4. **Viral inactivation** – after use, PPE may contain coronavirus contamination embedded within a matrix of spittle and sputum. Salts from perspiration of the wearer may also be present. Decontamination must be validated for coronavirus inactivation and other residual microbes.
5. **Material performance** – certain reprocessing conditions can damage the critical material properties, such as the extent to which gowns are splash-proof or the structure and electrostatic attraction properties of the respirator mask's filtration system making it less effective.
6. **Respirator fit** – reprocessing and repeated use of single-use PPE can damage the shape, fit and elasticated attachment of respirators. The capability to retain fit seals must remain effective after reprocessing.

Before use, any decontamination method should be evaluated against these risks for its ability to retain its functional performance, fit characteristics achieved prior to decontamination, and safety of the wearer. The PPE should meet the original ISO standard following any reprocessing procedure.

B. Decontamination approaches

There are several different methods that can be used that vary in applicability to the different types of PPE; this section provides a high-level description of the methods. Little data exists to support the effectiveness of these decontamination methods

¹⁸ Institute of Healthcare Engineering and Estate Management (2020) [Reprocessing of Personal Protective Equipment \(PPE\) - An IHEEM Factsheet](#)

against SARS-CoV-2 specifically, on respirators or disposable face masks and gowns. Where shared with us, international examples are used to illustrate how the approach has been operationalised – this is not an endorsement of these approaches.

Hydrogen peroxide vapour (HPV)

HPV can be used in two forms. The first is where a solution of HP is passed through an aerosoliser, which creates a fine mist or fog of HP. This is typically used for the decontamination of surfaces in rooms or isolators in a healthcare or industrial setting. The second is where a purpose-built steriliser uses vaporised or gaseous HP in a sealed chamber under very low pressure in a carefully designed and controlled process, which is typically designed to sterilise medical devices. The vapour would cloak the PPE for a defined period to sterilise it and then the generator sucks the vapour back in. The PPE needs to be aerated for up to five hours before they are breathed through as HP is an irritant. This process and time varies depending on the specific HPV process, HPV concentration and volume. This method is quite expensive and requires trained personnel.

This method can be used for respirator maskS including N-95, FFP2 and FFP3. Evidence suggests that some respirators could withstand up to 20 to 30 cycles of this decontamination method after which some of the components deteriorated (especially elastic straps that secure the mask to an individual's face).¹⁹ This method has limited potential to be used for a wide variety of PPE as it is not compatible with cellulose.

Case study two: Mass General Brigham COVID-19 Innovation Centre, US

Regulatory context: the Food and Drug Administration (FDA) has issued an employment use authorisation (EUA), which enables decontamination protocols to be used throughout the declared emergency and after which the right to use is lost.

Equipment: deploying four Battelle HPV systems for sterilisation of single-use N-95 masks.

Pre-clinical testing: before the system was deployed, a research study compared the effectiveness of all test methodologies for decontamination of N-95 from COVID-19. This test provided confidence that the HPV method did not impair the filter functionality or fit for certain mask designs, even after 20 decontamination cycles.

Operational process

- Used N-95 masks that have not been soiled by makeup, blood or other substances are disposed of in bins as rubbish (rather than a biohazard).
- These bins are collected by Battelle biohazard transport in conditions with handlers equipped with PPE to a biosafety level two standard.

¹⁹ Centers for Disease Control and Prevention (2020) [Decontamination and Reuse](#).

- The qualified handlers put the contaminated PPE into a shipping container where the HPV is released and maintained for several hours after which decontamination is considered complete.
- The containers of decontaminated masks are returned to a hospital conference room where they are sorted, marked with a fine Sharpie (so the ink doesn't transfer through onto faces) then placed in a clam shell container, which is given a name, department and barcode.
- The boxes can then be collected by the healthcare workers at their departments.
- This process requires a three-day turnaround.
- Protocol is to repeat the decontamination of one mask for five cycles before being disposed of.
- The hospital had agreed to pay \$3.25 per mask decontaminated before the government stepped in to arrange a service contract worth \$400 million to provide decontamination services across the USA.

Key components that enable the deployment of HPV to decontaminate 80,000 N-95 masks a week:

- Local confidence in the effectiveness of the approach from having rigorously tested it.
- Pace of FDA approval and Battelle's capability to scale up to meet needs.
- Masks are returned to the same individual.
- The entire service is operated by an organisation with trained individuals and experience delivering a similar service across the US.
- Specific mask design and material composition must be considered as some are more suited to the process than others.

Case study three: based on guidance from the Ministry of Health, Labour and Welfare, Japan

Regulatory context: following FDA allowance and the research published by the CDC, the Japanese Ministry of Health, Labour and Welfare shared guidance based on the CDC approach to inform the handling of N-95 masks in exceptional circumstances. This was followed by an announcement of exceptional handling of surgical masks, long-sleeved gowns, goggles and face shields.

Equipment: Deploying Sterrad hydrogen peroxide plasma sterilisers to enable reuse of single-use N-95 masks.

Mask requirements

- Five N-95 used masks should be distributed per person in a clean, well-sealed bag and replaced daily on a five-day cycle.
- Masks should only be reused twice.

Case study four: HEDE project in Finland

Initiation: On 6 April, a project working group was established involving the Finnish Defence Research Agency (FDRA), Technical Research Centre of Finland Ltd (VTT) Finnish National Institute of Health and Welfare, Finish Defence Forces (FDF) Logistics Command, Lappeenranta-Lahti University of Technology (LUT) and LAB University of Applied Sciences. Together, engineers, infectious diseases physicians, infection control nurses, and experts of medical equipment management and hospital logistics designed and implemented a large-scale decontamination plant for single-use respirators. This was completed on 26 June.

Equipment: Cleamix Oy HPV equipment.

Scale: in the first phase, three hospital districts with five intensive care units participated in the piloting. Soon the piloting was expanded, and all Finnish hospital districts were invited to collect respirators. Nine hospital districts (N=9) joined the project.

Pre-clinical testing: the FDF implemented a large-scale decontamination facility to pilot the cleaning process for respirator masks. VTT carried out laboratory tests and played a significant role in the design and implementation of the HPV chamber in the decontamination unit. VTT was responsible for verifying the microbiological decontamination results of cleaned respirators and for testing the persistence of particle removal efficiency and breathing resistance of the respirators.

Operational process:

- At the decontamination facility, the packaged respirator masks are stored in a refrigerated container.
- From the storage, packaged respirator masks are delivered into a preparatory area where the incoming respirator masks are placed in wire baskets. The wire baskets are placed in rack trolleys, after which the racks are transferred to the decontamination chamber for processing.
- In the preparatory area, the respirators are treated as infectious and the workers are protected with protective masks, protective suits, rubber boots and protective gloves.
- Respirators are treated in the decontamination chamber with HVP using appropriate concentration and exposure time to effectively kill all microbes. After the treatment, the chamber is flushed with HEPA-filtered air until the hydrogen peroxide concentration is at a safe level to take the racks to the post-treatment space. The residual hydrogen peroxide remaining in the respirators is evaporated in a post-treatment unit.
- The respirators are then inspected, sorted, tested, marked and packaged and respirators not suitable for reuse (for example smeared) are rejected.
- Cleaned respirators are treated using PPE to avoid contamination of the treated respirators by the workers.
- Based on the embedded testing procedure and third-party evaluation, the decontaminated respirators are clean and functional for re-use up to 10 times, if necessary.
- The capacity of the plant is about 60 000 respirators/day.

Ultraviolet germicidal irradiation (UVGI)

This method relies on using short-wavelength ultraviolet (UV-C) light, which inactivates a range of microorganisms including coronaviruses, by damaging the DNA and RNA of the virus.

This method could be operationalised by using UV radiation in biosafety cabinets (BSCs), which are common in public health and hospital laboratories. Conveyor-style rapid UV disinfectors have also been developed. However, effective decontamination requires a relatively high dose of UV-C light, which is dependent on the light source, the distance of the PPE from the light source and exposure time.²⁰ Research suggests that PPE integrity, especially for certain models of respirators, may be impacted by high-intensity UV exposure and multiple cycles performed.²¹ UVGI is only effective on the visible surfaces therefore it may be less effective for respirator masks, where there may be shadow effects, and for respirator straps.²² UVGI is harmful and proper precautions are required to avoid UV exposure to skin or the eyes. UVGI sanitising cabinets are available that provide a controlled exposure process.

Case study five: Mass General Brigham COVID-19 Innovation Centre, US, detailing its approach for smaller, less accessible parts of the hospital group

Regulatory context: the FDA has issued an EUA that enables decontamination protocols to be used throughout the declared emergency and after which the right to use is lost.

Method:

- Developed a UV-C light box for sterilisation in its hospitals in Martha's Vineyard and Cape Cod where mask transportation would create logistical challenges.
- This technique allows point of care decontamination for 12 masks in two minutes.
- This service would need to be provided by individuals trained in sterile processes who can maintain the dose by extending the exposure time as the light source degrades.
- Pursuing an FDA EUA to which the FDA have been highly agile, providing feedback within 24 hours and sharing best practice to enable the required tests to be carried out to ensure standards are met.

See case study two for an example of the Battelle process used for major hospitals.

²⁰ Card et al. (2020) Preprint: [UV Sterilization of Personal Protective Equipment with Idle Laboratory Biosafety Cabinets During the Covid-19 Pandemic](#)

²¹ Lindsley et al. (2015) [Effects of Ultraviolet Germicidal Irradiation \(UVGI\) on N95 Respirator Filtration Performance and Structural Integrity](#). *Journal of Occupational and Environmental Hygiene* 12(8):509-17.

²² Public Health Ontario (2020) [COVID-19 – What We Know So Far About... Reuse of Personal Protective Equipment](#)

Moist heat

The CDC method uses water at a high-pressure level in an autoclave. Although the temperature of the steam is lower when compared to dry heat sterilisation techniques, the presence of moisture enhances the effectiveness of the sterilisation process. The comparative advantage of this method is that it can be used for temperature sensitive materials through which steam can permeate.

Heating for 15 to 30 minutes at 60°C and 80% relative humidity has been shown to cause minimal degradation in the filtration and fit performance of respirator masks. However, there is uncertainty of the disinfection efficacy for various pathogens.²³

It should be noted that these conditions are very different to steam sterilisation of medical devices, which deploys saturated steam at high temperature and pressure, typically 121°C for 15 minutes or 134°C for three minutes.

Case study six: Beijing University of Chemical Technology, China

Context: China has experienced shortages of protective masks, while also being aware of the environmental impacts of mask waste. In the absence of any specific requirements, guidance, scientific theory or experimental data to inform safe and effective reuse of single use masks, a team at Beijing University designed and tested user-friendly methods to effectively extend mask service time. The testing focused primarily on assessing retained levels of filtration efficiency in a range of different masks.

Equipment: the team at Beijing University initially designed a household-level reuse method involving hot water, a hair dryer and scraps of paper. They then extended their investigations to clinical settings involving use of autoclaves.

Pre-clinical testing: the team at Beijing University conducted lab testing on the above methods to inform practical application within households and clinical settings.

Operational process:

Household-level method:

1. Soak mask in hot water at a temperature greater than 56°C for 30 minutes.
2. Dry masks for 10 minutes using an ordinary household hair dryer (to re-establish the masks' electrostatic charge and recover their filtration function).
3. Successful regeneration is confirmed by sprinkling the mask with small scraps of paper – if the paper sticks, the electrostatic charge has been restored.

The Beijing University team ran bacterial filtration efficiency (BFE) tests on disposable medical masks and surgical masks and found that regenerated masks of both types retained over 95% efficiency. Surgical masks and KN-95-grade masks underwent particle filtration efficiency (PFE) tests and the regenerated masks exceeded respective efficiency thresholds defined by filtration standards. The team

²³ Centers for Disease Control and Prevention (2020) [Decontamination and Reuse](#).

tested five different brands across all types and found that up to 10 cycles of treatment had little effect on filtration properties.

Clinical-level application:

The team extended its investigation to test KN-95-type masks at higher temperature using an autoclave for steam sterilisation. The masks were placed in the autoclave covered with a clean piece of cloth to avoid damage from heavy turbulence, and were treated by pressurised steam at 121°C for 30 minutes (in line with US CDC guidance).

The average PFE of the respirator masks after steam sterilisation was measured to be 99.2% and that of the KF94 masks was 96.6%. The team states that the regenerated masks should therefore retain significant efficiency on blocking microorganisms, droplets, pollen, and other particles.

To study the influence of actual service processing on masks, the team examined mask samples that had been worn for eight hours by participants. For surgical masks, the effects of wearing varied among individuals and for the same individuals at different times. After being worn for eight hours, followed by hot water decontamination and charge regeneration, the PFE values of the surgical masks decreased by 0.5% to 12%, based on the testing of 15 samples. However, all the tested KN-95-grade masks (10 samples) that had been worn for eight hours, followed by hot water decontamination and charge regeneration, were able to retain filtration efficiencies greater than 95%.

Practical application:

The 'hot water decontamination and charge-regeneration method' was applied by Zhejiang Runtu Co Ltd, a large-scale stock enterprise with over 4,000 staff members engaged in producing and selling chemicals. Between 20 February and 30 March 2020, mask usage at Runtu was reduced from one mask per day per person to one mask every three days per person, saving a total of 122,500 masks.

Dry heat

This method uses dry heat sterilisation, which requires high temperatures over extended periods of time in order to kill pathogens. The temperature required by this method is higher than using moist heat and requires longer cycles, typically 160°C for two hours exposure. This method is currently used in Germany (See case study seven).

Research suggests that microwave steam protocols are effective at decontaminating some respirator mask designs²⁴, but more research is needed to assess the impact on the structural integrity of the equipment.²⁵ A potential risk of this method is water

²⁴ Pascoe et al. (2020) [Dry heat and microwave generated steam protocols for the rapid decontamination of respiratory personal protective equipment in response to COVID-19-related shortages](#). *Journal of Hospital Infection*. Volume 106, Issue 1, Pages 10-19.

²⁵ Public Health Ontario (2020) [COVID-19 – What We Know So Far About... Reuse of Personal Protective Equipment](#)

absorption, which varies by model – hydrophilic materials absorb more water. This method would be low-cost and logistically easy and could be especially significant for lower- and middle-income countries.

Case study seven: from Germany

Regulatory context: accepting there might continue to be shortages in PPE and distribution challenges, the German government issued a guide that defines which masks can be reused for emergency cases and how they should be reprocessed. The advice for reuse applies for six months from 31 March, during this period reprocessing will be further evaluated.

For the period between 14 April and 31 August, the Robert Koch Institute issued additional advice to allow reuse of masks for different patients, although not following aerosol-generating procedures with COVID-19 positive patients.

Equipment: existing dry heat decontamination facilities at hospitals.

Conflicting advice: the German Society for Sterile Supply (DGSV) criticises the heat treatment proposed in this guide as not sufficient. Since it is not guaranteed that the virus is removed after being exposed to 65-70°, the society recommends alternative approaches, for example the vacuum–steam–vacuum process for steam disinfection (VDV process at 105°C) or steam sterilisation (for example fractional vacuum process at 121°C for 20 minutes).

Applicability: the type of mask influences the approach to reprocessing.

- Disposable mouth–nose protection masks and respirator masks with CE certification can be reused after an adequate processing at 65-70°C, which involves exposing the mask to dry heat for at least 30 minutes. Where appropriate for mask design, higher temperatures can be used. As this treatment is only sterilisation the masks must be returned to their owner.
- Masks without a CE mark must be tested for their heat resistance before processing with heat.

Process

- It is the responsibility of the institution to develop a process to safely collect worn masks and dirty or defective masks must be disposed of immediately. It is strongly discouraged to temporarily store masks in closed containers while they are still moist, as this can lead to a massive increase in bacteria and mould within a short time.
- Masks must be personalised and can be used only by the same person after decontamination.
- The facility must check at least visually and physically that the masks were not affected by the process after decontamination (shape and properties of the material).
- The masks should be decontaminated no more than twice.
- All procedural steps must be documented in such a way that an inspection is possible. The facility should set up a system to indicate that a mask has been decontaminated and track the number of decontamination steps per mask.

- The persons who perform the collection, verification and decontamination processes must be qualified and trained to do so.

Additional steps from Robert Koch Institute advice

- After removing the mask, it should be stored in a dry place in open air avoiding contamination of the inside of the mask. This temporary space should not be accessible to the public and must be properly disinfected immediately after removal of the mask.
- The gloves must be disposed of properly after the storage of the masks and the hands must be disinfected.
- The used mask must be clearly assigned to one person to prevent it from being worn by other persons (for example by marking the masks).
- Used masks should not be cleaned with disinfectant as this may have a negative effect on the functionality of the mask.
- When putting on the mask again, using clean, unused gloves, care should be taken to prevent the pathogens from spreading from the contaminated outer surface to the inner surface.

Ionizing radiation

This includes various methods of radiation sterilisation by exposing PPE to high-energy electromagnetic radiation (gamma ray) or high-energy particles (electrons). These methods destroy microorganisms through ionizing events that lead to the destruction of macromolecules such as DNA and RNA within microbial cells, eliminating their reproductive capability.

Gamma irradiation typically used for biocontainment has been tested for SARS-CoV, using a Cobalt-60 source to inactivate the virus. Contaminated masks can be packaged and sealed in a container, transported to the gamma radiation source, sterilised and then removed without breaking the seal.²⁶ However, gamma irradiation using Cobalt-60 is a highly specialised technology that isn't found at UK hospitals; instead it is used exclusively in the UK's industry sterilisation facilities for critical medical devices. There is a risk that the method may damage the fibre materials of PPE, which can lead to cracking and degradation during deployment and/or fitting. There is some evidence suggesting that the filtering efficiency declined because of exposure to the ionizing radiation, concluding it was not appropriate for respirator masks.²⁷

Electron beam sterilisation requires a higher dose of electrons and has a short effective range, which may be applicable for surgical masks. Electron penetration of the PPE correlates with the energy of the electron and the density of the material and it cannot be used with PPE where there is an electrostatic charge. However, this method decreases the exposure time required and the fit is unaffected.

²⁶ Feldmann et al. (2019) [Gamma Irradiation as an Effective Method for Inactivation of Emerging Viral Pathogens](#). The American Journal of Tropical Medicine and Hygiene May;100(5):1275-1277

²⁷ Cramer et al. (2020) Preprint: [Disposable N95 masks pass qualitative fit-test but have decreased filtration efficiency after cobalt-60 gamma irradiation](#)

Ethylene oxide

Ethylene oxide gas is used for sterilisation of medical devices because of its effectiveness and compatibility with most materials.²⁸ However, when it comes to employing this method in decontamination of PPE, it is not recommended for respirator masks because of toxic gas residue.

Liquid hydrogen peroxide

This method would require submerging the PPE fully into the chemical for a period ranging from 1 second to 30 minutes at the range of 3% to 6% hydrogen peroxide concentration. Although there is evidence that this method does not affect filtration efficiency of respirator masks, no tests have been performed to assess the fit and disinfection efficacy.²⁹ They would need to be washed after this process to remove any toxic residue.

Table 1. Indicative applicability of different decontamination approaches.

Decontamination method	PPE suitability	PPE material properties	Risks and operational considerations
HPV	Only suitable for specific types of masks.	PPE cannot contain cellulose. Can be used on plastics and other heat-sensitive materials.	Minimal effect on filtration and fit. Mask fit unaffected up to 20 cycles but fewer cycles (approx. five) would be optimal. Cycles last approx. 120 minutes but need time to off-gas. Can penetrate dark spaces (unlike light). Breakdown products not harmful.
UVGI	Could work for respirator masks but not surgical masks. Face shields.	UV radiation degrades polymers. High UVGI doses could destroy the strength of the respirator materials by >90%. ³⁰	Efficacy dependent on dose. Materials (elastic band) can become brittle with multiple cycles.

²⁸ Shintani (2017) [Ethylene Oxide Gas Sterilization of Medical Devices](#). Biocontrol Science, 2017, Vol. 22, No.1, 1 – 16

²⁹ Centers for Disease Control and Prevention (2020) [Decontamination and Reuse](#).

³⁰ Lindsley et al. (2015) [Effects of Ultraviolet Germicidal Irradiation \(UVGI\) on N95 Respirator Filtration Performance and Structural Integrity](#). Journal of Occupational and Environmental Hygiene 12(8):509-17.

Problems with shadow effect if there are multiple layers.

Proper precautions are required to avoid UVGI exposure to skin or the eyes.

Masks must be handled individually.

Simplicity of use.

Ability to rapidly scale.

Moist heat	Suitable for specific types of masks.	Depends on whether the material can take the high temperatures.	Minimal degradation in the filtration and fit performance. Uncertainty of the disinfection efficacy for various pathogens.
Dry heating	Suitable for specific types of masks.	Materials cannot be temperature sensitive.	Minimal effect on respirator mask filtration and fit performance.
Gamma radiation or electron beam	Gowns.	Not compatible with any materials susceptible to radiation (polymers).	Deactivates the filtering function of respirator masks. Can impart a faint odour. High range of gamma radiation enables batch sterilisation – good for large volumes.
Ethylene oxide	Suitable for specific types of masks.		Residuals are toxic so can be harmful to the wearer. Used extensively for industrial sterilisation of medical devices but little used in hospitals.
Liquid hydrogen peroxide	Suitable for specific types of masks.		No effect on respirator mask filtration performance. No data available for fit and disinfection efficacy. Possible toxic residue.

C. Operational challenges

There are several considerations and challenges to deploying any of these systems at scale in the UK as PPE flows through the process (figure 1). The Institution of Chemical Engineers and International Society for Pharmaceutical Engineering UK Affiliate PPE reprocessing workflow diagram developed for an HPV method has been used to structure these operational challenges. There will be some process variation depending on the decontamination approach deployed so the applicability of these steps should be considered in that context.

Figure 1. High level steps of the decontamination process

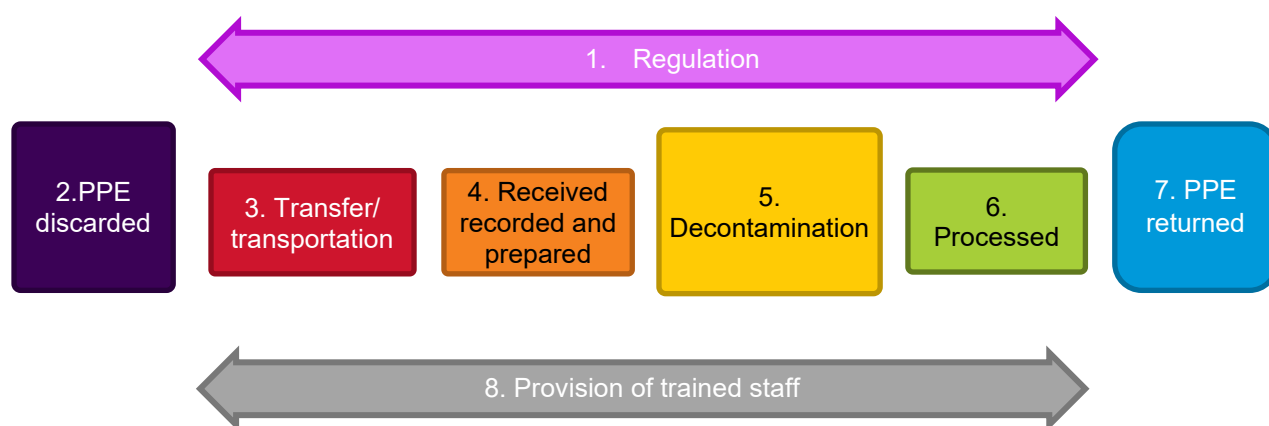
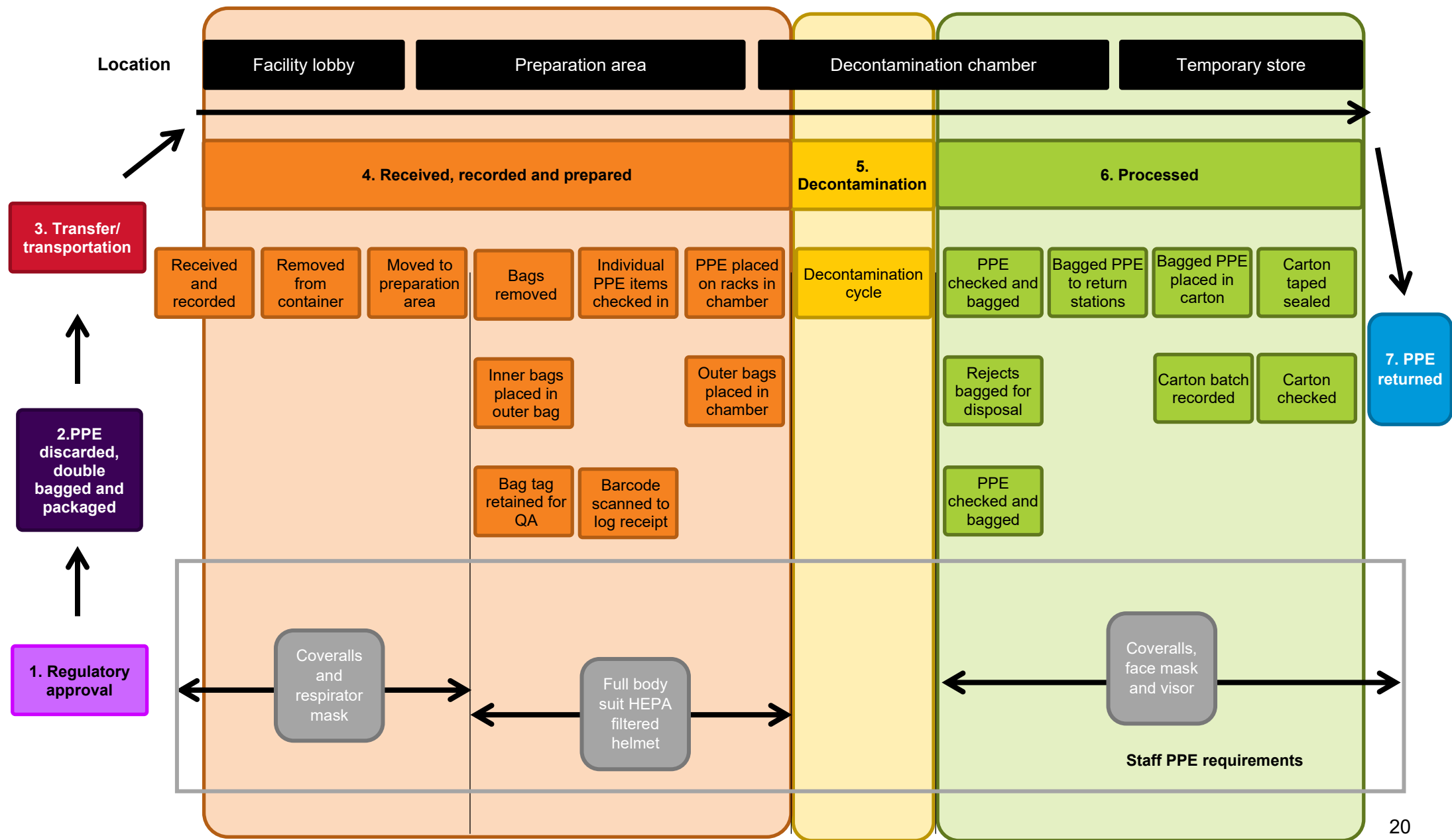


Figure 2. Institution of Chemical Engineers and International Society for Pharmaceutical Engineering UK Affiliate PPE reprocessing workflow diagram proposed for establishing an HPV decontamination process in an NHS hospital



1. Regulatory approval

There are multiple routes that can overcome the regulatory challenges. However, these must be very carefully considered.

Under current Department of Health and Social Care operating policies, UK sterile service departments (SSDs) must be registered as medical device manufacturers and compliant with ISO13485. The legislation relating to such registration is the Medical Device Directive and the body of legislation empowering such into UK law. The mechanism for registration includes development of a documented quality system including operational procedures that are audited by a Notified Body and overseen by the national Competent Authority, which in the UK is the MHRA. This enables SSDs to respond to local needs but with that they assume liability and risk.

Manufacturers could apply to change their single use marker, starting with the instructions for use (IFU) for each device, which lists the reasons why the product is classified as single use. Changing this classification would create litigation and practical issues for the manufacturers. Each series of devices would then have to be aligned with the Medical Devices Directives and the essential requirements outlined there. To complete this, a risk analysis would have to be conducted to clarify the essential tests required and what ISO and HSE standards need to be met.

As has been seen with certain medical devices in the COVID-19 pandemic and some of the international case studies presented, regulatory exemptions can allow exemptions from devices regulations during the coronavirus (COVID-19) outbreak. With approval from HSE, MHRA and NHS England/Improvement a similar approach could be taken to allow reprocessing of single-use PPE to be carried out in case of emergencies.

2. PPE disposed of by owner

- Personalisation

For hygiene reasons and to reflect the preferences of the end users, respirators should be individually identified to be able to be returned to the same user after reprocessing. This is also likely to influence the acceptability of PPE reprocessing. To operationalise personalisation will require an identification process and influence how the PPE items are disposed of, likely requiring individual bags.

3. Transfer/transportation

The applicability of this step depends on the location of the reprocessing facility and whether items are individually reprocessed via some UV methods or in larger quantities for HPV treatment.

- Transfer

Although hospitals are used to sterilising contaminated medical devices, there is less experience with contaminated textiles and PPE in general, which are normally used

once then bagged and disposed of. Storage of contaminated PPE prior to reprocessing must be considered and appropriate containers provided.

- **Transport**

The transport must be appropriate for the degree of biohazard being carried, regulations for the transportation of dangerous and infectious goods apply.

4. Received, recorded and prepared

- **Check in**

PPE should be checked into the facility and logged for quality assurance purposes. This may control the number of times the PPE has been reprocessed to inform whether it should be disposed of. Items that are visibly soiled, for example from makeup, should also be discarded.

- **Set up for sterilisation**

Some HPV facilities place the PPE on racks for sterilisation. If the PPE is kept in a container, its properties may need to be considered to be able to understand the appropriate choice of decontamination.

5. Decontamination

- **Existing in-hospital facilities**

Autoclaves are commonplace in UK SSDs and some have free-standing HPV sterilisers in use within their departments. Products from Advanced Sterilization Products (ASP) STERRAD Sterilization Systems and the STERIS VPRO Sterilization Systems are predominantly found within UK SSDs. These designs have been granted approval for decontamination of respirators in the US.

However, if contaminated PPE is incorporated into the SSD workflow, it would join the final step of sterilisation in an autoclave or by HPV, bypassing the initial manual and automated cleaning stages that remove the majority of residual soil and microbiological contamination before sterilisation. The introduction of contaminated PPE at this final stage of the workflow would involve presenting the steriliser with individually packaged respirators, which are potentially contaminated. This risks contaminating the areas within the department normally protected by the prior cleaning.

- **Existing centralised facilities**

Several centres across the UK already provide hospitals with MHRA-registered, ISO-accredited reprocessing services. These services include transport and logistics with trained employees and tracking and tracing of the devices throughout the decontamination cycle. These are designed and regulated for reprocessing reusable medical devices not single-use PPE.

- **Provision of new facilities**

Many of the decontamination approaches could be set up in existing hospital rooms or in temporary facilities onsite. These facilities will require decontamination equipment, which the UK has some capability to provide, but this will be determined by the scale and approach chosen.

Centralised reprocessing facilities could also be established to cover the demand for local regions. However, this will have implications for transportation. Adverse weather events could cause disruption during winter.

6. Process

- **Safety assessment**

The operational aspects of the chosen routes need to be assessed for process safety for both the operators and users. This needs to be done on a case-by-case basis to account for variations across the reprocessing system.

- **Validation**

Before it is implemented, rigorous validation and verification will be required of any approach to the reprocessing of single-use PPE to ensure the PPE decontamination process is effective and hasn't introduced other risks. This will include bioburden assessments to ensure process efficacy at eliminating SARS-CoV-2 and other micro-organisms, quantitative fit tests for filtration and accelerated life tests. Validation should be carried out at various points throughout the process to ensure risks are not introduced at any stage of the cycle.

Once in operation, regular testing will be required to ensure continued process efficacy.

- **Quality assurance**

Quality assurance will be required throughout the process. This will ensure the reprocessed PPE is tracked, any soiled or damaged PPE is disposed of appropriately and the PPE does not exceed the recommended number of cycles.

- **Preparation for return**

The decontaminated PPE should be processed in a clean room, as would be the case for new PPE, and appropriately bagged, sealed and boxed for return to the individual owners.

- **Packaging**

The packaging needs to be tested to ensure it has the correct shelf life, is easily transportable and provides correct protection. Depending on the method deployed, the packaging may also need to allow the PPE to continue off-gassing. Packaging

will need to have the appropriate hazard labelling for the transporter and be clearly labelled as reprocessed to ensure the user is aware.

7. PPE returned to owner

- Return of PPE to owner

Once through the decontamination process, the PPE should be returned to the hospital department in a sealed container, preferably to the individual staff members through a formalised return mechanism. This should ensure the PPE has not exceeded the allowed number of reprocessing cycles.

- Donning decontaminated PPE

The CDC suggests several precautionary measures that healthcare providers should take before applying the decontaminated PPE. These include:

- cleaning hands with soap and water or an alcohol-based hand sanitiser with at least 60% alcohol before and after touching or adjusting the respirator
- avoiding touching the inside of the respirator
- using a pair of clean (non-sterile) gloves when donning the respirator and performing a user seal check
- visually inspecting the respirator to determine if its integrity has been compromised
- checking that respirator components such as the straps, nose bridge and nose foam material, have not degraded, which can affect the quality of the fit, and seal
- discarding and trying another respirator if the integrity of any part of the respirator is compromised, or if a successful user seal check cannot be performed
- performing a user seal check immediately after donning each respirator and not using a respirator on which a successful user seal check cannot be performed.³¹

8. Provision of trained staff

- Trained staff

Access to the right skills will be critical to establishing the facilities to meet regulations and safety assurance. These staff will need to be provided with the required standard of PPE for the processes they are responsible for.

The competencies of decontamination staff will be critical to the success of any decontamination intervention. In US operations, these trained professionals are provided as part of a holistic decontamination service. Individuals working in SSDs

³¹Centers for Disease Control and Prevention (2020) [Decontamination and Reuse](#).

will have the technical skills to deploy many of the reprocessing approaches. However, further skills will be required and training will be required.

Conclusions and recommendations

The considerations for reprocessing are complex, but have been successfully tackled for respirator masks in certain international contexts, although without full support from health and care professionals.³² Should the NHS, HSE and MHRA adjust regulations and guidance to advise on reprocessing of single-use PPE for emergency shortages, or in the longer term, manufacturers produce PPE that is designed for multi-use and reprocessing, these recommendations should inform the approach:

1. International examples have illustrated popular techniques delivered through different mechanisms. These should be drawn on to ensure the learning is transferred. However, any reprocessing solution should be cost-effective and bespoke to the specific requirement of the UK's NHS and wider healthcare sector and regulatory system.
2. NHS England/Improvement should lead the development of appropriate reprocessing facilities in consultation with experts across the delivery pipeline. This will ensure all of the component parts, including reprocessing equipment, personal containers, and the provision of skilled personnel, can scale simultaneously to meet potential demand.
3. Choice of decontamination method will inform the details of the approach to deployment, the PPE applicable, necessary validations, potential risks, and the limit on the number of times the PPE can be reprocessed. Standardisation of the approach across the UK would be beneficial.
4. Accompanying procedures for operationalising the use of decontaminated PPE should be developed, such as protocols for the safe collection, transfer and transportation of used PPE, and protocols to identify and return decontaminated PPE to its owner.
5. Quality management records will be critical to ensure good practice, traceability, and auditability alongside robust health and safety protocols to assess and manage risk assessments. Health and care professionals should be consulted to ensure any outstanding risks are fully understood.
6. Any process deployed should be validated locally but remain under review as international scientific evidence continues to emerge.
7. Different PPE designs from different manufacturers should be individually assessed to ensure functionality has not been compromised because of reprocessing. The list of products that can be reprocessed should be kept up to date as new suppliers and designs are sourced. Compliance with international standards should be maintained and where possible manufacturers' guidance should be sought and employed.

³² National Nurses United (2020) [Warning » Battelle N95 decontamination system is not safe and may not work](#)

8. Emergency reprocessing of single-use PPE is not an alternative to increasing the supply. Investing in significant facilities should be done with a view to their longer-term sustainability. Increasing UK capacity to reprocess PPE safely could support the use of reprocessed multi-use PPE, therefore reducing the cost and waste produced across the whole PPE lifecycle.