RESP-FIT: An Australian Respirator Fit Testing Competency Program

Authors

Mr. Mark Reggers - Australian Institute of Occupational Hygienists (AIOH); Mrs. Jane Whitelaw - University of Wollongong

Abstract

The challenge of competent respirator fit testers is an international issue, highlighted most recently with the pandemic. Hear about the highs and lows of the journey of the Australian respirator fit testing accreditation and training program, RESP-FIT. How it went from conception, development, launch and operation over the past three years; and how assisted the Australian Institute of Occupational Hygienists (AIOH) assisted this journey. The program is based on the competent person criteria from ISO 16975-3, elements of AS/NZS 1715 and the UK Fit2Fit established program. It has filled a much-needed gap in the design of RPE programs and protecting workers from respiratory hazards.

The AIOH committed to developing an RPE fit testing approval process in 2019 and appointed a chair to lead the development of a program. Expressions of interest from like-minded, passionate Occupational Hygienists and respirator fit testers helped create various working groups to begin working on the mammoth task. A review of international best practice programs was conducted over two years. The working groups developed a wide range of documentation, platforms, processes, communication strategies, partners & supporters programs with blood, sweat and tears from many volunteers.

RESP-FIT (https://respfit.org.au/) was officially launched at the AIOH Virtual Symposium in December 2019 by the chairperson of SafeWork Australia. In the first 12 months of the program, two training courses/providers were approved, and over 150 people fit tasters undertook the accreditation process.
The program was designed to be an online process to make it more accessible given the size and geography of Australia. This critical decision was further reinforced during the global pandemic and with the challenges of in-person assessment presented during this time. In the short time since launch, many lessons have been learned around the assessment process, which consists of an invigilated online theory exam and submission of recorded practical assessment. The development of robust and consistent tools has been vital.
Early feedback from industry and qualified testers has been incredibly positive as RESP-FIT focuses and sets a consistent competence benchmark (based on ISO standards). We all don't know what we don't know, and the program has highlighted several practices that fit testers had accepted but were not in line with the protocols and could lead to inconsistent and incorrect fit testing results and risk to the RPE wearer.
In early 2020, fit testing was essentially an unknown practice in the Australian Healthcare industry. This changed very quickly with the pandemic, and RESP-FIT provided a professional and central reference point. The long lead time on the development of programs such as RESP-FIT makes it even more imperative that we start today to give solutions to foreseeable issues to have a product ready to support and protect the health of our workers

Submission ID: 11

An Innovative Approach to Evaluating Protection Level of PAPRs' Tight-Fitting Facepiece when the Face Seal Is Compromised

Authors

Mr. Dmitri Kazakov - Safety Equipment Australia Pty Ltd

Abstract

Background:

Powered Air Purifying Respirators (PAPR) offer two protective layers for the wearer: the mask face seal and the positive pressure performance (PPP). If one layer fails, the other layer would keep the wearer protected. However during the certification process there is no test which evaluates the PPP. The test, on the power OFF mode of the PAPR when the mask face seal is evaluated, is not testing the PPP directly. During the overall performance tests (the TIL test for example) and in the event the PAPR had a PPP deficiency, the issue would be "masked" by the good face seal and such problem would remain unnoticed, however in the event of a mask seal breakage the user would be exposed by the threat.

Methods:

The proposed method is based on monitoring and analysing the negative pressure event inside the respirator, which can be used to assist in the certification of PAPR's PPP and for assessing the PAPR's suitability of tasks during various working environments.

Results:

This paper presents the study that shows the variability of PPP from different brands of PAPRs. It is based on the assumption that the same mask leak with known characteristic is introduced on all tested PAPRs. The negative pressure events are subsequently collected and converted into the total inward leak volume. This gives us a relative indication of PPP on tested PAPRs.

This work also provides a brief analysis on the technical reasons for differences in PPP.

Conclusions:

The result shows that the PPP variation between different types of PAPRs could vary by hundreds of times, while respirators variation in breathing resistance is significantly less and the resistance could sometimes be even higher than negative-pressure respirators. Therefore the ability to maintain positive pressure is the major factor that characterises the PPP's efficiency of different PAPRs and it should therefore be tested separately during PAPR certification.

Submission ID: 15

Do respirators have a thermoregulatory impact on volunteer firefighters?

Authors

Mrs. Jane Whitelaw, Dr. Jennifer Hines, Dr. Vinod Gopaldasani - University of Wollongong

Abstract

This pilot study evaluated the thermoregulatory effects of respirator use on Rural Fire Service (RFS) Volunteers completing a nine-stage obstacle course while wearing a disposable, half-face or full-face respirator compared to no respirator.

An experimental study was conducted with 33 participants over the obstacle course designed to simulate in-field activities. Core temperature was measured prior to, during and post each course run while maximum heart rate and heart rate recovery were measured during and post each course run. Participants self-evaluated relative perceived dyspnoea (RPD) post course; and a comfort and PPE compatibility questionnaire was completed for each respirator.

Core body temperature exceeded 38 °C with and without a respirator, however there was no statistically significant difference when wearing the different respirators compared to not wearing a respirator; nor was there a significant difference in core body temperatures between the respirator types ($p > 0.05$). There is thus a potential for heat related illness regardless of whether a respirator is worn.

Heart rate increased with the use of any of the three respirators compared with no respirator, and more participants exceeded their sustained heart rate limit wearing a respirator during the obstacle course run than without. However, there was no statistically significant difference in heart rate recovery while wearing the different respirators as compared with not wearing a respirator.

Whilst some of the thermoregulatory outcomes are mixed, the RPD was significantly higher for each of the three (3) respirator types when compared to no respirator, which may lead to low wear time or individuals removing their respirators in high-risk situations.

Further research is required during actual firefighting conditions with increased radiant thermal load to evaluate the physiological effects of respiratory protective equipment (RPE) use on RFS Volunteers and to inform the adoption of an RPE program.

Submission ID: 16

How effective are P2 respirators against bushfire smoke?

Authors

Mrs. Jane Whitelaw, Dr. Jennifer Hines, Ms. Linda Apthorpe - University of Wollongong

Abstract

This unique study funded by the AIOH Foundation and the NSW Rural Fire Services (RFS), evaluated whether current Respiratory Protection Equipment (RPE) worn by volunteer firefighters provides adequate protection against respirable bushfire emissions, specifically the highly toxic PAHs and nanoparticle components.

The findings of this study will inform the RFS and other agencies of the efficacy of P2/3 respiratory protection to control exposure to bushfire emissions and enable better management of the health risk for their volunteers.

The catastrophic 2019/20 summer bushfire season highlighted the lack of an appropriate respiratory protection program for RFS firefighters. Images of firefighters ill-equipped to protect their respiratory health bombarded the media daily. In July, the NSW RFS released a tender document for the provision of respiratory protection equipment (RPE), with half-face P2 respirators nominated for most frontline operations.

Whilst bushfire emissions contain a cocktail of respirable toxic and carcinogenic substances such as PAH's and nanoparticles; the efficacy of P2 filtration against these substances has not been evaluated.

Previous research conducted by the University of Wollongong [1,2] has demonstrated lower than expected performance of RPE commonly used for thermally generated particles. With the generous support of the AIOH Foundation and the NSW RFS, this work was extended to assess efficacy of RPE against bushfire emissions. Respirator filtration efficiency was evaluated for respirable particulates, PAHs and nanoparticles.

The findings of this study will inform the NSW RFS and other agencies of the efficacy of respiratory protection to control exposure to bushfire emissions and enable better management of the health risk for their volunteers. It will also contribute to respirator manufacturers' knowledge to improve design and filtration required for use against bushfire emissions to protect the health of firefighters.

References

1. Whitelaw, J. L., Burton, K. A., Davies, B. & Jones, A. L. (2019). Respiratory Protection: Do PAPRs adequately protect workers against DPM?. Coal Services Health & Safety Trust *https://www.coalservices.com.au/wp-content/uploads/2017/11/Project-No.-20641-Final-Report.pdf.*
2. Burton, K. A., Whitelaw, J. L., Jones, A. L. & Davies, B. (2016). Efficiency of respirator filter media against diesel particulate matter: a comparison study using two diesel particulate sources. Annals of Occupational Hygiene, 60 (6), 771-779.

Submission ID: 17

A Laboratory-based Quantitative Fit Assessment of N95 Filtering Facepiece Respirators with the Application of Skin Protectants

Authors

Michael Bergman, Dr. Ziqing Zhuang, Brooke Vollmer, Dr. Katherine N. Yoon - NIOSH NPPTL; Dr. Sergey Grinshpun, Dr. Michael Yermakov - University of Cincinnati, Center for Health-Related Aerosol Studies

Abstract

Widespread disease outbreaks can result in supply shortages of NIOSH-approved N95 filtering facepiece respirators (FFRs). Extended use practices are a strategy to maintain supplies; however, prolonged wear times can lead to the development of various types of adverse facial skin conditions including dryness, forms of contact dermatitis, device-induced pressure and friction, and superficial wounds or cuts. Healthcare personnel have been reported to apply "skin protectants" (e.g., bandages, creams, surgical tapes, and hydrocolloidal dressings) to the face to reduce the pressure and friction of FFRs. Because FFRs rely on a good seal to the face to protect the wearer, it is important to understand if the fit is affected if skin protectants are used.

This laboratory study included 10 volunteers who performed an OSHA-accepted quantitative fit testing protocol to evaluate respirator fit while wearing skin protectants. The evaluation was conducted using a PortaCount® respirator fit tester set in N95-mode. The N95 FFR models evaluated were the 3M Aura 1870+, Kimberly-Clark Fluidshield, and 3M 8210. The evaluated skin protectants were Band-Aid® Flexible Fabric Bandage (Johnson & Johnson), Durapore™ Surgical Tape (3M), and Cavilon™ Durable Barrier Cream, product no. 3355 (3M). Three replicate fit tests were performed for each tested combination of subject, skin protectant, and FFR model. Control condition fit testing was also performed without skin protectants.

Designating Overall Fit Factor as the continuous dependent variable, Analysis of Variance (ANOVA) was performed to examine the main effect of protectant type (the three skin protectants and the control condition/no protectant), the main effect of FFR model, and their two-way interaction. Additionally, a binomial logit model was used to explain the effect of protectant and FFR model on the ability to pass the fit test, where "pass" or "fail" was a binary outcome.

Overall Fit Factor was affected differently by the combination of protectant type and FFR model. In general, using Cavilon™ cream showed less of a reduction in mean Overall Fit Factor compared to using Band-Aid® or Durapore™. The ANOVA test found that the main effects of protectant type and FFR model were both significant (p-values <0.001); additionally, their interaction was significant ($p=0.02$), indicating that Overall Fit Factor is affected by the combined effects of protectant type and FFR model.

Compared to the control condition, using Band-Aid® decreased the odds of passing the fit test by 76.7% ($p<0.001$) across all models. Durapore™ decreased the odds of passing the fit test by 74.2% ($p<0.001$) compared to the control condition. Compared to the control condition, using Cavilon™ decreased the odds of passing the fit test by 37.4% across all models; however, the probability of passing a fit test was not statistically significantly different from the control condition ($p=0.174$).

These results imply that various types of skin protectants may have an impact on the sealing surfaces of respirator models differently. Users should follow the respirator manufacturer's guidance (if available) on using skin protectants. Additionally, prior to it being worn in the workplace, the fit of the FFR with the protectant should be evaluated with a fit test.

Submission ID: 18

A New Respirator Performance Standard and Certification System for Canada

Authors

Dr. Simon Smith - CSA Standards Committee; Prof. Eva Dickson - Defence Research and Development Canada, and Royal Military College of Canada; Mr. Dennis Nikkel - DKN Occupational Health Consulting

Abstract

In Canada, strong demand for respirators for healthcare use in the first year of the COVID-19- pandemic drove implementation of new manufacturing operations: new and existing companies started production of filtering facepieces and other types of respirators. Canadian legislation requires regulatory approval for respirators used in workplaces. Historically the US National Institute for Occupational Safety and Health (NIOSH) has been the accepted approval body. High demands on NIOSH, plus prioritization of domestic over external applications, resulted in extended approval delays for Canadian manufacturers.

Early action was taken by the government agency Health Canada which issued an Interim Specification for approval of certain respirator types for healthcare use. For the long-term, a new Canadian certification system was developed, which required creation of a respirator performance standard. This was undertaken by an expert technical committee drawn from the manufacturing, regulatory, healthcare, and occupational health and safety practitioner communities. The document was issued in October 2021 after an extremely accelerated timescale of only ten months including committee and public review stages, while 3-4 years is usual. The new certification system addresses products used only in Canada, and is applied in parallel with NIOSH approvals, so that existing manufacturers are unaffected.

Decades of familiarity with NIOSH standards by respirator users and manufacturers meant that major departure from existing classifications and requirements would be problematic: trust and acceptance of the new certification is desirable. But creation of a new standard brought opportunities to augment existing criteria beneficially.

Learnings from ISO standard development were imported, such as foundation on human performance requirements and protection needs, to avoid specifying or presuming design aspects beyond those. ISO-standard terminology was also introduced, and aspects such as practical performance testing were considered, but deferred for later deliberation. The first edition of the standard only addresses particle-filtering respirators, but it is planned sequentially to expand coverage to all types.

Non-powered and powered respirator classifications follow NIOSH with slight changes:

- Additional designation is appended for N95-class respirators indicating which one of three ranges of airflow resistance the product matches – to aid user selection, as wearer fatigue induced by airflow resistance was identified as a key user issue;
- A specific class for respirators evaluated for fluid and flammability resistance in accordance with ASTM standards is incorporated in the main classification structure – though only Level 3 fluid resistance is included to simplify selection;
- “CA-” is appended to each designation due to legal protection of the classifications by NIOSH.

Performance requirements for corresponding classes match NIOSH, with some additions:

- Quantitative fit testing is required for all respirator types for a user population, based on the NIOSH bivariate panel;
- A shelf life and validation data must be stated;
- A failure modes effects analysis is required; plus
- An attachment mechanism strength test based on European standards;
- Biocompatibility to ISO standards;
- Inclusion of quantitative performance criteria in some cases where the NIOSH standard has general statements.

The new standard and the associated certification system are now in effect and managed by the Canadian Standards Association.

Submission ID: 23

Respiratory Standards in Europe - recent developments

Authors

Dr. Gabriele Troescher - 3M Deutschland GmbH

Abstract

European standards for Personal Protective Equipment, including respirators, are part of a regulatory system in the European single market. In this system, Regulation (EU) 2016/425 of the European Parliament and of the Council for Personal Protective Equipment establishes essential health and safety requirements, whereas so called “harmonized standards” complying with these requirements imply presumption of conformity with the Regulation.

This system is in place since 1985 (“New Approach”), has been modified in 2008 considerably (“New Legislative Framework”), and the current news and challenges are intended to be summarized by this presentation.

Submission ID: 24

Efficiency of KN95 FFR and qualitative knowledge on numerous FFRs during the COVID-19 pandemic

Authors

Dr. Clothilde Brochot – IRSST; Dr. Mohamed Nejib Saidi – IRSST; Dr. Ali Bahloul - IRSST

Abstract

Authors: C. Brochot, M. N. Saidi. A. Bahloul - IRSST

BACKGROUND: The high demand for filtering facepiece respirators (FFRs) worldwide during the COVID-19 pandemic period pushed decision makers to a critical supply situation. Pressure on health centers to obtain N95 FFRs and pressure on the manufacturing sector led to a diversification of supply chains, with the support of several government authorities. After allowing the use of certified FFRs from other parts of the world, decision makers in many countries have published alerts, especially regarding 'KN95' FFRs. The main issue then is whether these purchased FFRs were as effective as the FFRs commonly used in the pre-COVID-19 period.

METHODS: The most efficient method is to test these FFRs under normative conditions. This paper investigated the filtration performance of different FFRs using an experimental setup already used in several studies. This setup, using high-resolution measurement devices, allows the measurement of pressure drop Δp (mbar) and filtration efficiency E (%) of FFRs at a 85 Liter per minute flowrate. In addition, visible markers were collected as they could indicate a possible defect (intentional or unintentional) or a possible counterfeit. Therefore, performance measurements and visual inspections of 43 types of FFRs have been compared and analyzed.

RESULTS: The results show a large disparity between the different FFRs. The 'KN95' types have pressure drops that meet the normative value; however, their efficiencies may be lower than the normative minimum value of 95%. 35% of the FFRs received in the laboratory have a minimum filtration efficiency greater than 95%, and 28% have a minimum efficiency less than 80%.

CONCLUSIONS: The results show that the markers on FFRs are not a clear and accurate indicator of FFR efficiency. However, visual inspection and a preliminary fit test could identify some inefficient FFRs.

Submission ID: 25

Extending Supplies During Respirator Shortages - How Does Repeated Decontamination of Healthcare's Most Used Respirator Impact Respirator Performance?

Authors

Brooke Vollmer, Michael Bergman, Jonisha Pollard, Dr. Ziqing Zhuang, Andrew Wilson, Kevin Strickland, Dr. Tyler Quinn, Jordan Meyers, Rebecca Streeter - NIOSH NPPTL

Abstract

NIOSH-approved N95 filtering facepiece respirators (FFRs) are the most used respirator in healthcare and are treated as single-use products. These respirators cover the nose and mouth, and are held in place using straps to ensure that a tight seal to the user's face is maintained and airborne particulates are filtered out by the filter media. Prolonged supply shortages have occurred throughout public health emergencies, triggering supply optimization strategies that include the decontamination and reuse of N95 FFRs. While decontamination and subsequent reuse of N95 FFRs is not consistent with approved usage, a variety of decontamination techniques has been implemented in various workplaces as part of a crisis strategy. Therefore, the National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) explored the impacts various decontamination techniques being used by organizations may have on N95 FFR performance. Filtration efficiency, manikin fit factor, and strap tensile strength were assessed for decontaminated N95 FFRs that were submitted to NIOSH NPPTL by external organizations for evaluation.

As part of this assessment, NIOSH conducted testing to provide decontamination technique developers and healthcare providers with laboratory-based data to ascertain the impact of their techniques on respirator performance. The selection of respirators provided to NIOSH for testing was at the discretion of the submitter; however, NIOSH requested 15 decontaminated respirators and five new respirators to use as testing controls. Prior to sample testing, FFRs were visually inspected for signs of damage or discoloration compared to the new (untreated) controls. These assessments used new N95 FFRs that had not been worn or exposed to any pathogenic organisms.

A total of 19 different decontamination techniques across 29 different N95 FFR models were evaluated. Eight of the 19 decontamination techniques (42%) had a negative impact on fit and/or filtration efficiency (three techniques negatively impacted both filtration efficiency and fit, one technique negatively impacted filtration efficiency only, and four techniques negatively impacted fit only). Regarding strap tensile strength testing, only two decontamination techniques resulted in a large increase in tensile force when compared to the controls. In total, 44 assessment reports were posted on the NIOSH NPPTL website for review by the worldwide audience. The reports were further utilized and accepted as evidence to support its addition or removal from approved emergency methods.

Although not assessed within this study, it is important to note that any decontamination technique should reduce the number of pathogens on used FFRs before reuse, be safe for the wearer, and must not have a negative impact on FFR performance. Further, users should check with FFR manufacturers to see if decontamination-specific data is available for their models before performing decontamination.

Submission ID: 28

A next-generation fit testing approach for the Canadian Armed Forces

Authors

Prof. Eva Dickson, Dr. Paul Bodurtha - Defence Research and Development Canada; Ms. Hannah Mills, Ms. Linda Tremblay, Ms. Lisa Prior - Royal Military College of Canada, Department of National Defence; Maj. Christian Doucet - Canadian Armed Forces

Abstract

Background. The Canadian Armed Forces (CAF) is looking to modernize its approach to Quantitative Fit Testing for CBRN respirators, which was first introduced in the early 2000's. While the approach is functional, it is logistically burdensome and works best when large groups of individuals are being fit tested domestically prior to deployment, and when the fit testing team exercises their skills and the test equipment regularly. However, there are times when single individuals need to be fit tested, in the field or in locations where the capability is not currently available. It would also be preferable to couple together the issue of the respirator with the fit test process, as currently the respirator is issued first, used for training, and then must later be exchanged if found to be the incorrect size in fit testing. Therefore a new, lower footprint, approach that could be used at point of respirator issue is being investigated, to accommodate improvements in the process.

Methods. The key to achieving the lower footprint is the use of a prototype Wearable Respiratory Protection Assessment System (WRPAS, TSI Inc.), a small, battery-powered system that incorporates two condensation nucleus counters that can simultaneously read outside (ambient) concentration and within respirator concentration, permitting real-time determination of fit factor (FF) when incorporated into a fitting exercise. As the respirators are fit to a high FF value of 10,000, generation of aerosol within an enclosure is required. We are investigating smaller collapsible enclosures that can be rapidly deployed for a single individual, and the use of battery-powered generators such as portable miniaturized humidifiers and nebulizers to generate salt aerosol, as well as methods to ensure aerosol uniformity within the enclosure and during the exercise protocol. We are also considering various improvements to the prototype system such as an automated filling station for the water used as condensation medium, Bluetooth technology for wireless communication, and development of a graphical user interface via a tablet that will step the operator simply through the procedure.

Results. The investigations are still at their early stages, but we have demonstrated that routinely available and inexpensive generators can be used with small pop-up enclosures, and that the WRPAS generates comparable results in less time compared to the more traditional CAF method that uses a larger tent and a PortaCount. Therefore the project is planning to accelerate the investigations in order to develop a system potentially suitable for fielding in the next few years.

Conclusions. The focus on making the method more accessible and automated, and with a smaller footprint, should make it possible to perform fit tests at point of issue and in more remote locations, even potentially for expedient fit verification in the field.

Submission ID: 33

Respiratory protection for Canadian Armed Forces members with headdress and/or beards Part 1: A non-powered accessory for the C5 respirator for use in CBRN training

Authors

Prof. Eva Dickson - Defence Research and Development Canada and Royal Military College of Canada; Dr. Paul Bodurtha - Defence Research and Development Canada; Maj. Christian Doucet - Canadian Armed Forces; Ms. Lisa Prior, Ms. Linda Tremblay, Ms. Hannah Mills - Calian and Royal Military College of Canada, Department of National Defence.

Abstract

Background. In 2020, the Department of National Defence (DND) identified the need for all new recruits to participate fully in Chemical, Biological, Radiological and Nuclear (CBRN) defence training. Providing inclusive respiratory protection presents some challenges, as the seals of standard respirator masks are not designed to fit wearers with beards or those who wear headdress for religious or other reasons.

While a full operational solution for the CBRN environment is the long-term objective, the CAF would benefit now from early implementation of a solution for use in basic training, including the gas hut. This solution (the C5B) would allow CAF members with beards, headdress, and other hard-to-fit members, to safely wear the in-service C5 CBRN respirator during recruit training, with the requirement that it protect against CS and be suitable for use during the remainder of field training activities. A key requirement was that the solution be simple and non-powered, with no requirement that it be consistent with existing civilian regulatory guidance for permissible options for bearded individuals. A government team is providing requirements for and evaluating a series of prototype accessories designed to work with the C5, produced by Airboss Defense Group. This presentation will focus on the requirements and evaluation results mid-way through the development.

Methods. A series of C5B prototype concepts was produced, starting with three and down-selecting to one concept to be further refined. The design and evaluation process has been performed with the full engagement of a diverse and representative group of users and advisers to help define solutions that are compatible with the CAF training mission and user requirements. Initial evaluations consisted of tabletop activities in which 15-20 users provided feedback based on user acceptance (Likert scale evaluations) and compatibility with training equipment and procedures. Measurements of the CS concentration in the gas hut were performed in order to define the protection requirement. Additionally, quantitative respiratory protection evaluations (fit factor and simulated workplace protection factor) were performed on the third round of prototypes. Subsequent evaluations will add CS gas hut training activities, leading to a full-scale user trial in fall of 2022.

Results. Requirements have been developed relating to the key performance parameters associated with the concept of use. These requirements have been translated into a series of primarily user-based assessments that have resulted in down-selection to a single concept, which has demonstrated adequate protection performance in the laboratory and is being further refined for comfort and utility.

Conclusions. The extensive involvement of users and trainers throughout the process has been successful in driving a design that should have high acceptance and utility, and has fostered a spirit of collaboration with this group of users, demonstrating the value of this inclusive approach.

Submission ID: 34

Healthcare and first responder initial experiences with elastomeric half mask respirators and the likelihood of their adoption

Authors

Dr. Emily Haas, Ms. Alexa Furek, Dr. Lee Greenawald - CDC/NIOSH/NPPTL

Abstract

Background: Elastomeric half mask respirators (EHMRs) are used in a variety of workplace settings. Recently, EHMRs have been encouraged for routine and surge use in health delivery settings as an alternative to disposable N95 filtering facepiece respirators. However, barriers to use exist including a tested model for implementing EHMRs in a variety of health delivery settings as well as the availability of operationalized guidelines. Therefore, the National Institute for Occupational Safety and Health (NIOSH) sought to understand not only best practices for the integration and maintenance of EHMRs but also consistent barriers that are still impeding both user and organizational adoption of this type of respiratory protection. To aid this effort, Memorandums of Understanding were established among NIOSH, the Strategic National Stockpile (SNS), and a variety of health delivery settings that volunteered to participate in NIOSH demonstration projects after receiving EHMRs from the SNS. Participating organizations began to receive EHMRs in October 2021 and continue to receive them on a rolling basis.

Methods: The EHMR demonstration projects, currently underway, include opportunities for longitudinal feedback. Users can voluntarily complete pre-/post-surveys and organizations can voluntarily participate in initial-/mid-/post-interviews to share feedback about EHMR experiences, including barriers and benefits to use, updates made to their organizational respiratory protection programs, and other health and safety directives. This presentation focuses on initial interviews completed with organizations to date, which includes interviews with 50 individuals representing 28 organizations (eight hospitals, one dental clinic, and 19 first responder settings including fire, police, emergency medical services, and county health departments). Ranging from 21-65 minutes, the average interview time was 41 minutes. These interviews probed experiences with fit testing, disinfection, cleaning, storage, and perceived benefits and limitations of EHMRs specific to job types and work settings. The interviews conducted to date were thematically analyzed using the constant comparison method with an emphasis on technology acceptance constructs.

Results: This presentation situates the initial results within validated constructs that have been shown to hinder technology or product adoption (i.e., perceived usefulness and perceived ease of use). So far, subtle differences exist between healthcare and first responder settings that will be explored such as perceived protection offered by EHMRs, respirator comfort and design, and ease in appropriate cleaning and disinfection, especially as organizations increase their rollout efforts. Additionally, most organizations report a desire for manufacturer-specific resources and guidelines to share with their workforce, with that availability serving as a benefit or barrier to initial distribution.

Conclusions: Although interviews are ongoing, initial data analysis reveals useful themes from which to build for interviews moving forward and to eventually address in future EHMR design and implementation efforts. The results provide insights for manufacturers to consider not only in EHMR design but also in the development of complementary materials that come with the EHMR. Additionally, these results show areas of overlap but also highlight differences between healthcare and first responder settings that may need to be

considered when developing implementation guidelines that relate to organizational resources and support.

Submission ID: 35

Laboratory Assessment of Bacterial Contamination of a Sterile Environment when Using Respirators Not Traditionally Used in a Sterile Field Environment

Authors

Dr. Ziqing Zhuang - NIOSH NPPTL; Warren Myers, Segun Ajewole - West Virginia University; Susan Xu, Patrick Yorio, Adam Hornbeck - NIOSH/NPPTL

Abstract

Introduction: Healthcare workers typically wear surgical masks (SMs) that are cleared by the Food and Drug Administration (FDA) when a sterile field is needed such as in operating rooms (ORs). When respiratory protection for the worker is also needed, N95 filtering facepiece respirators (FFRs) approved by the National Institute for Occupational Safety and Health (NIOSH) that also meet additional FDA requirements (i.e., fluid resistance, flammability, biocompatibility) for use in a sterile field (surgical N95s) are worn. During infectious disease outbreaks or pandemics, there is an increased demand for surgical N95s that may create shortages and necessitate the use of alternative NIOSH-approved respiratory protective devices (RPDs) that do not meet the FDA's additional requirements.

Objective: The objective of this research was to quantify the level of bacterial contamination resulting from wearing NIOSH-approved respirators lacking the additional protections afforded by surgical N95s.

Methods: The study was conducted in a simulated OR. Eighteen participants were grouped into nine teams of two and performed simulated healthcare tasks while wearing five different NIOSH-approved respirators. The respirators included two N95 FFRs (one without an exhalation valve), an elastomeric half-mask respirator (EHMR), and two PAPRs. Sterile field contamination resulting from use of a surgical mask (SM) cleared by the FDA served as a baseline for comparison with the NIOSH-approved respirators. Contamination was determined by active biological sampling using sheep's blood agar plates. Collected samples were incubated and the resulting bacterial colony-forming units (CFU) were counted.

Results: The data analysis showed that the bacterial contamination produced by a pair of subjects wearing the N95 FFR without an exhalation valve, the PAPR with an assigned protection factor (APF) of 25, and the PAPR with an APF of 1000 was not significantly different compared to the contamination resulting from wearing the SM. The bacterial contamination resulting from wearing the N95 FFR with an exhalation valve and EHMR with an exhalation valve was found to be statistically significantly higher than the bacterial contamination resulting from wearing the SM.

Conclusions: Overall, NIOSH-approved RPDs without exhalation valves that do not have the additional FDA protections for use in ORs maintain a sterile field as well as a SM. These findings inform respiratory guidance on the selection of RPDs where sterile fields are needed during surgical N95 shortages.

Submission ID: 36

Robust measurement of particle filtration efficiencies: Evaluated quantities and experimental sensitivities

Authors

Dr. Timothy Sipkens, Dr. Joel Corbin, Dr. Gregory Smallwood, Dr. Andrew Oldershaw, Dr. Ian Leroux, Dr. Jalal Norooz Oliaee, Dr. Fengshan Liu, Dr. Thierry Lavoie, Dr. Triantafillos Koukoulas, Dr. Richard Green, Dr. Prem Lobo - National Research Council Canada

Abstract

Background. The COVID-19 pandemic has led to a resurgence of academic studies and new standards targeting respiratory protection. Studies and standards differ in the measured quantities, for instance, whether they employ size-resolved (mostly scientific studies), number-weighted (e.g., in the ASTM F2299 test method), or mass-weighted (e.g., in the NIOSH TEB-APR-STP-0059 test method) particle filtration efficiency (PFE). This work examines the aerosol principles underlying the associated measurements, providing a discussion of the different types of particle size (e.g., mobility and aerodynamic diameters), the differences between number- and mass-weighted PFE, and the sensitivity of these quantities to various experimental parameters.

Methods. Measurements are made with a custom-built system, the PFEMS, capable of measuring PFE as a function of particle size, and a pair of TSI 8130As, one of the standard instruments used in conjunction with the NIOSH TEB-APR-STP-0059 test method. Data spans several thousand samples, characterized over a year and a half period. Data also spans different challenge aerosols (NaCl and two kinds of latex particles), a range of face velocities, conditioned and unconditional samples, and varying levels of particle charge.

Results. The size-resolved measurements allow for conversion between number- and mass-based filtration efficiency, which allows for discussion of the non-trivial relationship between the two types of PFE. The number-weighted PFE is typically more conservative (smaller) for conditions relevant to PFE standards. Discussion of the important experimental parameters indicate the characteristics that must be constrained to develop robust standards, for example, mandating particle neutralization.

Conclusions. We conclude with consequences for standard developers and the researchers that support their development. Particle sizes should be reported clearly, in addition to the type of PFE being reported. Notes are made about a set of unifying characteristics that could allow for the universalization of test methods internationally, namely the use of neutralized NaCl at a fixed face velocity. Standards targeting specific use cases should then be separate from the test methods and help in translating standard test results to a given application (e.g., bioaerosols, dust, or forest fire smoke).

Submission ID: 40

Respiratory protection for Canadian Armed Forces members with headdress and/or beards Part 2: Powered-air purifying respirators for interim use in CBRN training

Authors

Dr. Paul Bodurtha - Defence Research and Development Canada; Prof. Eva Dickson - Defence Research and Development Canada and Royal Military College of Canada; Maj. Christian Doucet - Canadian Armed Forces; Dr. Steven Trepanier, Mulu Gebremedhin - Defence Research and Development Canada

Abstract

Background. The Canadian Department of National Defence (DND) and the CAF are in the process of developing inclusive solutions for respiratory protection for CAF users. The C5B project discussed in Part 1 aims to develop a non-powered accessory for CBRN training use for wearers with facial hair and/or headdress, as well as providing those individuals with hard to fit faces an alternate solution to ensure they have adequate respiratory protection. However this solution is more than a year from fielding, and the CAF is motivated to provide interim solutions as early as possible to facilitate recruiting and retention of diverse members, understanding that full operational solutions will take some time.

Like the C5B accessory, an interim solution must protect during tear gas training and be suitable for use during the remainder of field training activities. However, for the interim solution, the only requirement was that the solution permit recruits to be trained in as similar a manner as possible to recruits wearing in-service CBRN respirators. Therefore the solution was mandated to work for a user issued either the in-service C4 or C5 CBRN respirator. The option of providing these two respirators in a powered-air form was investigated for their ability to provide adequate protection, and for training procedures to be suitably adapted and implemented.

Methods. The respirator supplier (Airboss Defense Group) supplied an appropriate blower configuration to be used with each of the two respirators. This configuration was assessed for its ability to provide adequate protection in the powered air (PA) mode, in comparison with the non-powered (NP) mode, using simulated workplace protection factor (SWPF) testing of selected users with beards and/or headdress. An additional set of evaluations was performed in the gas hut to replicate user training, using bearded CBRN instructors with considerable training experience, in order to understand how training procedures could be modified.

Results. For SWPF testing, the users consisted of eight CAF members, four of whom wore religious headgear (patka, turban, hijab), six of whom were bearded, and one of whom was a female with no hard-to-fit features who fit the C5 respirator (control). While all wearers except the control failed the fit factor (FF) requirement of 10,000 in NP mode, all obtained a passing FF in PA mode. All obtained a SWPF of > 10,000 in PA mode. For gas hut testing, eight bearded individuals similarly obtained a passing FF and successfully passed through the gas hut in PA mode, with training procedures slightly modified to accommodate the PAPR configuration.

Conclusions. Individuals with beards and/or headdresses can successfully pass through the gas hut, when wearing either the C4 or C5 respirator, and having achieved a FF of at least 10,000, in PA mode. The interim solution should be further demonstrated in the gas hut for a larger group of representative users with headdress and other hard-to-fit features. The CAF is adopting the use of the PA configurations for basic training at the Canadian Forces Leadership and Recruit School and other related training and qualification activities.

Submission ID: 41

Improving surgical mask efficacy with 3D-printed frames

Authors

Ms. Nathalie Duponsel - Concordia University; Dr. Clothilde Brochot, Dr. Ali Bahloul – IRSST; Prof. Barbara Layne, Dr. Ann-Louise Davidson - Concordia University

Abstract

BACKGROUND: In 2020, COVID-19 created unique challenges for our society and masks became an essential part of our lives both N95 in health centers and surgical masks for everyday use. The increasing demand for respiratory protection equipment, combined with periods of shortage, has driven individuals and industries to seek alternatives, including homemade reusable masks and other equipment. Filtering facepiece respirators N95 (FFRs N95) are NIOSH-certified and provide at least 95% filtration efficiency. However, the available scientific evidence on the filtration performance and breathability of improvised materials used in homemade masks is limited, is sometimes contradictory, or designed without consideration of the specifics of SARS-CoV-2 virus. The aim of this study was to test the efficacy of 3D-printed mask frames fitted over certified surgical masks and KN95 respirators to determine if the frames can improve the efficacy of surgical masks and KN95 respirators during times of FFR supply shortages.

METHODS: Four models of 3D-printed mask frames fitted over three models of certified surgical and procedural masks and one certified KN95 respirator were quantitatively fit tested using the same equipment used for fit testing in hospitals (PortaCount 8038 from TSI). To act as a point of comparison, the results obtained from the mask frame and mask/respirator configurations were compared with an FFR N95. All configurations were tested on two participants.

RESULTS: Using the FFR N95 standard of a minimum fit factor score of 100 as the passing score, all masks and the KN95 respirator were able to achieve passing fit scores for both participants with at least one of the mask frame models while, with the exception of the FFR N95 respirator, all three masks and the KN95 respirator failed to achieve a fit factor score of 100 or above for both participants.

CONCLUSION: Results suggest that 3D-printed mask frames worn over certified surgical masks and KN95 respirators can produce fit factor scores similar to those of an FFR N95. Although these results are still preliminary, they show that the combination of a certified surgical mask or respirator and a frame may provide improved protection than wearing certified masks alone.

Submission ID: 43

Do Stockpiled Conditions Impact Respirator Performance?

Authors

Dr. Lee Greenawald, Dr. Susan Moore, Dr. F. Selcen Kilinc-Balci - CDC/NIOSH/NPPTL

Abstract

Background. Personal protective equipment (PPE), such as respirators and surgical gowns, are stockpiled in large quantities to protect over 18 million healthcare workers and other first responders in preparation for public health emergencies. Prior to 2020, much of the stockpiled PPE was purchased during previous public health emergencies (e.g., H1N1), leading to facilities nationwide storing PPE that 1) are in environments that do not meet manufacturer storage recommendations; 2) exceed their shelf life; or 3) do not have a shelf life. As a result, the viability of the nation's stockpiled PPE were unknown, and there was a need to fill this gap to inform distribution decisions. Stockpiling PPE best practices guidance is needed that considers purchasing, storage, rotation, quality assurance, replacement, and disposal of stockpiled PPE. The objective of this study was to explore the effect of stockpiling conditions on the performance of stockpiled respirators and surgical gowns. This presentation will focus on the evaluation of stockpiled respirators.

Methods. Between 2018 and 2019, NIOSH-approved N95 filtering facepiece respirators (FFRs) and Level 3 and 4 surgical gowns were sampled from 10 U.S. stockpile facilities ranging in inventory type, quantity, storage conditions, and geographic location. Environmental storage conditions data collection, PPE visual inspections, and laboratory performance testing were conducted, including non-stockpiled samples for each model. Over 4,300 stockpiled respirators from 12 models were collected, tested, and evaluated. For these respirators, filtration efficiency, inhalation/exhalation resistance, strap integrity, and fit using a panel of human subjects were evaluated.

Results. These results provide the first evidence that many respirator models kept under varying storage conditions (e.g., hot environments, stored 10+ years) retain their performance. Of the 3,971 stockpiled FFRs that were evaluated for inhalation/exhalation resistance and filtration efficiency, 3,895 (98%) continued to meet NIOSH performance requirements. Thirty-six FFRs from three models did not meet NIOSH performance requirements. When 293 stockpiled N95 FFRs from a single facility were evaluated for fit, product- and lot-specific differences between stockpiled and non-stockpiled respirators were found. Data for stockpiled and non-stockpiled surgical gowns indicated potential quality issues.

Conclusions. NIOSH published 12 PPE CASE reports detailing the findings of these respirator assessments (including performance, visual inspection, temperature, and relative humidity data), with the Level 3 surgical gown report forthcoming. The findings of this study will culminate in a NIOSH Stockpiling Best Practices Guide to assist stockpile managers, manufacturers, and regulators with evidence-based recommendations related to purchasing, storage, shelf life, rotation, quality assurance/testing, and disposal for respirators, surgical and isolation gowns, gloves, eye and face protection, surgical and procedure masks, and barrier face coverings. The surgical gown results highlighted the need for the scope of ANSI/AAMI PB70 to be expanded to include guidance for post-market quality assurance sampling and data interpretation for third-party entities.

Submission ID: 44

NIOSH Expands its CBRN Air-purifying Respirator Protection List: An Evaluation of Emerging Chemical and Radiological Threats

Authors

Dr. Lee Greenawald, Mr. Jonathan Szalajda - CDC/NIOSH/NPPTL

Abstract

Background: NIOSH-approved air-purifying respirators (APR) equipped with chemical, biological, radiological, and nuclear (CBRN) canisters provide protection against dozens of hazards that may be present in an emergency environment. In 2001, NIOSH and its partners conducted a hazard assessment to identify the most probable homeland CBRN threats which resulted in the identification of 139 CBRN hazards categorized into seven NIOSH chemical families, known as the NIOSH CBRN APR Protection List. NIOSH uses 11 test representative agents (TRAs) to test the protective ability of a CBRN canister. Since 2001, CBRN hazards have evolved in type, usage, and dissemination and thus it is critical that contemporary hazards are continuously identified and reviewed to ensure emergency responders are protected. In this effort NIOSH partnered with the Department of Homeland Security (DHS) and the Department of Defense (DoD) to determine if current NIOSH CBRN TRAs or chemical families need to be updated to ensure NIOSH testing is representative of emerging CBRN hazards.

Methods: Chemical and radiological hazards were first identified by reviewing five recent DoD and DHS risk-based hazard assessments relevant to emergency responders. A systematic evaluation process was developed to assess each identified hazard, including: (1) evaluating its chemical and physical properties; (2) evaluating its actual or anticipated filtration behavior within the CBRN canister; (3) categorizing it into one of NIOSH's Chemical Families; and (4) comparing it against the existing TRAs in its respective Chemical Family to determine if the current TRA needed to be replaced with the new hazard. Laboratory testing was then conducted to verify the protective capabilities of CBRN canisters against several chemical and radiological hazards.

Results: A total of 238 hazards (192 chemicals and 46 radiologicals) were identified including some hazards previously identified in 2001. Of the 238 hazards, 207 hazards were grouped into one of the existing NIOSH Chemical Families. These hazards were added to the existing 2001 NIOSH CBRN APR Protection List, bringing the total to 286 hazards on this list. Twenty-five hazards were not categorized due to being too unstable in the emergency responder operational environment (e.g., they decompose quickly) or required further testing and evaluation to confirm their categorization into a NIOSH Chemical Family. Six hazards underwent additional testing, with NIOSH determining it was appropriate to categorize these six hazards within the existing seven NIOSH Chemical Families.

Conclusions: NIOSH CBRN TRAs continue to be representative of the newly identified hazards and should remain the basis for NIOSH CBRN respirator approval testing; no updates to NIOSH's Statement of Standards are needed at this time. However, because of the described evaluation, NIOSH has expanded its original CBRN APR Protection List of 139 hazards to 286 hazards to combine previously and newly identified hazards. The results will provide confidence to the nation's emergency responders that NIOSH-approved respirators with CBRN canisters continue to provide the necessary protection against the latest identified chemical and radiological threats. Additionally, a standardized methodology was developed

for conducting future CBRN hazard assessments, which will be highly valuable to future researchers across federal agencies.

Submission ID: 45

A National Strategy for Promoting Equitable Personal Protective Equipment Protections for all U.S. Workers

Authors

Dr. Susan Moore, Dr. Patrick Dempsey, Dr. Tyler Quinn, Dr. Katherine N. Yoon, Mr. Mathew Duling, Ms. Crystal Forester, Dr. F. Selcen Kilinc-Balci, Dr. Adam Smith - CDC/NIOSH/NPPTL

Abstract

Background. In 2019, the National Institute for Occupational Safety and Health (NIOSH) announced its initiative to achieve diversity, equity, and inclusion (DEI) in the NIOSH workforce, workplace, and beyond. As part of this initiative, NIOSH will promote DEI in its hiring, research, interventions, and services to reflect the solutions needed for the full spectrum of the U.S. workforce.

Methods. NIOSH is developing a national strategy to provide equitable personal protective equipment (PPE) protections for all U.S. workers that considers PPE use, availability, accessibility, acceptability, and knowledge. This national strategy will address gaps and challenges by identifying and prioritizing goals into near-, mid-, and long-term efforts. It will further provide a roadmap and timelines for how members of the PPE community can work in complement to systematically address the identified gaps and challenges. As the national leader in PPE**,** NIOSH's National Personal Protective Technology Laboratory (NPPTL) will coordinate across the PPE community to: 1) document the existence and characteristics of gaps and challenges related to equitable PPE protections; 2) identify and organize collaborators; 3) identify viable solutions and approaches to address gaps and challenges; 4) establish a prioritization framework for meeting gaps and challenges; 5) identify and describe roles for members of the PPE community and establish participant buy-in as needed; and 6) establish a roadmap with timelines, linkages to PPE community member roles, and metrics for success.

Results. To achieve meaningful results, it is essential that NPPTL scopes step one of this effort. Potential ways to scope include focusing on specific PPE user populations, types of PPE, hazards, sectors, occupations, or issues that span multiple areas. It is further crucial to have a robust mechanism for organizing members of the PPE community, which will be accomplished through a NIOSH Partnership for Equitable PPE Protection. Finally, meaningful results are also only possible if innovative and viable solutions are provided for the identified problems—NPPTL is leveraging crowdsourcing tools, communications with potential Partnership members, information received from a Federal Register Notice, and is also exploring other mechanisms such as workshops and symposiums.

Conclusions. This presentation allows members of ISRP an opportunity to engage in discussion with NPPTL regarding its proposed six-step process. It will further provide ISRP members with an opportunity to self-identify as being interested in participation in the partnership and to propose innovative approaches to identifying viable solutions to identified challenges. The eventual national strategy will lay the groundwork for a coordinated effort across PPE community members towards a shared goal of providing equitable PPE protections to all U.S. workers.

Submission ID: 46

An analysis of three-dimensional head anthropometric data to select respirators for Korean users

Authors

Dr. Jung-Keun Park, Mr. Se-Dong Kim, Mrs. Hyoun-Min Cho, Ms. Eunji Lee – ISRP Korea section

Abstract

Background: Prior to establishment of face dimensions database and development of respirator fit test panels in a large project, it was vital to initiate a preliminary study. The aims of this study were to examine and explore the elements of Size Korea's 6th 3D head anthropometric database and to provide basic information for the selection of respirators in Korea.

Methods: This was a pilot study for the first year of work in a two-year-project undertaken at KOSHA in 2021. 3D head dimensions data were obtained from the Size Korea Center managing the Size Korea 6th 3D national anthropometry survey databases. The 3D head dimensions data, including 45 dimensions, were used in line with ISO standards (e.g., ISO/TS 16976-2) for examinations, comparisons, statistical analyses, etc.

Results: A total of 3,088 subjects were investigated in this study. The main features were: Male subjects constituted 52.5%; the highest percentage age group was 15-29 at 36.7%; unhealthy weight group based on BMI was 31.7%; and survey area was the capital region. For the 6th 3D head dimensions data with 45 items, the means and standard deviations for 'Face length' were 115.9±7.5 cm for males and 107.3±6.9 cm for females respectively while those for 'Face width' item were not available since there was no such item in the data. Numerous findings were discussed accordingly.

Conclusions: This study showed that there were likely requirements for improvements in the 6th 3D head anthropometric data as follows: Standardization of Korean and English terms; addition of head dimensions items missed in the Size Korea survey; and reliability of generalizability for subjects, suggesting that the study results can be used for further studies or improvement of respirator selection in Korea.

Submission ID: 47

Enhanced Duration SCBA

Authors

Mr. Hans Almqvist - Createc LLC

Abstract

Background. The Open-Circuit SCBA has been used for almost a century in the fire service world-wide and contributed to keeping firefighters safe and enhancing their performance. Several improvements have been made over the years; filling pressure has been increased to reduce the size of the SCBA, new cylinder materials have contributed to lower weight, positive pressure breathing has been introduced to improve the protection factor, electronics have been utilized to improve safety and efficiency, etc. However, the breathing pattern is still the same as one hundred years ago. All the exhaled air is vented to the surroundings, including the air that has not participated in the oxygen/carbon dioxide exchange in the lungs. It is the purpose of the presented concept to change the breathing pattern with the goal to make the SCBA more efficient.

Concept. With every breath we take, about 0.2 liter of the exhaled air comes from the mouth and trachea having not entered the lungs for the oxygen/carbon dioxide exchange, consequently being possible to re-breathe. If a breathing mask with valves is used, the amount of re-breathable air increases. In average, 0.4 -0.5 liter of exhaled air has full oxygen content and is free from carbon dioxide. By capturing the unused air in a reservoir and re-using it for the next breath, the air consumption can be substantially reduced.

By re-using the air as described and always keeping the gas concentrations within acceptable limits it is estimated that the Duration/Weight (D/W) ratio for a SCBA can be increased by 50-100%, compared to present technology, depending on the degree of electronics sophistication.

A human pilot test with a laboratory prototype without any advanced electronics has been performed at Duke University, NC, USA, and an increase in D/W ratio of 30% was recorded.

Purpose. The fire service is in charge when it comes to the choice of rated service time of the SCBA used and the work time selected for the firefighters. What manufacturers can do is to increase the options. The following is a citation from an Illinois Fire Service Institute report:

“If extended duration SCBA are to be utilized, it is recommended that the work-rest cycles typical of the 30-minute SCBA still be followed (and the extra air considered reserve) instead of relying on the End of Service Time Indicator to indicate time to exit the structure”

Conclusion. It is well known the present 30-minute rated SCBA lasts 15-20 minutes in firefighting and the 45-minute SCBA lasts less than 45 minutes. The new techology can give the firefighter more duration and extra reseve in case of getting trapped or disorientated, without increased weight. As an example it can offer a true, in contrast to rated, 30-minute SCBA with extra reserve in case of emergancy, without increasing weigth compared to currently used 30-minute rated SCBA.

Submission ID: 49

Consideration of a Tiered Approach to Respiratory Protection for Emergency Workers Responding to a Nuclear/Radiological Incident

Authors

Armin Ansari, Adela Salame-Alfie, Frieda Fisher-Tyler – US National Council on Radiation Protection and Measurements

Abstract

Background - After a large-scale nuclear/radiological incident, it is anticipated that a large population will be displaced and evacuated. This population can be externally contaminated with radioactive material from direct deposition or resuspension of radioactive materials. The contaminated, but otherwise uninjured, population may report to public shelters or other mass care facilities to receive contamination screening, decontamination, housing, referral, or other types of public health services, and they could pose a potential inhalation hazard to staff or volunteers who are providing these services. Many of these emergency workers may not already be part of an established occupational respiratory protection program. This constitutes a gap in guidance that could cause a delay in provision of critical public health services to the affected population.

Methods - The National Council on Radiation Protection and Measurements (NCRP) is a scientific body, chartered by the United States Congress, with a mission to formulate and widely disseminate information, guidance, and recommendations on radiation protection and measurements which represent the consensus of leading scientific thinking. The NCRP convened the Scientific Committee 3-3 to examine existing guidance for respiratory protection of emergency responders and propose a practical approach to address the health and safety needs of this group of emergency workers who are not already part of an occupational respiratory protection program. The scope of work excludes first responders (firefighters, law enforcement, emergency medical services) as well as first receivers (clinical staff at hospitals) for whom adequate guidance is already available.

Results - In the context of the hierarchy of controls, use of personal protective equipment, including respiratory protection against inhalation hazards, should be considered as the last option after every effort is made to eliminate the hazard or mitigate it through implementation of engineering and administrative controls. Respiratory protection standards and guidelines that are suitable for occupational exposure scenarios will be difficult to immediately implement for all emergency workers who will be called upon to interact with and provide services to potentially contaminated people. Unlike the medical response to mass casualties or crises, there is currently no equivalent provision for “crisis standards of care” when it comes to addressing the health and safety needs of this group of emergency workers. Lack of guidance and potential confusion about acceptable approaches to protect the health and safety of these individuals can impede emergency response operations. Lack or delay in provision of these services may significantly increase morbidity and mortality in the affected population.

Conclusions - To address the health and safety needs of this group of emergency workers in a manner that is commensurate with limitations and circumstances imposed as a result of a large public health disaster, the NCRP is considering a tiered approach to providing respiratory protection to emergency workers that is comparable to the Crisis Standards of Care established by the National Academies of Sciences, Institute of Medicine, for provision

of medical care in response to catastrophic disasters such as that caused by natural disasters, terrorist incidents, or pandemics.

Submission ID: 51

Differences in fit of N95 respirators by face size

Authors

Ms. Huiju Kim - Shinhan University, Prof. Hyekyung Seo,Mr. Hoyeong Jang, Ms. Sua Shim, Mr. SungWook Park - Shinhan University

Abstract

Background: Following the prolonged corona virus 2-19 (COVID-19) pandemic, wearing a mask has become a daily routine. However, wearing a mask that does not fit the size of the face, leakage may occur. This greatly decreases the effectiveness of a mask, leaving one vulnerable to exposure to infectious diseases. Therefore, the purpose of this study was to investigate the differences in N95 respirators fit by face size.

Methods: The face length and the width of 50 participants (male, n = 25; female, n = 25) of various age groups were measured using a sliding and spreading caliper. As no test panel is available in Korea, cells of 1-3, 4-7, and 8-10 were classified as small, medium, and large, respectively, compared to the internationally recognized US NIOSH test panel. OSHA new protocol (4 exercise) fit factors (FFs) was calculated using Portacount Pro+®(model 8038, TSI, U.S) after wearing N95 mask (DOBU MASK 201 N95, DOBU LIFE TECH Co., Ltd. Korea). Pass/Fail criteria for determining were set to FF 100. Data were analyzed through t-test using SPSS system ver. 20 (IBM SPSS Inc.USA).

Results: The overall face size of the participants was slightly skewed to the lower left corner of NIOSH Test panel with one person having measured values outside of the range. The mean FF for small face in 1-3 cell was 110.88, which was significantly different from the mean FF of 74.31 for medium face in 4-7 cell (p=0.083). Only two participants had a large face in 8-10 cell, and were excluded from analysis. Therefore, the experimental mask available in one size had a higher FF for small faces than medium faces.

Conclusion: The results of this study show that wearing a mask with the right size for the face is essential to prevent various infectious diseases.

Submission ID: 53

The Inherent Variability of Count-based Measurements of Respirator Fit

Authors

Mr. Andrew Viner - 3M

Abstract

Background. A key characteristic of count-based measurements of steady state processes is that the frequency distribution of counts can be described by a Poisson distribution, wherein the variance of a measurement is equal to the mean. Assuming a given fit test exercise can be described as a steady state process, then the expected variability of the measured fit factor can be calculated from first principles. From a single measurement of respirator fit it is possible to estimate the 95% confidence interval of that fit value. The confidence interval can also be used to determine whether two separate measurements of fit are truly different from each other.

Methods. A mathematical model was developed establishing the relationship between Overall Fit Factor, fit factors for each individual exercise, the concentration of particles in the ambient air during the fit test, the flowrate of air through the detector element, the number of exercises in the fit test, and the duration of the measurements of particle concentration in the ambient air and inside the respirator. A propagation of errors method coupled with Poisson statistics were used to estimate the variance of the fit factors from individual exercises, as well as that of the Overall Fit Factor. The 95% confidence intervals were estimated based on the calculated variances.

Results / Conclusions. For a given set of operating conditions, the precision of a measured fit factor decreases with increasing fit factor. Under most operating conditions, the confidence interval at the fit factor limit is small. In other words, the inherent variability of the count measurements will have little effect on either the alpha or the beta error. The widest confidence intervals occur at the highest fit factors. Depending on the conditions of the measurement, a fit factor of 100 measured with a low concentration of ambient particles can actually range from 90 to 110. A fit factor of 100,000 can range from 80,000 to 120,000.

Applications and limitations of the model are also discussed.

Submission ID: 55

Needs and Challenges in Personal Protective Equipment for Underserved User Populations: Responses to a Federal Register Notice (June–October 2021)

Authors

Dr. Katherine N. Yoon, Dr. Maryann D'Alessandro, Dr. Patrick Dempsey, Dr. Susan Moore, Dr. Tyler Quinn - CDC/NIOSH/NPPTL

Abstract

Background. As part of implementing an initiative towards equitable personal protective equipment (PPE) protections for all workers, the National Institute for Occupational Safety and Health (NIOSH) is expanding its portfolio to include activities that specifically consider the needs and challenges of United States worker populations that are underserved in relation to PPE use, availability, accessibility, acceptability, and/or knowledge.

Methods. During June 24–October 15, 2021, NIOSH's National Personal Protective Technology Laboratory (NPPTL) opened a federal register notice (FRN) to collect information from the public on the needs and challenges of underserved PPE user populations. NPPTL announced this FRN via social media and emails to industry, labor, academia, and manufacturer partners. To clarify the objective of this initiative, the FRN provided examples of underserved PPE user populations such as workers who: (1) are of an atypical size; (2) are members of a gender, racial, ethnic, or linguistic minority group; (3) conduct non-traditional activities on the job; or (4) are members of sub-disciplines that are not the primary focus of the current PPE activities within their larger field. The responses NPPTL received were analyzed to identify key issues/themes, underserved PPE user populations, industry sectors, and occupations that are impacted.

Results. A total of 39 responses were received. The largest percentage of responses came from private entities including manufacturers, healthcare organizations, and safety consulting and management professionals (41%), followed by professional associations/advocacy groups (31%), academia (15%), and government (13%). PPE size, fit, availability, and accessibility issues were the most frequently identified needs and challenges. Other challenges identified included language barriers, lack of training opportunities, and cognitive/behavioral issues. The most frequently identified underserved groups were workers of atypical size, female workers, and/or racial/ethnic minorities (Asian, Latinx/Hispanic, and African American). Construction, manufacturing, public safety, and healthcare were the most frequently mentioned sectors in the responses.

Conclusions. Diverse members of the PPE community from various sectors and occupations responded to the FRN. These responses will inform NIOSH's National Strategy for Equitable PPE Protections for all US Workers, intended to identify the needs and challenges of underserved PPE user populations. This presentation provides conference participants an opportunity to learn about the underserved user population challenges revealed, discuss the challenges, and explore the causes of these challenges identified in the FRN.

Submission ID: 63

Size-specific Filtration Efficiency and Pressure Drop of School-aged Children's Woven and Nonwoven Masks

Authors

Solbee Seo, Conor A. Ruzycki, Warren Finlay, Dan L. Romanyk, Andrew R. Martin - University of Alberta

Abstract

Background. The US National Institute for Occupational Safety & Health's (NIOSH) certification procedure for non-powered particulate masks has been used to test the filtration efficiency (FE) of masks and respirators. The flow rate used during the procedure, 85 L/min, is based on a minute volume for adults under high workload, while children typically breathe with lower flow rates. Flow rate (more generally, face velocity, v_f) is known to affect filtration through various physical mechanisms. The objective of the present work was to evaluate children's masks using a v_f typical during children's high workload and to compare with results obtained at a higher v_f corresponding to the NIOSH procedure.

Methods. A custom-designed setup with an Electrical Low Pressure Impactor (ELPI+; Dekati Ltd., Finland) similar to the setup in Seo et al. (2021)[1] was used to measure FEs at different v_f. Pressure drops (ΔP) and size-specific FEs were measured for particle aerodynamic diameters between 0.02 and 2.01 μm. The surface area (SA) of adults' masks was approximated as 150 cm^2, while the SA of children's masks was averaged as 141 cm^2 based on the nine brands used in this experiment. An average inhalation flow rate of 33.7 L/min was assumed for children (6 to 11 years old) during high workload based on the previous literature. Resulting v_f of 9.4±0.1 cm/s for adults and 4.0±0.0 cm/s for children were achieved by exposing a portion of each mask. Three different groups were used: control (one brand of adult N95 respirator), children's woven masks (two brands of cotton-based and three mixed-materials masks), and children's nonwoven masks (one KN95 respirator and three brands of surgical masks). Four samples were tested for each combination of v_f and mask brand.

Results. The minimum FE across all particle sizes was influenced by v_f for two of the three mask groups, increasing from 97.8% (high v_f) to 99.1% (low v_f) for the N95 respirator, and from a range of 82.9 to 92.6% (high v_f) to a range of 91.6 to 95.8 % (low v_f) for the four nonwoven masks. In contrast, for the five woven masks, the minimum FE was unaffected by v_f, with a range of 6.5 to 21.5 % for high v_f and a range of 6.4 to 22.7 % for low v_f. The trend of lower FE for woven compared to nonwoven masks was consistent throughout all particle sizes tested. At the lower v_f, all three mask groups had a decrease in ΔP such that filter quality ($\ln(1/(1-FE))/\Delta P$) increased by 2 to 3 times compared to the higher v_f.

Conclusions. FEs measured for the three mask groups were higher at the lower v_f representative of school-aged children, while ΔP were lower. These effects led to higher filter quality for all mask groups at the lower v_f. In terms of FE across all particle sizes tested, nonwoven masks consistently outperformed woven masks.

Reference

[1] Seo et al.: Size-Specific Filtration Performance of N95 Respirators after Decontamination by Moist Heat Incubation. J. Aerosol Med. Pulm. Drug Deliv. 2022;35(1):41-49. DOI: 10.1089/jamp.2021.0002

Submission ID: 65

Filtration characteristics and effective lifetime of an electret filter with intermittent use

Authors

Ms. Jiyul Lee, Ms. Kyeongeun Lee, Ms. Hanjou Park, Ms. Jooyoun Kim - Seoul National University

Abstract

As the concerns about the COVID-19 are increasing, various preventative measures are suggested to respond to COVID-19 transmission. Among them, wearing a mask is a rational way to combat the coronavirus. Public users often use masks repeatedly with recurrent storage during the day or for an extended period of time. This study explored the effect of recurrent storage temperature and humidity on the filtration performance during the intermittent and repeated exposure to sodium chloride aerosol. The structural characteristics and charges of a filter media were analyzed to associate the intermittent performance.

In this study, a scenario was planned to mimic the practical application of intermittent and repeated use of masks. If a 250 cm^2 mask is used in a harsh particulate concentration of 300 $\mu g/m^3$ for 10 h with 30 L/min of inhalation rate (face velocity of 2 cm/s), a total mass of 22 µg/cm aerosol would be challenged to the mask every day. Based on this, the mass loading of 2.2 mg sodium chloride aerosol was challenged to the 100 cm^2 filter media for 37 days. Then, the storage conditions were applied to filter media: 1) 40 ℃, 75% RH; 2) 40 ℃, ~0% RH; 3) 90 ℃, ~0% RH. The sequence of aerosol exposure and storage was conducted at an interval of 24 h. For analysis of charge decay and internal structure of filter media and particle morphology, surface potential measurement, X-ray computed tomography and SEM were performed.

With the recurrent heated storage, the filter media became fluffier because of the relaxation of internal stress, and this led to a lowered a mechanical filtration efficiency during the intermittent use. The repeated storage at high temperature even caused the fiber breakage, and the weakened filter media could not stand the weight of deposited mass. A humid storage significantly deteriorated the filtration efficiency because hygroscopic particles quickly wetted the surface and masked the surface charges. This study provides an informative discussion on the effect of storage conditions on the filter morphology and performance in practical use scenarios.

Submission ID: 67

Source-control mask provides significant wearer protection, accommodates underserved populations, and is reusable

Authors

Dr. Paul Baglin, Ms. Chris Baglin, Mr. Axel Bawor – tensARC; Dr. Ngozi Amaeze, Dr. Mia Burleigh, Dr. Claire Chalmers, Dr. Chris Easton, Dr. Fiona Henriquez, Dr. William "Gordie" Mackay - University of the West of Scotland

Abstract

Background. Reusable masks are needed for respiratory protection from hazards such as pathogens, other bioaerosols (mold, allergens), ash (wildfire, volcanic), dust (construction, agricultural, dirt roads, sandstorms). The pandemic highlighted unmet needs by race, sex, and other factors. Chopra J., et al. The influence of gender and ethnicity on facemasks and respiratory protective equipment fit: a systematic review and meta- analysis. BMJ Global Health 2021;6: e005537.

Research was conducted to design a reusable mask providing two-way protection from respiratory hazards utilizing common materials and low-tech manufacturing. Initial design parameters prioritized source control and leak mitigation, evaluating the whole mask as a barrier to hazards. This approach drove R&D to produce a quality cloth mask that performs consistently across all face shapes.

Methods. To create a two-way barrier, we sought to optimize the seal wherever the mask meets the face. A tubular shape gave a stronger, more consistent seal using a pliable fabric that conforms to the face. We pinpointed points of failure by visualizing outward leakage using traceable aerosols and lasers, quantified leaks in both directions for wet and dry aerosols using particle counters and used this information to enhance seal design.

To design for both high filter performance and high breathability using stable common fabrics, we increased the filter's surface area by 200% to reduce air velocity and utilized a plenum internally to moderate peak airflows. The oversize filter is embedded permanently for protection and stability; a 3D warp knit material was chosen to increase the length of the flow path, enhance filtration by impaction and provide durability over 100s of washes.

The product's tubular shape avoids the uneven contours of the nose and mouth, so jaw movements do not disrupt the seal. Deformable foam fills concave areas between the nose and cheekbone with a positive seal. This enables an excellent, universal fit for a larger range of face types, e.g., small-boned and/or non-European features, and for other populations whose concerns, e.g., fogging eyewear, hearing aids, breathing difficulties, are underserved.

Results. Sample results follow.

Breathability (ASTM 3502-21). Filter A: <1.7mm H_2O. Filter B: <4.9mm H_2O

PFE (ASTM 3502-21). Filter B: 94.1% (1 wash); 96.5% (50 washes)

BFE (BS EN14683). Filter A: 99% (100 washes)

Whole mask (edge and filter penetration, ambient aerosols 0.3-0.5um, tidal breathing): Filter A: <4%

Laundering. Filter A: >4 log (99.99%) log reduction in bacterial load, domestic machine washing at 40 ^{O}C and 60^{O}C, meeting BS EN14683 for cleanliness.

Durability. Filter A: 2% drop in whole mask performance after 200 washes.

Conclusions. A mechanistic approach was used to design, develop, and prepare for mass-manufacture, a reusable, recyclable, highly breathable tubular shaped mask (“facegaiter”) and its safety, handling, and care instructions. This approach inherently mitigates leakage and provides an effective fit and seal suitable for a broad range of face shapes, accommodating some underserved populations. Future work will study the user experience and validate leakage control for a large cohort of wearers while, currently, independent tests show >95% filtration performance after extensive washing.

Submission ID: 68

3D Modeling of Head Forms Representing Japanese Facial Features for Adequate Respirator Fit Testing

Authors

Hiroki Haruta - KOKEN LTD.

Abstract

Respirator fit is essential in respiratory protection for respirator wearers and it is reported that respirator fit is significantly affected by wearers' facial characteristics. In the US, a new fit test panel (NIOSH-PCA panel) using a principal component analysis of the facial dimension data of U.S. workers has been developed. Also newly created head forms (3D digital models) were designed based on five categories of facial features in the NIOSH-PCA panel (Small, Medium, Large, Long-Narrow, Short-Wide) have been proposed to the International Organization for Standardization (ISO) as a new evaluation tool for respiratory protection. Since the facial features of US and Japanese workers were considered to be different, we investigated in our previous study the applicability of the NIOSH-PCA panel to Japanese facial shapes and reported that the plot distribution of PC scores calculated from Japanese facial dimensions was not uniform, and it was hard to observe differences in individual facial shapes on the NIOSH-PCA panel. Thus, using the same techniques for creating the NIOSH-PCA panel, we also developed a PCA panel for Japanese (Specified PCA panel for Japanese) that better represents the characteristics of the Japanese facial shape based on the facial dimension data of Japanese subjects. In this study, using homologous models obtained from 3D scan data of Japanese subjects in the Specified PCA panel for Japanese, we conducted 3D modeling of head forms representing Japanese average and various facial features (size and shape) shown in the each category of the PCA panel. It was found that the average head form model showed details of facial features of human face, and it represented the standard size and shape of Japanese faces since the plot of PC score of the average model was located near the center of the panel. Therefore, the average model can be a standard model that enables better evaluation of respirator fit as compared with conventional JIS head form. Moreover, since 4 models representing each size and shape category in the PCA panel were modeled by a simulation method using difference vectors between opposing categories, these models emphasize detailed facial features of each category as their plots of PC scores were located near 2σ boundary line. These 3D models obtained in this study represent various facial features found in real Japanese faces and are considered to be available for more adequate evaluation of respirator fit.

Submission ID: 69

Biomechanical and physiological evaluation of respiratory protective equipment application

Authors

Dr. Silvia Caggiari, Prof. Dan L. Bader, Dr. Peter R. Worsley - University of Southampton

Abstract

Background: Respirators are designed to fit tightly against the face to create a seal to protect individuals from airborne particles. However, their design is not suitable for all users to the variability in face shape across genders and ethnicities. Accordingly, they are regularly overtightened to compensate for a poor fit, resulting in high non-uniform pressures, which can lead to damage to the underlying skin and soft tissues of the face (Abiakam, 2021). Recent studies have examined the relationship between facial dimensions and goodness of fit (GoF) in different sub-populations, identifying specific facial measures that may predict fitting outcomes (Manganyi, 2017). However, there is limited knowledge of the association between GoF and markers of skin health. This motivated the present study, which investigates pressure, microclimate and biophysical markers of health at the skin-respirator interface.

Methods: Eight volunteers were purposefully recruited to reflect a range of age, gender, and ethnic backgrounds, with institutional ethical approval. A scan of each individual face was taken with a 3D scanner (GoScanner, Creaform), which was imported into a modified version of the python module AmpScan (Verberne, 2020) to estimate four facial anthropometrics, namely, facial length, alar and bio-ocular width, dorsal nasal length. Four single use commercial respirators were chosen to reflect different geometries, sizes and material interfaces. Participants were asked to wear each respirator in a random order for a period of 20min while interface pressure was measured at two investigation sites, namely nasal bridge and right maxilla. Temperature and relative humidity inside the respirator were also recorded. Biophysical measures of skin barrier function (TEWL) and hydration were taken pre- and post-respirator application, and after a 20min of recovery. Statistical analysis assessed differences between respirator designs and evaluate associations between demographic, biomechanical and biophysical parameters.

Results: Results show a statistically significant negative correlation ($p<0.05$) between the alar width and interface pressures at the nasal bridge, for three of the respirator designs (Fig. 1A). This implies that the wider noses attributed to the non-Caucasian participants resulted in lower interface pressures. Temperature and humidity significantly increased ($p<0.05$) during each respirator application. Markers of skin health, namely TEWL values, revealed statistically significant increases after the application of the respirators, which were most apparent at the nasal bridge (Fig. 1B). Such changes in skin barrier properties and hydration differed between the respirator designs.

Conclusions: This study used an array of objective parameters to determine the biomechanical and physiological interactions between the skin and a single use respirator. The results revealed specific facial features affected the distribution of interface pressures and depending on the design and material; changes in skin barrier function were also evident. The development of standard test methods is required to assess the impact of long-term respirator use and the design considerations should accommodate a diverse range of facial features and skin tolerance levels while optimising the GOF.

Acknowledgements: This work was supported by UK Research and Innovation as part of a funded project “A Bio-Engineering approach for the SAFE design and fitting of Respiratory Protective Equipment” (EP/V045563/1).

Submission ID: 70

Animatronic Headform Evaluation of Face Coverings Used by First Responders in the COVID-19 Pandemic

Authors

Melissa Armistead, Anuja Dandekar, Marc Mathews, R. Bryan Ormond - North Carolina State University

Abstract

First responders are on the front line of the COVID-19 pandemic, placing them at higher risk of exposure. Supply shortages made it difficult to obtain traditional respiratory protection and alternative products such as surgical and cloth masks have been sought out. These products can provide variable efficacy depending on the material properties, fit to the face, and environment in which they are worn. Current testing and standards evaluate these products at the material level or as a sealed product, which does not account for the impacts of fit or dynamic wear. An animatronic headform was used to evaluate the total filtration efficiency and breathing resistance of commercially available face coverings. Each test cycle consisted of separate five-minute static and dynamic segments with a sinusoidal breathing sequence while a polydisperse NaCl aerosol was generated inside the chamber. Total filtration efficiency was calculated from the differential particle counts recorded inside and outside the sample. A modified version of this test cycle was repeated to determine breathing resistance from the differential pressure during exhalation. The headform test was able to successfully differentiate between products. Higher filtering products generally had higher breathing resistance. The N95s maintained consistently high performance. The surgical masks showed moderate filtration and variable breathing resistance that can be attributed to poor fit. Both increased when an external bracket was used to improve the seal. Cloth face coverings generally had the lowest efficiency, although material selection and design could improve performance. Alternative products can provide some degree of filtration, however they are not replacements for certified respirators. Material, fit, and design should all be considered when selecting products for use in the field based on the perceived risk. The headform test may be adapted in the future to evaluate other respiratory threats faced by first responders.

Submission ID: 71

Respiratory protection effect of disposable type dust respirators and non-medical face masks using non-woven fabric

Authors

Dr. Yukiko Iida - Environmental Control Center Co., Ltd.; Mr. Takuya Iwamoto - Kuraray Kuraflex Co., Ltd.; Mr. Toshiyuki Toyoguchi - Environmental Control Center Co., Ltd.; Prof. Narufumi Suganuma - Kochi University

Abstract

Objective. The objective of this study was to provide quantitative information for appropriate selection and use of masks to control infection, such as COVID-19. We examined the leak rates of disposable type dust respirators and non-medical face masks using human subjects before and after instructions for wearing masks.

Background. Due to the epidemic of COVID-19 that has been ongoing since December 2019, the evaluation of the respiratory protection effect is being required even for masks used in the general environment for infection prevention. In the research on industrial respiratory protective devices (RPDs), it is recognized that the respiratory protection effect of RPDs changes depending on the facial features of the wearer, the wearing method, and the movement when donning it. However, there are few research reports on non-medical face masks that evaluate their respiratory protection effect, including the viewpoints mentioned above.

Method.

Masks: Three types of disposable type dust respirators and ten types of non-medical face masks with non-woven fabric.

Subjects: Nine subjects (one woman, eight men), aged 22-36 years.

Fit test method: Using a Mask Fitting tester MT-05U^{TM} (Shibata Science Co., Ltd, Japan), air sampling in the masks was performed using the push-on-ring method. The leak rate was measured while performing eight movements (breathing normally, deep breathing, turning head side to side, moving head up and down, talking, grimacing, bending over, breathing normally). Furthermore, measurements were taken before and after instruction for wearing masks. Additionally, the filtering efficiency and pressure loss of the filter were measured to confirm the mask-specific performance.

Results. Based on the results, the measured leak rate of disposable type dust respirators A~C improved 3.8 to 5.9 times after instruction for wearing masks. Moreover, the respiratory protection effect of non-medical face masks D~M with non-woven fabric improved 1.1 to 1.7 times after instruction for wearing masks. It was suggested that instruction for wearing masks have a greater effect on disposable type dust respirators. The leak rate of masks A〜C after instruction for wearing masks was 2.1~17.9%, and the average leak rate was 12.0%. The leak rate of masks D~M after instruction for wearing masks was 24.7~73.7%, and the average leak rate was 49.8%. Differences were found in the respiratory protection effectiveness depending on the product, even in the category of non-medical face masks with non-woven fabric.

Submission ID: 76

Comparisons of fit factors between two quantitative fit testers

Authors

Prof. Don-Hee Han - Inje University; Prof. Hyekyung Seo - Korea section; Mr. Hoyeong Jang, Ms. Huiju Kim, Ms. Sua Shim - Shinhan University

Abstract

Background: This study evaluated the consistency required by the American National Standards Institute (ANSI) and the correlation of fit factors (FFs) between two quantitative fit test (QNFT) devices with different methods of aerosol counting.

Methods: Three respirators (N95 filtering facepiece respirators (FFR), half mask, and full facepiece) were worn by 50 participants (male, n = 25; female, n = 25), PortaCount® (Pro+ 8038) and MT® (05U) were connected to one probe in a Y-shape to one mask, and FFs were measured simultaneously with the original and modified protocols.

Results: As a result of comparing MT® FFs with PortaCount® FFs as references and by applying the pass/fail criteria of the Occupational Safety and Health Administration, the consistency between the two devices for half masks and full facepieces was very high. N95 FFR was somewhat weaker than the half mask and full face piece in the consistency required by ANSI; however, the correlation between the two devices was very strong (p-value < 0.0001).

Conclusions: The study suggests that the pass criteria for N95 FFR by MT®-05U in the modified protocol (four exercises) should be 75.

Submission ID: 79

Healthcare Worker User Acceptance and Tolerability Ratings of CleanSpace Halo Respirators Over Time

Authors

Dr. Eileen Zhuang - Division of Pulmonary & Critical Care Medicine, University of Maryland Medical Center; Dr. Hegang Chen - Dept of Epidemiology & Public Health, University of Maryland School of Medicine; Dr. Stella Hines - Division of Occupational & Environmental Medicine, Division of Pulmonary & Critical Care Medicine, University of Maryland School of Medicine

Abstract

Background: Reusable respirators, such as elastomeric half-mask respirators and powered air-purifying respirators, found greater use in healthcare settings during the COVID-19 pandemic. However, healthcare workers (HCWs) may find features such as size and bulk unappealing or disruptive. A novel reusable respirator, the CleanSpace Technology Halo, combines a clear, tight-fitting face mask harnessed to a positive pressure powered air supply with HEPA filtration, without belts or hoses. User acceptance of this new device has not been assessed systematically during routine clinical use.

Methods: Between May and July 2021, we recruited a convenience sample of HCWs at five sites within a US academic medical system, where Halo respirators were in routine clinical use. Subjects completed an initial survey (week 0) which included the Respirator Comfort, Wearing Experience, and Function Instrument (R-COMFI), a validated survey designed by the National Institute for Occupational Safety and Health to assess comfort and tolerability of N95 filtering facepiece and prototype respirators. Its three subscales - Discomfort (score 0-20), General Wearing Experience (0-12), and Function (0-15) - give a total score of 0-47. Higher scores indicate greater discomfort and less tolerability. Subjects were invited to complete subsequent surveys containing the R-COMFI tool at week 4 and week 8. Differences in total R-COMFI and subscale scores over time were analyzed using mixed regression models adjusting for covariates such as work unit, job type, age, experience, and frequency of use. We hypothesized that scores would improve over time as HCWs became familiarized with the respirator.

Results: Of 113 HCWs who completed the initial survey, 49 HCWs completed the week 4 survey, and 42 completed the week 8 survey. Subsequent survey completers were 74% female, 54% under 35 years old, and 56% with ≤ 9 years healthcare work experience. They included 48% registered nurses, 22% physicians, 18% respiratory therapists, and 12% other job categories. 34% worked in the emergency department, 34% in dedicated COVID-19 units, and 32% in other units. The mean R-COMFI score of HCWs who completed subsequent surveys was 8.9 at week 0, 9.8 at week 4, and 9.0 at week 8. The mean subscale scores at week 0, week 4, and week 8 were 3.6, 4.4, and 4.9 for Discomfort; 0.5, 0.6, and 0.5 for General Wearing Experience; and 4.8, 4.8, and 4.6 for Function. There was no significant difference in R-COMFI total score ($P = 0.52$), or in the Discomfort ($P = 0.22$), General Wearing Experience ($P = 0.95$), or Function ($P = 0.92$) subscales, over time.

Conclusions: HCWs rated the novel Halo respirator favorably using the R-COMFI instrument at several points over time. Ratings did not significantly change when assessed 4 and 8 weeks after the initial survey. Characteristics of initial and subsequent survey responders were similar. Our results suggest that HCWs' favorable perception of the Halo respirator remains stable over time. This study occurred when the Halo respirator had been in

use for several months at these sites, so future studies may evaluate whether ratings change over time when assessed earlier during respirator implementation.

Submission ID: 80

Mask wearing time and changes in microbial growth

Authors

Mr. Hoyeong Jang, Prof. Hyekyung Seo, Ms. Huiju Kim, Ms. Sua Shim, Mr. SungWook Park, Prof. Young-Il Kwon - Shinhan University

Abstract

Background: Although the use of masks has increased due to the global pandemic of corona-virus 19 (COVID-19), the repeated and long-term use of masks has become an important health problem. Re-use of masks leads to contamination, which increases the risk of adverse health effects. The purpose of this study was to assess the increase in the growth of microorganisms inside masks with the extended wearing time of masks.

Methods: A total of 25 participants (9 males and 16 females) were asked to wear masks for a different amount of time: less than 2 hours, 2–4 hours, and 4–6. A questionnaire was used to assess mask change cycle and wearing time. The masks used by the participants were inoculated on culture medium to measure the number of bacterial colonies formed (CFU). Changes in microbial growth were analyzed through staining and microscopy. Data were analyzed using SPSS system ver. 20(IBM SPSS Inc. USA).

Results: One (4%), one (4%), and 23 (92%) participants wore the mask for less than four hours, four to eight hours, and more than eight hours, respectively. Masks from those working in hospital laboratories who talked more with patients had more bacteria inside the mask compared to the masks from other participants. The number of bacteria increased with wearing time and was significantly correlated with laboratory ($p=0.044$), followed by outpatient environment ($p=0.061$).

Conclusion:The number of bacteria increased with mask wearing time. In particular, there was a significant difference in the number of bacteria after more than four hours of use. The inside of the mask has a warm temperature and humid environment suitable for the growth of microorganisms due to mouth breathing, and the growth of microorganisms increased after more than four hours of use. The results of this study suggested the importance of promoting the awareness of changing masks for safe use.

Submission ID: 81

Use of Elastomeric Half-Face Respirators during the COVID-19 Pandemic in Healthcare Settings in British Columbia, Canada

Authors

Rita Ciconte - Fraser Health Authority; Joseph Tio, Jesse Cooper - Vancouver Coastal Health Authority

Abstract

Background. At the beginning of the COVID-19 pandemic, supplies of N95 respirators globally quickly depleted. Locally, demand for respirators outstripped warehouse stock, and supply chains were unable to keep up with demand. To alleviate this pressure, healthcare workers within the province of British Columbia, Canada from high N95-usage departments were provided, fit tested and trained on reusable elastomeric half face respirators (EHFRs) to use in lieu of disposable N95 respirators.

Methods. To enable widespread, rapid deployment of EHFRs, the following steps were taken:

- The highest N95 usage departments were identified and prioritized for EHFR deployment;
- A cleaning and reprocessing system for EHFRs was established to ensure staff had a supply of clean respirators for use;
- Workflow for overall EHFR usage, including pick/drop off, transport, and decontamination were developed with/communicated to end users, medical device reprocessing departments, transport staff;
- Widespread fit testing and training on EHFR use;
- The risk of the exhalation valve in pathogen transmission, as staff would be beside immunocompromised and other vulnerable groups. A Literature Review on source control requirements was conducted, finding limited evidence for or against the use of EHFRs within healthcare settings.
- Ongoing tracking of EHFR reprocessing numbers and resolving usage issues (eg. source control);
- User feedback surveys on staff perceptions and use of EHFRs are reported here from one regional health authority

Results. EHFRs were successfully deployed across the province of British Columbia. Between March 2020 and July 2021, over 250,000 EHFRs were reprocessed, resulting in a sizable decrease in the use of N95s. This was enabled by having the medical device reprocessing department transition from reprocessing medical instruments to respirators. Longer term, however, this was untenable due to increasing workload from other medical device reprocessing demands. So staff were given personal respirators that had to be cleaned by the user after each use.

Feedback on the use of EHFRs were generally positive with users indicated they enjoyed how secure and protected EHFRs feel in comparison to N95 respirators. Others were fond of the reduced environmental impact of having a reusable respirator. However, the most common drawback to using the EHFRs was reduced speech intelligibility and communication, such that some departments discontinued their use. Comfort was a mixed parameter, with some users preferring EHFRs to N95s, while others experienced strong

discomfort and even pain after donning it for short times. Overall a majority of staff indicated they would be interested in the continued use of EHFRs.

Conclusions. The use of EHFRs throughout the past two years have shown that EHFRs can be used successfully within the healthcare settings. However, persistent challenges include concerns regarding ease of cleaning, source control, speech intelligibility, and comfort.

Submission ID: 82

Changes in filtration efficiency according to mask wearing time

Authors

Mr. SungWook Park, Prof. Hyekyung Seo, Mr. Hoyeong Jang, Ms. Huiju Kim, Ms. Sua Shim, Prof. Young-Il Kwon - Shinhan University

Abstract

Background: Mask use has become mandatory due to the corona virus 2019 (COVID-19) pandemic. To prevent the spread of COVID-19, the quarantine authority recommends wearing health-care face masks (N95, KF94, KF80) than dental or cotton masks. Herein, this study assessed changes in the filtration efficiency of masks according to increase in mask wearing time.

Methods: A total of 45 participants were recruited from the general public in multiple facilities, school environments, and office environments without age and sex restrictions. To assess changes in the filter function according to the wearing time, filtration efficiency meter (Filtration Efficiency, Filter tester 8130A, TSI, USA) using NaCl test particles was used. KF94 (Dobu Life Tech Co., Ltd.) was used in this study, and filtration efficiency was measured after wearing the three masks provided at work for two, four, and six hours. ANOVA was conducted to assess changes in dust collection over time.

Results: The mean filtration efficiency in office environments was 96.2% after two hours of wearing the mask, 96.6% after four hours, and 95.7% after six hours. In multiple facilities, the mean filtration efficiency was 96.6%, 97.3%, and 96.6% after two, four and six hours of wearing the mask. In school environments, the mean filtration efficiency was 98.8% after two hours, 97.7% after four hours, and 97.9% after six hours. However, no statistically significant changes were observed ($p>0.05$).

Conclusions: Talking during work will lead to increased secretion of saliva and flow of air. In addition, it was expected that the filter would be separated as one touches the mask to adjust the fit after prolonged use and that the filtration efficiency would subsequently decrease from 95.4%. However, all masks used in this study maintained the filtration efficiency above the certification regulations. After use, the filtration efficiency slightly increased, which may have been due to clogging effects. These results suggest no changes in mask filter function after prolonged wearing of masks.

Submission ID: 83

Correlation of fit factor in two inspections devices according to differences in method

Authors

Ms. Sua Shim, Prof. Hyekyung Seo, Mr. Hoyeong Jang, Ms. Huiju Kim, Mr. SungWook Park - Shinhan University

Abstract

Background: In South Korea, many individuals complain of leakage as wearing a mask has become mandatory due to the corona virus 2019 (COVID-19) pandemic. ISO(International Standards Organization) recommends that workers undergo a fit test to minimize leakage. In this study, the correlation of fit factor (FF) was studied using different methods of CNC and OPC.

Methods: A total of 50 university students (25 males and 25 females) regardless of the age, excluding those with lung diseases who could not wear masks, underwent fit test using Portacount Pro+®(model 8038, TSI, U.S) (CNC method) and MT® (model 05U, SIBATA, Japan) (OPC method). Full facepiece (6800 Full Facepiece Reusable Respirator 6800, 3M, USA), half facepiece (Half Facepiece 7502, 3M, USA), and N95 mask (Dobu 201 N95, Dobu Life Tech Co., Ltd.) were used. A probe plugged into the respirator was connected to Teflon tube in a Y-shape, and FF was calculated through both CNC and OPC methods. The correlation between the two devices was analyzed using interclass correlation coefficient (ICCs).

Results: The level of agreement between CNC and OPC methods was high for full and half facepieces (half facepiece ICCs=0.88). In contrast, for N95 mask, the level of agreement between the two methods was low compared to that for full and half facepieces (Original Protocol ICCs=0.76/Modified Protocol ICCs=0.65). FF was measured lower using OPC device than using CNC device.

Conclusion: The difference in FF between the two methods may be attributed to the particle counting method. OPC method counts a smaller number of particles compared to CNC method, which may lead to lower FF value. Therefore, follow-up studies must be conducted by using the same particle conditions between the two methods.

Key word: Fit test, Fit Factor, Mask fitting tester, CNC, OPC

Submission ID: 87

PAPRs in the Pandemic Hospital

Authors

Mr. Cade Hines - CleanSpace

Abstract

During the COVID pandemic, the number of PAPRs in use in hospitals around the world increased by many thousands. This roll out necessitated the rapid development of strategies for cleaning, disinfection, distribution, and source control. Before COVID, many hospitals were unsure how they would clean and disinfect PAPRs. During (and in some cases immediately before) the pandemic, many hospitals developed cleaning and disinfection protocols. We report on several of these methods and their effectiveness. Some of the disinfectants and cleaning chemicals used proved to cause damage to PAPRs and while some hospitals could use alternative procedures, in most cases it was the material or construction of the PAPR that had to be modified. We report on these material robustness issues. Later in the pandemic, attention switched from the risk of transmission from patient to nurse or doctor and towards the need for source control (filtering of the exhaled air). The requirement for source control affects different types of PAPR in different ways and few have been successfully certified. In addition, the standards that normally govern PAPRs (EN 12942 and 42 CFR Part 84 amongst others) do not include tests that fully characterise an exhalation filter. We discuss the technical challenges posed by exhalation filters on PAPRs, some approaches that have been found effective and some additional standards that can provide useful assurance of an exhalation filter's utility.

Submission ID: 89

Workplace Protection Factors for Workers with and without Facial Hair Wearing a PAPR

Authors

Mr. Alex Virr, Ms. Tiffany Beeson - CleanSpace

Abstract

This presentation reports on a pilot study of workplace protection factors (WPF) offered by a close-fitting PAPR in staff with and without facial hair while performing their normal work tasks in their normal work environment.

A total of 12 workers in three independent workplaces participated in the study. Of these, three were considered "clean shaven" while the other 9 subjects sported facial hair (light stubble to full beards).

All subjects wore close-fitting PAPRs with either a half or full-face mask and commercially available activity/heart rate monitors. The level of protection provided was measured using a TSI PortaCount device, together with batteries, a tablet PC and supporting electronics, all carried in a small backpack.

Thus equipped, all workers were able to perform their normal duties, which included walking / climbing to inspect equipment, carrying out repairs, cutting stone and assembling benchtops. Only one task, normally carried out at one of the sites, was not possible while wearing the backpack. This was crawling under a crusher screen to inspect it. Work sessions were recorded by observation, photographs, or video depending on site policy and interviews were conducted to confirm tasks and work effort. Exertion rates were classified according to ISO 8996:2004.

Each study participant carried out two 25-minute work sessions. Before the first session, they had to don the equipment themselves. Between sessions, they were required to doff and re-don their respirator. Study participants were familiar with the use of CleanSpace PAPRs and most had a minimum of 6 months experience with the devices prior to the study. CleanSpace staff were onsite to conduct fit-testing and ensure the mobile PortaCount system functioned correctly.

Workplace Protection Factors were measured for each minute of each work session. Both Power-ON and Power-OFF fit tests were also performed before the participants started work.

The study highlighted the complexity of gathering data in a real workplace and many of the factors that are known to complicate such a study (low and variable ambient dust levels, participants coughing or suffering mishaps of various sorts during their work sessions) were experienced. Care had to be taken to ensure that each data point gathered was legitimate and not affected by peculiarities of the work site, the work pattern, or the measuring equipment.

Nevertheless, a substantial data set was collected and it showed, contrary to received wisdom, that good levels of protection were provided to all participants, including those with facial hair. Details of these results are provided. Some analysis of the mode of operation of a PAPRs is provided to explain why this result should not have been entirely unexpected. A comparison is made between the results of the study and the assigned protection factors from various international standards. Plans for a proposed larger study are discussed.

Submission ID: 90

Themed Session - The work of HSE's PPE Task Force during COVID-19

Authors

Mrs. Helen Beattie, Mr. Duncan Smith - HSE

Abstract

During the COVID-19 pandemic, the supply of personal protective equipment (PPE) to the National Health Service (NHS) had to be significantly increased. In March 2020, to accommodate the European Commission recommendation on "*conformity assessment and market surveillance procedures within the context of the COVID-19 threat*" (2020/403), the HSE PPE Task Force was set up to meet the increased level of PPE Market Surveillance Authority (MSA) activities.

Working with the Department of Health and Social Care (DHSC), and in collaboration with the Medicines and Healthcare products Regulatory Agency (MHRA), the team applied their expertise in human exposure management, infection control and PPE to develop COVID-specific Essential Technical Requirements for a range of different PPE devices, including eye/face protection, respirators, gloves and isolation gowns. Products were assessed against this document, and the relevant EN standards.

The Task Force rapidly evaluated PPE compliance with relevant British Standards and the EU PPE Regulation 2016/425. This involved ensuring that the PPE was correctly conformity assessed by Notified Bodies and satisfied the performance requirements needed for use by healthcare workers during the COVID pandemic.

An estimated several hundred new and novel suppliers have been supported, enabling the supply of billions of items of PPE.

As well as the rapid facilitation of supply, the team identified items that did not meet standards and stopped ineffective PPE from entering the supply chain through a combination of product safety enforcement and safety alerts, for example the "KN95".

In addition, extensive training on PPE has also been provided to NHS purchasing and technical assurance teams. Team specialists and their expert knowledge has also fostered innovation with many non-traditional manufacturers setting up to make PPE.

Submission ID: 91

Roles for Data and Data-Analysis in Respiratory Protection

Authors

Mr. Alex Virr, Dr. Alex Birrell, Mr. Alex Maunder - CleanSpace

Abstract

A modern PAPR measures many parameters of its own performance and its user's breathing, every second. Analysis of these data - without the need for additional sensors or measuring equipment - has been shown to permit the assessment of the protection factor being offered with surprising accuracy. Further experiments and calculations bearing on "on-board fit" are presented, together with other observations of the usefulness of an "app" that allows users to carry out checks on their device, get feedback on how well it is protecting them and learn about how to use it. A second type of app, which allows multiple users to check, in real time, their protection factor and battery level is also discussed, together with privacy issues that have to be addressed in developing such platforms.

Submission ID: 92

Physiological Effects of N95 by Age According to Exercise Intensity

Authors

Ms. Sulbee Go, Ms. Yeram Yang, Prof. Chungsik Yoon - Graduate School of Public Health, Seoul National University, Seoul, Korea

Abstract

Objective. As the coronavirus disease 2019 (COVID-19) pandemic continues, many health authorities recommend wearing facepiece filter respirators (FFRs) in public places; some even make it mandatory. There are several concerns about the burden of wearing an FFR and the resulting physiological indicators. The purpose of this study was to evaluate the physiological effects of FFRs by age and various exercise intensities, and to determine the effects of deadspace, which is the internal volume of air between the FFR and the surface of the skin.

Methods. A total of 28 participants were recruited and divided into three age groups: children (n = 10), young adults (n =10), and older adults (n = 8). Studies were conducted with participants wearing no mask (control), and three different designs of N95s –cup-shaped (Cup), flat-folded (FF), and an FFR with an exhalation valve (Valve). Participants performed cardiopulmonary exercise testing (CPET) on a treadmill according to the modified Bruce protocol. During the test, various physiological effects (respiratory frequency (Rf), minute ventilation (VE), carbon dioxide production (VCO_2), oxygen consumption (VO_2), heart rate (HR), metabolic equivalents (METs), percutaneous oxygen saturation (SpO_2), and the participant's perceived exertion were measured.

Results. Rf, VE, VCO_2, VO_2, METs, and HR increased in all exercise sessions, but there was no difference in results between the control and FFR types. Differences in the participants' perception of their amount of exertion in the presence or absence of wearing a mask were only mild.

Conclusions. For daily activities and short-term exercise, wearing an N95, even at high intensity, has little physiological effect.

Submission ID: 93

Development of a Proof of Concept Respirator Lens Fog Test Chamber

Authors

Cody Kendig - Chemical Biological Center

Abstract

Lens fog is a common issue experienced by wearers of full-facepiece air-purifying respirators (APR) which can impede the wearer's ability to perform their job accurately and safely. Most commonly, this fog occurs when the wearer is working within a cold-weather environment, or in hot-humid environments. The temperature differential across the lens, and the high humidity environment contained within the facepiece lead to ideal conditions for condensation to begin to form. As fog forms within a respirator, the effective field of view decreases, leading to performance degradation for visually demanding tasks. As such, a common element of respirator certification programs is a standard test procedure that evaluates a respirators resistance to fogging effects.

In the case of the National Institute of Safety and Health (NIOSH) full-facepiece APR fog determination test procedure No. CET-APRS-STP-CBRN-0314, human subjects are required to don the respirator, enter a walk-in freezer, and conduct a series of visual acuity tests and exercises to the best of their ability. All measurements are subjective, qualitative, and reliant on the human test subject's opinions and observations.

The ultimate goal of the development of a proof of concept respirator lens fog test chamber was to eliminate the subjective human element, and provide a repeatable, objective measure of lens fogging. This would provide a method that could potentially be used to obtain consistent results for a respirator across individual laboratories without the need for the introduction of the human variable.

The test system consists of a temperature-controlled freezer, containing a heated metal headform which is capable of simulated breathing of heated humidified air, and contains a camera mounted behind the right eye. The freezer contains a visual target set across from the head-mounted camera. To conduct a test, a respirator is donned upon this headform, and the internal camera takes images of the visual target as seen through the respirator lens at set intervals. Custom software compares these images to a set of calibration photos taken through a variable diopter lens set at known, diopter values to determine the magnitude of blurring caused by the fog buildup on the respirator lens. Additionally, this software compares the average pixel brightness of each image to a baseline photo through an unfogged lens as a secondary metric to characterize the fog buildup.

Submission ID: 96

Analysis of the Performance of Medical Masks

Authors

Anuja Dandekar, Melissa Armistead, Marc Mathews, Mark Gaskill, R. Bryan Ormond – North Carolina State University

Abstract

Medical face masks have been used primarily in healthcare settings for many years as a means of source capture. Over the course of the pandemic, the use of these masks has expanded into the general public. With a number of manufacturers creating these masks, the performance levels may vary. A set of 13 masks were selected for testing based on varying levels of performance by ASTM F2100. The preconditioned samples were tested using an animatronic headform to determine the total filtration efficiency and breathing resistance. Material level assessments were also conducted for filtration efficiency and air permeability in accordance with ASTM D737. It was found the majority of masks fell within the range of 40-60% total filtration efficiency with a breathing resistance of 25-37 Pa on the animatronic headform. At the material level, the filtration efficiency range fell between 85-98%. The air permeability range was also between 25-40 CFM with one outlier at 95 CFM. With further analysis, there was little to no correlation between the material level test and the headform system-level test for filtration efficiency. The lower filtration efficiency at the system level was likely due to the fit of masks causing leakage around the sides of the face, nose bridge, and under the chin.

Submission ID: 97

Proposal of New APFs for PAPRs with Half Mask Facepiece and Face-Shield through SWPF Study

Authors

Yoshimi Matsumura, Naoyuki Iijima, Yohei Fujimori - Technology Institution of Industrial Safety (TIIS); Isao Kuniya - 3M Japan lnnovation Ltd.; Makoto Noguchi, Hiroshi Yamada - Shigematsu Works CO., Ltd., Shoichi Higuchi, Hisashi Yuasa, - Koken Ltd.

Abstract

A simulated workplace protection factor (SWPF) study was performed with two types of PAPRs, the half-mask facepiece type and the faceshield type, all of which were certified by the Japanese government. This study aimed to explore higher assigned protection factors (APFs) for these kinds of PAPRs than those given by OSHA (50 for half-mask facepieces and 25 for face shields). The protocol for SWPF consisted of the 12 motions as reported by H. J. Cohen, et al. (2001) with and without two additional motions added for this study. The sample PAPRs were 3 types of a half-mask facepiece from Manufacturer A, 3 types with a half-mask facepiece from Manufacturer B, and 5 types of a faceshield from Manufacturer C. The l2 test subjects with male and female persons for each PAPR sample were chosen among the manufacturers' employees.

The SWPF test was performed at four laboratories: one at TIIS and the others at Manufacturers A, B and C. The fundamental equipment in these four laboratories were a test chamber with a volume between $4m^3$ and $7m^{3,}$ and aerosol counters with a sensing range wider than 6×10^5 by CNC counter or laser photometer. The test aerosol was NaCl in the laboratories of TIIS, Manufacturers B and C and polyethylene glycol in the laboratory of Manufacturer A.

At the TIIS laboratory, the SWPF tests were managed by the TIIS staffs with l2 subjects from the manufacturer of the sample PAPR. The SWPF study for one sample gave l44 PF values corresponding to the l2 motions and l68 PF values corresponding to the l4 motions. At each manufacturer's laboratory, multiple PAPR samples, including those tested in the TIIS laboratory, were tested with the same protocol and the same subjects adopted in the TIIS test. For each set of l44 or l68 PF values, the 5th percentile was determined and corrected with l/25 as the safety factor from which to derive the experimental APFs according to the scheme shown by H. J. Cohen et al.

The results showed that the experimental APFs ranged from l,893 to 5,929 for the PAPRs with ha1f-mask facepieces and from 840 to 5,776 for the PAPRs with face shields. Significant interlaboratory differences between TIIS and Manufacturers A, B and C were not found in the observed experimental APFs. The protocols of SWPF with l2 motions and l4 motions also showed no significant difference in the experimental APFs . Considering various factors lowering PF in practical uses at work, we determined that 300 is a very safe practical APF for the PAPRs with half-mask facepieces and faceshields. This APF value should be attached to PAPR products only after the manufacturer has confirmed it using the same method as above.

Submission ID: 98

The ISO Technical Specifications for Chemical-Biological-Radiological-Nuclear Respiratory Protective Devices

Authors

Dr. Simon Smith - CSA Standards Committee

Abstract

The International Organization for Standardization (ISO) exists to facilitate international coordination and unification of industrial standards. Its programme to create performance standards for respiratory protective devices is now largely complete. This project included generation of specifications for filtering and breathable gas supplying respirators for protection from Chemical, Biological, Radiological, and Nuclear (CBRN) hazards and, in the course of work, new performance criteria were added for respirators for workplace and emergency needs for radiological-nuclear (RN) hazards.

Development of these specifications proceeded over nine years with a committee of over fifty participants from fifteen countries.

There are very few national standards for CBRN or RN respirators, and so these new documents bring opportunities to support a wide user and manufacturer community with standardized definition of performance requirements. Target user groups include police, fire and emergency medical services, primary health care (first receiver), search and rescue, sampling teams, and workers with specific roles during response, as well as workers and emergency responders in nuclear plants. Content was developed in consultation with representatives of such agencies; existing standards were reviewed, and some characteristics carried over, as familiarity confers confidence in the new standard.

Proposed CBRN protection requirements augment those of other types of respirators in the ISO standard series, and include three levels of protection to address:

- First on-scene responders in an unknown environment,
- On-scene responders in a characterized environment,
- First receivers remote from an incident,

as well as CBRN escape devices for the regular workforce.

The CBRN specifications follow the principles used for development of ISO standards, which are based on human performance protection requirements, but there are some unique additions:

- Features to enable simple logistical choices for responders – such as use of the ISO standardized connector between system components, so that the same type of filters to be used directly on facepieces and on powered air devices.
- Test methods: verification of breathable gas supply, or filtration of a representative range of multiple gas/vapour types, plus:
- Requirements for radioactive methyl iodide filtration to demonstrate performance towards hazards from nuclear reactor accidents.
- Permeation tests addressing protection from aggressive agents, including a new concept for permeation testing of non-metallic cylinders.

An expert sub-group was convened to provide input on needs in workplaces and emergencies use involving radiological-nuclear materials. Laboratory studies were undertaken:

- Verification that elastomeric materials are not subject to methyl iodide permeation at concentrations two orders of magnitude above recorded exposure levels.
- Development of a test method and specification in conjunction with a commercial laboratory for filtration efficiency of radioactive methyl iodide.

“RN” requirements can be combined with industrial gas capabilities to serve the needs of laboratories in various roles in the nuclear industry.

The outcomes of the extensive working group activity are specifications defining performance criteria for CBRN- and RN-capable respiratory protective devices and for escape systems as part of the ISO respiratory protective device standard, which will serve the needs of emergency responders for years to come.

Submission ID: 99

A combined 3D imaging and registration methodology to assess the goodness of fit of respiratory protective equipment

Authors

Dr. Silvia Caggiari - University of Southampton; Dr. Bethany Keenan, Prof. Sam Evans - Cardiff University; Prof. Dan L. Bader, Dr. Peter R. Worsley - University of Southampton

Abstract

Introduction: Tight-fitting respirators such as disposable FFP3 types, rely on a good seal around the nose and mouth to effectively protect the user from inhaling harmful particulates. Respirators are often selected following a fit testing process to identify the most appropriate device for the user. However, current respirator designs provide a limited range of size and geometry [TUC, 2017]. This can result in poor fitting outcomes, particularly in women and minority ethnic groups [Green et al 2021]. There is a critical need to characterise the goodness of fit (GoF) in an objective manner. This study adopts a novel methodology to evaluate the GoF of a respirator using a combination of imaging and registration algorithm. In addition, it aims at identifying quantitative parameters to objectively characterise facial tissue deformation and GoF parameters.

Methods: An MRI-based methodology was developed to estimate soft tissue deformation during a single use respirator application for a group of healthy volunteers (n=10). The corresponding deformation of the internal geometry of the respirator was characterised using MicroCT, while it was attached to a 3D printed head model. This data were used to corroborate a predicted respirator alignment, deformation and displacement algorithm, using a modified version of the Ampscan GUI [Verberne et al 2020], which was initially tested on a cohort of 15 individuals. The resulting registration shape depicts the respirator - facial skin distance. Three GoF parameters were estimated namely, the percentage of respirator surface which both gaps from the skin (>0mm) and indents the skin (< -3 mm) and the resulting area which provides an adequate seal (range -3 to 0 mm). In addition, facial anthropometrics including facial length, alar and bio-ocular width, and dorsal nasal length were estimated. Respirator deformation was then compared to values estimated from pre- to post- loaded MRI scans (Fig. 1).

Results: Maximum soft tissue deformation estimated using MRI was shown to be ~5mm. The alignment and magnitude of deformation was shown to be similar in the predicted AmpScan models. Results revealed a statistically significant correlation ($p<0.05$) between the percentage of respirator surface area providing an adequate seal and the alar width (Fig. 2). Close examination of the cohort revealed higher values of adequate seal corresponding to the Caucasian participants in the study and clusters with respect to ethnic groups.

Conclusion: This study used a combination of imaging and alignment algorithms to characterise the GoF of a single use respirator. The predicted fit was shown to be comparable with deformations estimated from MRI scans. The results revealed that specific facial features were related to GoF with clusters identified according to the inherent alar widths, which varied with ethnicity. The development of an intelligent fitting software could be used to support respirator selection and identify new design features, which can accommodate a diverse range of face geometries.

Acknowledgements: The research was funded by the Engineering and Physical Science Research Council (EPSRC, EP/V045563/1).

Submission ID: 102

Finite element modelling of respirators interacting with the soft tissues of the face

Authors

Prof. Sam Evans, Dr. Bethany Keenan - Cardiff University; Dr. Silvia Caggiari, Dr. Peter R. Worsley, Prof. Dan L. Bader - University of Southampton

Abstract

Background. Poor fit of FFP3/N95 respirators can lead to leakage, discomfort, or facial injuries. The mechanics of a respirator interacting with the face are complicated as both can deform substantially and this deformation is difficult to measure or predict. Computational modelling offers the possibility of greater insights into the mechanics of respirator fit and allows estimation of tissue strains within the soft tissues under the device.

Methods. A typical bifold respirator mask (GVS FFP3) was modelled using the FEBio finite element package (www.FEBio.org). Dimensions were obtained by direct measurement and the mask mesh was constructed in GMsh (GMsh.info) and imported into FEBio Studio. A rigid head form based on the small NIOSH head form was modelled. The surface mesh was down-sampled using MeshLab (www.MeshLab.net). Subjects were scanned with a Siemens 3T Prisma MRI scanner and deformable models of the soft tissues were created using Simpleware ScanIP (Synopsys, Inc).

Results. Initial results show that the respirator may be unstable and can sit in multiple different positions on the face, some of which permit leakage. This corroborates the importance of reproducing the mask position after a fit test. The curvature of the face is important for a flexible mask and leaks are likely to occur in flat or concave areas such as under the chin, the cheeks, and either side of the nose. Correctly bending an aluminium nose strip to obtain a proper seal in this area is difficult, both in the model and in real life, with over-bending required to compensate for spring back of the metal strip.

Conclusions. Modelling respirators is challenging due to large deformations and instability. However, it gives valuable insights into the mechanics of device fitting and the causes of leaks and discomfort. It also has the potential to allow simulation and preclinical testing so that the design of masks can be optimised to fit many different faces without expensive, time-consuming trial and error testing.

Acknowledgements: this project is funded by UKRI / EPSRC (EP/V045563/1).

Submission ID: 105

Evaluating facial soft tissue deformation through 3D imaging

Authors

Dr. Bethany Keenan, Prof. Sam Evans, Prof. Stephen Richmond - Cardiff University

Abstract

Background: Skin and soft tissue injuries related to the use of respiratory protective equipment (RPE) have been very common, particularly in females or those with smaller face shapes. Current designs for RPE are outdated and have solely been centred on a white male workforce, providing a limited range of size and geometry [TUC, 2017]. The use of a 'standard' male face shape in the manufacture of RPE has meant that most women as well as men from black and minority ethnic groups or with facial hair have experienced problems in finding suitable and comfortable RPE. To the best of the authors' knowledge, there have been no studies to date that have utilized Magnetic Resonance Imaging (MRI) techniques to measure the facial soft tissue deformation with different types of masks.

Methods: An MRI compatible head phantom was designed and 3D printed in order to identify which FFP3 respirators were MR safe for the volunteer. The head phantom was also used to capture the surface geometry of the RPE respirators using microCT. A high-resolution 3D MRI sequence was developed to clearly identify the anatomical face geometry in an unloaded (without a respirator) and loaded (with a respirator) state for a group of healthy volunteers. All volunteers were quantitively fit tested prior to their MRI examination and each underwent several MRI scans with different types of FFP3 respirators. The supine MRI scan was registered with a surface scan of the participant in an upright position in order to assess the impact of gravity of the facial soft tissue with an FFP3 respirator.

Results: Ten participants were recruited for this study, with a mean age 30.8yrs, height 1.70m and weight 72.3kg. The fit test results showed that the Easimask FSM18 and Handanhy 9632 were a good fit for 60% of participants compared to only 10% successful fit for the GVS F31000. Larger than expected deformations of the facial soft tissues, up to 10mm, were observed. Gravity flattened the cheek soft tissues up to 3mm in supine during the participants MRI scan (Figure 1).

Discussion: Optical scanning provides an estimate of respirator fit and / or injury, but is limited, as you cannot see the tissues beneath the respirator. MRI gives valuable insights into soft tissue deformation beneath the respirator, not visible with optical scanning. Digital volume correlation is currently being used to extract the soft tissue deformation from the MRI data. This study is part of a larger study that aims to inform international testing standards.

Acknowledgments: This project is kindly funded by UKRI / EPSRC (PR/V045563/1).

Submission ID: 106

Rapid Design of HCH-40, in Response to the COVID-19 Pandemic– The Development of a Non-Invasive, 'One Size Fits All' CPAP Hood.

Authors

Mr. Dominic Leatherland, Mr. Nick Hunter - Avon Protection

Abstract

March 2020 saw the outbreak of COVID-19 in the United Kingdom (UK) and across the globe. With the number of confirmed cases and deaths skyrocketing each day. Governments worldwide were forced to enter a state of emergency and enforce lockdowns, whilst the National Health Service (NHS) became overwhelmed and was at breaking point.

After academics at University College London (UCL) discovered the NH15 Escape Hood, they approached Chemical, Biological, Nuclear and Radioactive (CBRN) respiratory protection industry leaders, Avon Protection on 6th April 2020. After discussions about adapting the NH15 CBRN escape hood for medical use. The Product Development (PD) team at Avon Protection were tasked with rapidly developing and potentially manufacturing a Continuous Positive Airway Pressure (CPAP) hood; in response to the shortage of medical equipment, ventilators and hospitals struggling with demand for oxygen. It was here when the HCH-40 (Healthcare-Hood, 40mm ports) was born.

This was a unique opportunity, as Avon Protection had no prior experience with medical products and had never collaborated with academia to develop or test a product. Especially in such desperate and unprecedented times. It was therefore essential for the PD team to quickly understand CPAP treatment, and the rigorous medical standards they were unacquainted with. There were challenges to overcome such as Anti-asphyxiation valves, Nasal Gastric (NG) tube ports and developing a one size fits all solution. This was paramount if the HCH-40 was to achieve approval from the Medicines and Healthcare products Regulatory Agency (MHRA).

For Avon Protection to develop the HCH-40 in only 8 weeks, the PD team had to apply their newly learnt medical knowledge and expertise of CBRN respiratory protection, to utilise / adapt existing manufacturing processes, materials, and componentry. These were from products such as the FM12 respirator 40mm filter ports, the NH15's hood material and the CH15's radio frequency welding and 'one size fits all' neck seal. The use of existing materials and processes would help further accelerate the production line set up and manufacturing once the HCH-40 had been tested and validated.

Before the HCH-40 could be submitted to the MHRA, extensive in-house testing was performed as well as healthy patient trials, conducted by Avon Protection, UCL and medical experts at the UCL Hospital. It was during the testing and collaborative sessions, the design and function of the HCH-40 evolved into the potentially lifesaving medical device it is today.

The HCH-40 was approved for use on COVID-19 patients by the MHRA on the 3rd July 2020. The production line at Avon Protection's factory in Wiltshire, began manufacturing 2,500 units for delivery to NHS trusts across the country, in August 2020.

The entire process from design, MHRA approval, manufacture and delivery of the HCH-40's to NHS trusts, was complete in only 4 months. This was due to the urgency to provide a potentially lifesaving solution, the utilisation of Avon Protection's existing products and the unique blend of knowledge sharing and collaboration between academia and industry.

Submission ID: 110

Respirator Protection for Break in Mask Seals

Authors

Jordan Bray-Miners, Harry Angel - HumanSystems Incorporated

Abstract

Background: Citadel™ (patent pending) is a product in development that provides ocular and respiratory protection to bearded users wearing an air purifying respirator. Citadel™ provides protection for any cause of an imperfect seal (e.g., beards, long hair, eyewear temple arms, face shape, dynamic activity, clash, etc.).

The product concept was developed for the Canadian Innovation for Defence Excellence and Security (IDEaS) program challenge to provide respirator protection for service members with facial hair.

Methods: A review of past efforts to improve mask-face seals was conducted and confirmed that existing concepts and designs could not adequately resolve the bearded user problem. An innovative approach building on collective defence principles was chosen as the new way forward.

An iterative spiral design process was used, including building prototypes and evaluating the progress through benchtop and user testing. A preliminary design consisting of a micro-controlled blower and hood system showed that the concept worked in principle (Beta-1). Qualitative and quantitative results informed system component refinements to be incorporated into subsequent prototype developments (Beta-2 to Beta-5).

During the final stages of prototype validation, two phases of user testing were completed. One phase focused on validating the protection provided to users with facial hair and investigating the protection provided when loose hair breaks the seal on the side of the face. The other phase validated the protection provided to user with facial hair when eyewear temple arms broke the gas mask seal. Twenty-one participants were recruited including a mix of clean-shaven, stubble, and bearded personnel. A repeated measures experimental design was implemented with three counterbalanced blower conditions (system off, Citadel™ at 100% blower power, and Citadel™ in auto control) and two eyewear conditions (eyewear, no eyewear). Industry standard quantitative fit testing (QNFT) procedures were used to validate the level of protection being provided by Citadel™. A dynamic QNFT regime was also utilized to test the system using representative soldier tasks. Subjective questionnaires were administered to record acceptability of comfort, task compatibility, equipment compatibility, and overall usability.

Results: Standard QNFT testing results showed that Citadel™ allowed bearded users to achieve a fit factor over 20,000. Dynamic fit testing results showed similar increases in respiratory protection. Participants rated Citadel™ acceptable for both static and dynamic tasks, comfort and usability design criteria, and equipment compatibility. Weighing approximately 1 kg, the system does not impose a significant burden on the user and the system provides evaporative cooling to reduce the heat stress associated with CBRN hood ensembles.

Conclusion: Citadel™ is a novel and innovative solution that provides protection to underserved populations.

Submission ID: 111

Infectious exhaled particles: Experimental characterization of the source and estimation of the risk of infection

Authors

Dr. Mohsen Bagheri - Max Planck Institute for Dynamics and Self-Organization

Abstract

COVID-19 and other airborne diseases are transmitted to healthy individuals through the inhalation of pathogen-containing particles exhaled by infectious individuals. Here I provide an overview of the mechanisms involved in the formation of these particles and the effects of social distance and masking on transmission risk. I will present the results of our comprehensive experimental study to characterize the size distribution of exhaled particles from more than 130 individuals aged 5-80 years using aerosol size spectrometers and inline holography. In total, we collected and analyzed 200 hours of exhaled samples using the spectrometers and 9000 holograms. The breathing maneuvers studied are mouth/nose breathing, loud/normal speaking, singing, humming, shouting, coughing, and playing wind instruments. Using this database, the physics of exhalation flow, leakage from face masks of various types and fits measured in human subjects, consideration of particle shrinkage in ambient due to evaporation, and rehydration, inhalability, and deposition in the susceptible airways, we calculated the upper limit of infection with SARS-CoV-2 for one-to-one exposure. I will show that wearing appropriate masks in the community provides excellent protection for others and oneself and makes social distancing less important.

Submission ID: 113

The Evolving National U. S. Landscape for Respiratory Protection

Authors

Dr. Maryann D'Alessandro, Dr. Patrick Dempsey, Dr. Susan Moore, Dr. Adam Smith - CDC/NIOSH/NPPTL

Abstract

Background. In 2021 the U.S. Federal government published the *National Strategy for a Resilient Public Health Supply Chain.* This strategy includes two important personal protective equipment (PPE) initiatives that are driving U.S. respiratory protection efforts. One initiative is to promote innovative approaches and technologies to streamline respirator availability and use. The second initiative is to establish a Public Health Supplies Innovation Center that will include a focus on developing the next generation of masks and respirators a well as national efforts to build more resilient PPE supply chains. In parallel, the National Academies published a Consensus Study report on *Frameworks for Protecting Workers and the Public from Inhalation Hazards*.

Methods. Developed over decades, a solid respiratory protective device (RPD) infrastructure for many U.S. workers exists today with the U.S. Federal government having oversight of RPDs to occupational settings where hazards are identified. This infrastructure requires that appropriate NIOSH-approved RPDs are provided as part of an Occupational Safety and Health Administration (OSHA) respiratory protection program.

However, many workers are not covered by these OSHA requirements. As a result, according to the National Academies Framework report, the RPD needs of these workers are not being met. Additionally, those in low-paying positions, people with disabilities and other groups, are at increased risk of exposure to inhalation hazards and the complete needs of these groups are not addressed by current requirements.

Similarly, natural disasters and other public health concerns like infectious diseases have increasingly led the public to search for guidance on the use and value of RPDs. While OSHA has the primary oversight for RPD use in the workplace and NIOSH is charged with approving all RPDs used within OSHA respiratory protection programs, their authorities remain limited to occupational settings. There is no formal authority for coordinating the development and distribution of guidance to state and local health agencies or the public. Public health emergencies, including issues like wildfire hazards, have shown that there are gaps in the existing system for addressing RPDs for both workers and the general public.

The U.S. Federal government is directly addressing these gaps with the Interagency PPE Innovation Center concept, NIOSH's vision for its planned PPT Centers of Excellence, responding to the recent National Academies' Framework report, and strategic efforts to evolve RPD conformity assessment.

Results. This presentation will describe the U.S. vision regarding how governmental and non-governmental partners will act in a coordinated way to comprehensively address RPD efforts. The National Academies' Frameworks report will be described, and the initial NIOSH perspectives around implementation will be discussed.

Conclusions. Respiratory protection in the U.S. has traditionally focused on workers who are exposed to inhalation hazards at their workplace and respiratory protection is required by regulation. The need for respiratory protection extends beyond this group and includes the

general public. This presentation provides global ISRP participants an overview of the U.S. efforts to establish a more comprehensive strategy for respiratory protection that could be leveraged by other nations and provide opportunities for global collaboration.

Submission ID: 114

Respirator Fit Testing with Controlled Negative Pressure: Product Development Pandemic Response

Authors

Dr. Stephanie Lynch - OHD, LLLP

Abstract

This session will cover the basics of respirator fit testing with controlled negative pressure (CNP) as well as opportunities for improvement that were identified and executed in response to the pandemic. CNP is a globally approved method of respirator fit testing that is still not well understood by many in occupational safety and health. It was designed to measure respirator leakage directly and uses air as the test challenge agent. Because of how respirator fit testing is performed, with either fit test adapters or a probe, concerns about cross contamination were highlighted by the pandemic. These concerns altered the course of development for a new iteration of CNP fit testing technology which led to the development of a line of fit test adapters that can be fully disassembled for easier disinfection and have the option for the use of a 95% efficiency inline filter. Several updates to our user interface addressed other pandemic specific considerations, now allowing for physically distanced and touch free testing. Battery power was also introduced to allow fit testing to be more portable, so that testing could be performed in a space with improved ventilation, or outside. While these advancements were a reaction to the pandemic, they have likely altered how many of our customers will perform their fit respirator fit testing moving forward. We will also discuss lessons learned, missed opportunities, and possible future advancements.

Submission ID: 115

A Study on the Correlation Between Static Electricity and Filtration Efficiency of Particulate Respirators

Authors

Ms. Jimin Kim, Prof. Chungsik Yoon - Graduate School of Public Health, Seoul National University, Seoul, Korea

Abstract

Aerosols are absorbed in the respirator via various mechanisms. Increasing the efficiency of the respirator filter causes the pressure drop to increase, which can be a problem. By adding static electricity to the respirator, the efficiency can be improved while maintaining an almost constant pressure drop. However, static electricity could be reduced when exposed to moisture for a long time. The objective of this study was to evaluate the electrostatic properties and filtration efficiency of respirators according to their age, changes in humidity and temperature, and the mask-wearing duration. Furthermore, this study compared occupational-use and public-use of respirators.

Respirators from four manufacturers were selected, and two types of respirators from each manufacturer were tested; occupational-use respirators (1st class) and public-use respirators (KF-94). First, in order to observe how much static electricity contributes to filtration efficiency, static electricity was removed. To study the effect of time, the respirator was exposed to mask-wearing condition (38℃, 85%) for 8 hours, and subsequently stored at room temperature (20℃, 50%) for 16 hours per day. This was repeated for 1, 2, 4, and 8 d. To study the effect of humidity and temperature on the efficiency of the masks, i) the temperature was fixed at 25℃, and the samples were exposed to humidity of 30, 50, and 98%, and ii) humidity was fixed at 50%, and samples were exposed to temperatures of –30, 50, and 70℃. The static electricity on the surface of the respirator and on each inner layer filter were measured using a surface potential meter, and the filtration efficiency was measured for NaCl and paraffin oil using a filter tester.

Owing to the removal of static electricity from respirators, the filter efficiency of 1st class and KF-94 respirators decreased by 21.72% and 19.53%, respectively. Over time, a decrease in static electricity was observed in all respirators except for one product, and a decrease in filtration efficiency was also observed in one KF-94($p<0.001$). The filter efficiency decreased to less than 94% after 8 d. Both static electricity and filter efficiency decreased according to humidity, and the decrease was significant in both 1st class and KF-94($p<0.05$). The static electricity and filtration efficiency did not differ significantly according to temperature ($p>0.05$). Correlation analysis indicated a strong positive correlation between static electricity and filtration efficiency with respect to changing humidity; however, the correlation was weaker at variable temperature conditions. The decrease in the filtration efficiency of respirators in high humidity environments can be explained by the reduction in static electricity, however, the decrease in filtration efficiency at high temperatures was found to be the result of deformation of respirator properties rather than effect of static electricity.

Submission ID: 116

First Responders - the Multidimensional RPE Challenge.

Authors

Prof. David Crouch - 3M

Abstract

First responder populations, such as emergency services and the military, face a plethora of potential respiratory hazards during their everyday operations. Ranging from noxious fumes & vapours at road traffic accidents, house fires or chemical spills, to transmissible biological pathogens encountered at patient recovery incidents such as USAR operations and worst case scenario events such as CBRN related terrorist attacks.

Most first response events would not only require cooperation between government agencies, such as fire, ambulance, police and/or medical services, through effective communication, it would also necessitate changes in the requirements for, and capabilities of, Personal Protective Equipment (PPE) as the respiratory hazard or threat changes during any response.

While first responder PPE ensembles are designed to save life and prevent injury, they must also enable the responder to maintain operational tempo and allow effective movement within such contaminated environments. If the chosen PPE ensemble cannot allow operational tempo to be delivered in a timely and effective manner, then lives could potentially be put at risk – for example, a delay in dealing with an IED on a timer circuit, due to poor personal communications, or poor radio communications when providing at-scene medical triage to a wounded member of the public inside any contamination zone.

Therefore, when considering PPE choices for responding to such events, we must always consider the holistic approach. Unless designed correctly, an operator's PPE ensemble may inhibit key operations such as communications, and this needs to be considered before carrying out any hazard management activities, especially when CBRN agents are involved.

This paper will discuss the PPE challenges faced by military operatives and first responders when operating in such environments. From problem space to design requirements, the presentation will highlight modern advancements in not only state-of-the-art CBRN and first responder respiratory protection, enabling a range of Concept of Operations (CONOPS) and threat scenarios to be addressed, through the provision of multi-modal single respirator face pieces.

The paper will also discuss how industrial companies are leading this holistic protective equipment integration challenge through innovations in dedicated RPE capable communications system design, such as environmental listening features with level dependent functionality. Enabling auditory situational awareness and face-to-face communications to be realized and effectively integrated into platform PPE ensembles. The address will demonstrate how important holistic PPE selection is when considering first responder and counter-CBRNe operations.

Submission ID: 118

Mobile application supporting the selection of respiratory protective devices for use against biological agents

Authors

Prof. Katarzyna Majchrzycka, Dr. Małgorzata Okrasa - Central Institute for Labour Protection - National Research Institute, Poland; Dr. Justyna Szulc - Lodz Univrsity of Technology.

Abstract

Background. According to the EU-OSHA, nearly 320000 workers die every year due to infectious diseases around the world, of which around 5000 in the European Union. It is estimated that exposure to harmful biological agents is a global problem and occurs in nearly 160 specialized professional groups. The proper selection of respiratory protective devices (RPD) for biological hazards requires in-depth expert knowledge on the types of equipment and protection classes, rules of safe use, workplace characteristics and the possibility of developing harmful microorganisms in the filter material. A simple IT tool supporting users in selecting and properly using respirators protecting against biological hazards was developed to resolve this challenge.

Methods. The research was carried out to characterize three selected work environments (animal husbandry facilities, wastewater treatment plants, waste sorting plants) in terms of biological (type and concentration of microorganisms in the air, type and concentration of metabolites in the air and settled dust, dust cytotoxicity, bacterial and fungal biodiversity) and physicochemical hazards (air temperature, air humidity, airflow velocity, dust concentration), emphasizing the conditions related to RPD use. The collected data were used to develop an algorithm for selecting RPD and determining the safe-use timelines depending on the hazards identified in those environments. The following functionalities of the application were formulated: selection of the type and class of RPD based on the data entered by the user, providing guidelines for donning, doffing, and adjusting the selected RPD, displaying warnings related to its safe use, monitoring the time of use and notifying the user about the end of service life.

Results. The application was developed in a mobile version for iOS and Android and a desktop version. It is fully functional offline and can update online while preserving the input and archive data. A unique feature is a timer that counts down the time until replacing the RPD that is calculated based on the data provided by the user or based on the experimental data stored within the application itself.

Conclusions

The application is intended for individual users whose professional activity is related to exposure to biological agents, typical for three work environments: animal husbandry, sewage treatment plant, waste sorting plant, and does not require connection with the work safety management system. This ensures that it can be used by people operating in the self-employment system and micro and small companies.

Submission ID: 119

New materials for seals of respiratory protective devices

Authors

Dr. Małgorzata Okrasa - Central Institute for Labour Protection - National Research Institute; Dr. Milena Leszczyńska, Dr. Kamila Sałasińska - Warsaw University of Technology; Dr. Leonard Szczepkowski - Fampur

Abstract

Even the best respiratory protective device (RPD) does not ensure the required protection if it does not fit the user. Proper fit is essential to maintain the leak-tightness of the RPD throughout its use, especially in conditions where exposure to respiratory hazards is high. In such situations, the user can be either unaware of the danger or unable to adjust the fit due to lack or insufficient amount of training.

The problem of ensuring a leak-tight fit and maintaining it throughout RPD use is widely discussed in the literature and industrial practice, and it is directly related to the comfort of use. A good seal of RPD is usually achieved by tightening the headband/head harness and/or nose clip, causing the continuous pressure of the facepiece on the skin. This pressure often leads to indentation marks, irritation, and chafing. Some users may choose not to use RPDs even if there is an imminent threat to their life or health. Thus, to improve the performance and safety of RPDs, human factors should be highlighted in the design process.

Of particular interest is the idea of designing facepiece seals made of viscoelastic materials with relatively slow elastic recovery time, low resilience, and providing favorable comfort properties in the case of prolonged contact with the human body. The application of such materials in the construction of RPD seals could provide a protective solution with superior comfort properties compared to conventional RPDs and simultaneously self-adaptable to the user’s face due to specifically customized recovery time.

In this poster, a series of technological experiments related to the production of such viscoelastic materials with physical and chemical characteristics enabling their application as facepiece seals in respiratory protective devices will be discussed in the context of the conditions of RPD use and the safety and comfort of users.

Submission ID: 120

Mobile application SIZE 4 FACE supporting the determination of individual dimensions of the RPD users faces.

Authors

Mr. Krzysztof Makowski - Central Institute for Labour Protection - National Research Institute

Abstract

Background. Mobile application SIZE 4 FACE was developed to improve users' safety of respiratory protective devices exposed to toxic aerosols, gases, and vapors. This IT tool supports the measurements of user faces' dimensions. The basis on which the operation of the mobile application was developed was the international standards ISO 16900-5:2016 and ISO/TS16976-2:2015, defining five face sizes and the measurement algorithm.

Methods. Based on the performed analysis, the 3D method was selected to be used in the application for recognizing the dimensions of a human face and supporting the correct adjustment of the half-masks to the individual dimensions of the user's face, i.e., using the Google ARCore virtual reality technology and Open GL. The application operates in Android system. It was shown that the differences in measurements between the results from the application and the anthropometric measurements carried out for the head models and participants from the testing group are, on average, a few millimeters.

Results. The verifying tests of the correctness of face dimensioning by the developed mobile application for determining the dimensions of the face and assigning to one of the five defined head sizes and selecting a half-mask of the appropriate size from the database showed that the application correctly indicates the size of the face in 85 % of the measurements made. According to the half-mask fitting research results, it can be concluded that the application allowed for the correct fitting of the half-mask for 95% of the test subjects. From the main menu and face measurement, one can get acquainted with the practical information on the RPD use and about the application. This information is included in the drop-down MENU, which can be accessed from any application screen.

Conclusions. The application meets the assumed indication correctness threshold and is a tool that can significantly help users of respiratory protective devices and OHS services to select half-masks for their individual users correctly. Based on the application evaluation survey results among its potential users, it can be concluded that the application was assessed positively. After testing it, the respondents stated that it is intuitive and that navigating the application's functions does not pose any problems, and that it helps identify the face size and select half-masks.

Submission ID: 121

Rapid intrahospital modification of surgical helmets into a respiratory protective device as an emergency measure

Authors

Dr. Max Temmesfeld - Department of Orthopedics, Akershus University Hospital, Lørenskog, Norway; Northfix Medical AS, Høyenhall, Oslo, Norway; Institute of Health and Society, University of Oslo, Oslo, Norway; Dr. Agnieszka Gorzkowska-Sobas - Comprehensive Defence Division, FFI Norwegian Defence Research Establishment; Mr. Kenny Hedlund - Camfil Tech Center, Trosa, Sweden; Dr. Lars Kanten - Department of Sterile Supplies, Akershus University Hospital, Lørenskog, Norway; Dr. Peter Grant - Department of Orthopaedics, Institute of Clinical Sciences Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; Lovisenberg Diaconal Hospital, Nydalen, Oslo, Norway; Dr. Rune Bruhn Jakobsen - Department of Orthopedics, Akershus University Hospital, Lørenskog, Norway

Abstract

In case of an unexpected surge in admissions of patients infected with airborne diseases, there is an urgent need to provide adequate respiratory protective devices (RPD) to the health personnel (HCP) in hospitals. Failing to do so creates an immediate hazard to HCP's health and life. During the SARS-CoV-19 pandemic, shortages in supplying adequate personal protection equipment (PPE) resulted in the use of non-certified equipment or the reuse of single-use respiratory devices, with some disinfection methods affecting their robustness and filtering efficiency. Especially during the first wave, the risk of occupational infection was significantly higher compared to the general population. In this project, we investigated the possibilities of employing surgical helmets as respiratory protection devices (RPD) in times of crisis.

Surgical helmets are routinely used as personal protection equipment by HCP in orthopedic surgery to protect HCP from body splashes and the surgical site from surgeon-generated contaminants. Surgical helmets are tested and certified with respect to microbial penetration of the single-use hood and the field of vision, but they do not provide respiratory protection to HCP. A filter adapter (EURODAPTER) was designed and prototyped with the help of in-house available three-dimensional (3D) printer. The filter adapter renders surgical helmets into efficient powered air-purifying respirators (PAPR), compliant with the EN12941 with respect to TIL, CO_2 concentrations and airflow. The adapter was finally manufactured with industrial 3D-printers.The efficacy of the device was assessed by Total Inward Leakage (TIL) measurement using artificial head and torso, and human volunteers. We used the surgical helmets in their original design and with EURODAPTER assembly. Results show that the filtering efficiency of the modified device and the corresponding CO_2 levels make it an effective and comfortable emergency RPD providing protection comparable with powered air-purifying respirators (PAPR).

Submission ID: 122

Next-Generation Custom-Fit Reusable Respiratory Protective Device with Continuous Fit Monitoring

Authors

Dr. Sungmee Park, Ms. Yuanqing Tian - Georgia Institute of Technology; Michael Bergman, Dr. Ziqing Zhuang, Jonisha Pollard – CDC/NIOSH/NPPTL; Prof. Sundaresan Jayaraman - Georgia Institute of Technology

Abstract

The effectiveness of respiratory protection against an inhalation hazard for a user is a function of the efficacy of the device, means for the user to access the right device, adherence with its use instructions, and a commitment by manufacturers to produce the needed products. N95 filtering facepiece respirators (FFRs) are made in discrete sizes, which are limited in accommodating the size, gender, and ethnic diversity in the user population. Additionally, the pressure exerted by the generally stiff edges of an FFR on the face can affect user comfort. The pressure can also change during use, potentially compromising the fit of the FFR (https://doi.org/10.1080/15459624.2012.695962). Thus, there is a need to design and develop a respiratory protective device (RPD) customized to a user's facial features, which (1) flexes and moves with facial movements during use, (2) continuously monitors fit, and, (3) when needed, alerts the user to adjust the device. Additionally, reusability of RPDs is an important consideration for maintaining supplies during diseases outbreaks. See RPD definition in Glossary at https://doi.org/10.17226/26372.

The primary objective of this research has been to develop a next-generation custom-fit reusable respiratory protective device (RPD) with continuous fit monitoring by bringing together advancements in 3D digital scanning, flexible materials, additive manufacturing, fabric-based sensor networks, and application software. This capability would give the user confidence that the device has been donned correctly, is maintaining a good faceseal, and will provide the specified degree of protection. The customizability of such a device is intended to provide effective respiratory protection to a wide range of users, including children, for whom RPD designs are currently limited.

As the first step in customizing the prototype, a set of 21 facial anthropometric landmarks and 15 dimensions was selected for the design. Landmarks relevant to respirator fit were selected based on previous literature studies. The faces of three members of the research team were scanned using a 3dMD digital scanning system. From these scans, algorithms were developed to create digital representations of the contours of the RPD frame.

For fit monitoring, a fabric-based sensor network with five sensors distributed around the frame and placed at the interface with the user's face was developed. The number of sensors in the network can be varied. Bench testing of pressure loads showed their responsiveness to increasing pressure loads. Algorithms were then developed to standardize the locations of the sensors and a data bus conduit in the RPD frame. To hold the sensors and data bus in their positions, a "covering piece" was designed to mate with the base RPD frame. An interlocking mechanism was created to enhance the fit between the base frame and the covering piece to hold the filter. Based on an in-depth evaluation of 3D-printable materials to effectively balance RPD custom fit with comfort, materials were chosen and physical prototypes produced. The fit monitoring sensor network was integrated into the prototype. Initial tests of prototypes demonstrated that the customized RPD continuously monitors fit and responds effectively to changes in facial movement during use.

Submission ID: 123

Basics of Radiological Hazards

Authors

Mr. Christopher Jones, Mr. Amit Desai - AWE

Abstract

This talk serves as an introduction to the topic of radiation safety and the role that respiratory protective equipment can play in protecting the health and safety of those working with radioactive materials. Designed as an introduction for those who are unfamiliar with the hazards of ionising radiation or those who would benefit from a refresher on the topic, the talk will consider the sources of ionising radiation, the potential health effects that it can cause and introduce the basic concepts of how people can be protected from the hazards.

Submission ID: 124

A Study on the Use of Reusable Respiratory Protective Devices in a University Community Setting

Authors

Dr. Sungmee Park, Ms. Helen Liu, Prof. Sundaresan Jayaraman - Georgia Institute of Technology

Abstract

One of the means to reduce the spread of infectious diseases caused by inhalation hazards, such as the SARS-CoV-2 virus, is to wear respiratory protective devices (RPDs). An RPD may be defined as any personal device that provides protection against inhalation hazards when used effectively, acknowledging that each device may offer either personal protection or source control or both at varying levels (https://doi.org/10.17226/26372). Therefore, preparedness for public health emergencies caused by an inhalation hazard may include an understanding of the role that RPDs may play in reducing harm and an assessment of the individual perceptions and beliefs towards wearing RPDs in community settings. This information can help shape public policy aimed at developing measures to protect the respiratory health of individuals from inhalation hazards due to air pollution, wildfire smoke, and infectious agents.

The primary aim of this study is to test the effectiveness of a prototype reusable form-fitting fabric RPD ("focal" mask) in reducing infectious disease spread through respiratory secretions in undergraduate students living in dormitories at the Georgia Institute of Technology (Georgia Tech). The focal mask aims to overcome the shortcomings of commercial fabric masks (https://doi.org/10.1080/00405000.2020.1805971). Three iterations of prototype development and fit-testing led to the final design specifications for the focal mask, which met the Level 1 performance specified in ASTM F3502-21. One key refinement prior to this study was that the "filter" was integrated into the barrier component to ensure uniformity in the performance of the device.

A corollary aim is to assess the effectiveness of wearing any RPD type in reducing spread in the same community setting. A final aim is to assess the social, behavioral, aesthetic, and usability aspects of wearing RPDs in public settings. Undergraduate students living in Georgia Tech dormitories were selected as the community of the study due to the significant person-to-person contact that occurs in residences, classes, and social activities.

Two hundred undergraduate students were recruited for an IRB-approved six-week study consisting of three two-week phases: pre-treatment, treatment, and post-treatment. During the pre-treatment phase, all subjects wore an RPD of their preference (e.g., surgical mask, filtering facepiece respirator [KN95 or N95], or mask not claiming to meet any performance standards) or none. At the end of that phase, the subjects were split into control and treatment groups of 100 each. The treatment group subjects were given a recently developed focal mask for use during the treatment phase; instructions on using the focal mask and laundering the masks were provided. Control group subjects continued with the use of their preferred RPD. In the post-treatment phase, the subjects returned to the use of their preferred RPD; subjects in the treatment group were free to use the focal mask or other RPDs.

Throughout the study, the students completed surveys capturing information related to their demographics, health status, person-to-person interactions, and RPD usage (99% response rate). Data regarding the student survey responses (e.g., person-to-person interactions, health status, and RPD usage) and the iterative changes made to the focal mask will be presented.

Submission ID: 125

Interactive Control of Particle Generation in Quantitative Respirator Fit Testing

Authors

Mr. William Hill - AccuTec-IHS, Inc.

Abstract

Background: Quantitative Fit Testing using ambient respirable particulates dates back to 1981 when Klaus Willeke's group at University of Cincinnati used a TSI model 3020 Condensation Nuclei Counter to measure the concentration of particles in the ambient atmosphere and inside the respirator.[1]

Fortuitously, ambient concentration of respirable particles in Willeke's lab was of sufficient concentration to challenge respirator performance and produce meaningful ratios of ambient particles to those measured inside the respirator, resulting in what we call Fit Factor. This led to commercial development of systems using the Ambient Aerosol/Condensation Nuclei Counting method of fit testing which operate on the assumption that sufficient concentrations of ambient particles are present.

In the 40+ years following Willeke's findings, HVAC systems added more effective filtration resulting in lower ambient particulate concentrations. Many times, respirable particulate concentration is reduced to levels that make it impossible to conduct AA/CNC fit testing without generating more particles to be used as the challenge agent. This has become exacerbated as buildings have added extremely efficient filtration to mitigate transmission of harmful aerosols including SARS-CoV2

At one time, particulate generation was done by burning candles producing hydrocarbon-rich waxy particulates. More recently, producing aerosols using an ultrasonic 'humidifier' with water containing dissolved ionic salts (NaCl or $CaCO_3$, forming ultrafine crystals when water evaporates) is prevalent.

The dissolved salt method of particle generation works well but disadvantages include:

1. Concentration of particulates are difficult to control as HVAC systems cycle on/off
2. Fit Test operators may move generators too close to the CNC device inlet, which could result in the instrument ingesting partially-evaporated "nano-snowballs" inducing a 'clog'
3. Statistical aberrations from testing in widely-varying particulate concentrations.

A new system was developed for controlling the number of ambient particles by enabling a wireless sensing and control feedback loop between the particle generator and the CNC device such that all three of the above disadvantages are reduced or eliminated. This paper describes the configuration and performance of this interactive automated control system and resulting benefits for operators executing tests in challenging environments.

Methods: The AccuFit9000 CNC Fit Test instrument was set up as indicated using instructions contained in the Operator's manual and checked for proper operation in an environment containing differing amounts of ambient particles. The device was operated multiple times using a modified and standardized test protocol in both uncontrolled ambient environments and again in a like number of controlled environments using the described feedback-loop control.

Results: Increases in Fit Test efficiency and repeatability of Fit Factor were noted in the system using the Particle Control system

Conclusions: Practical benefits of using a wireless control system to cycle a Particle Generator on and off during Quantitative Fit Testing include greater efficiency and increased uptime in the typical daily regimen employed by Fit Test operators and others using CNC Fit Test devices in the field.

Citations: [1]KLAUS WILLEKE**,** HOWARD E. AYER & JAMES D. BLANCHARD (1981) New methods for quantitative respirator fit testing with aerosols, American Industrial Hygiene Association Journal, 42:2, 121-125

Submission ID: 126

Respiratory protection for children: lessons learned from volcanic eruption crises and COVID-19 mitigations

Authors

Prof. Claire Horwell - Department of Earth Sciences, Durham University

Abstract

Prior to the COVID-19 pandemic, it was relatively rare for the public to wear respiratory protection. In some countries, particularly in Asia, the use of facemasks (both face coverings and respirators) was becoming more common when outdoors, for ambient urban air pollution exposure reduction, especially when riding on scooters. In Japan, facemask use (mainly surgical masks) was already a cultural norm, viewed as polite and considerate to others, especially if one had a cold.

During air pollution crises, it was becoming more common for governmental and non-governmental humanitarian and civil protection agencies to recommend and distribute surgical masks and, sometimes N95 respirators. Some large PPE manufacturers had philanthropic sections which would distribute millions of N95 respirators, via NGOs, during volcanic eruptions and wildfire emergencies. However, due to a lack of clinical trials or other evidence proving the safety and efficacy of respirator use for children, agencies would usually recommend that children should stay indoors rather than wear respiratory protection.

Major PPE manufacturers primarily produced respirators for adult-sized faces because they were designed for industrial or healthcare occupational settings. There were some companies which were manufacturing respirators for children in Asia, but their use was uncommon in the rest of the world.

The COVID-19 pandemic has forced a global shift in the availability, use and acceptability of respiratory protection for the public and particularly for children. Concerns about safety (in terms of breathing resistance and lung development) and efficacy have been largely ignored. Manufacturers have capitalised on the need, producing face coverings made from cloth, surgical masks and N95 respirators to suit small face sizes. It has become normal for children to wear face coverings and respirators.

There is an urgent need for an evidence base on the safety and efficacy of respirators for children. Beyond the pandemic, use of respirators for children will no longer be taboo; they are likely to be used and even recommended for reducing both acute and chronic air pollution exposures. In South-East Asia, 99% of children under 5 years live in environments with airborne fine particulate (PM2.5) concentrations above WHO guidelines.

Reducing exposure to particulate pollution is one of four actions identified in UNICEF's framework for improving children's health. As a first step, the FACE-UP* project will test the efficacy (via fit testing) of a range of N95-certified respirators on children in Nepal and Indonesia, and consider the ethical implications and behaviour change required – in a post-pandemic world - for the widespread introduction of such interventions.

* Factors Affecting Childhood Exposures to Urban Particulates

Submission ID: 127

Protecting Firefighters from the effects of Wildfire smoke emissions.

Authors

Dr. Michael Logan - Queensland Fire and Emergency Service

Abstract

The State of Queensland is around 1. 7 million km^2 and the Queensland Fire and Emergency Services is the response agency for the state. It responds to more than 70,000 incidents annually and these include wildfires. Wildfire response includes professional firefighters, auxiliary firefighters, and volunteer firefighters.

A significant concern for responders is their exposure to wildfire smoke emissions. Over the past decades, a significant body of work has been created internationally to better understand wildfire emissions across a range of fire types and operational environments. This work has also extended to characterising firefighter exposures and the applicability of various risk control measures. However, many gaps are yet to be resolved. The recent NFPA 1984 Standard on respirators for wildland firefighting operations and wildland urban interface operations is an example of improvements to enhance firefighter safety.

Wildfire responses often require significant resources across wide areas of long timeframes for their successful management. These pose significant challenges for managing firefighter safety.

The QFES has undertaken a multi-staged program to investigate exposures of airborne contaminants at wildfires, and in particular prescribed burns as a surrogate for uncontrolled fires. The airborne contaminants characterised included:

- Carbon monoxide;
- Volatile organic compounds such as benzene and acrolein; and
- Poly-aromatic hydrocarbons (PAHs).

It is clear from measurements carbon monoxide is a significant airborne hazard. These measurements were also related to work type and work intensity undertaken by firefighters at the incident. The purpose of this was to determine if exposure was an issue, how significant an issue and what risk control measures could be applied to manage the exposures. Surveys and trials of various air purifying respirators were undertaken to determine if any were suitable and would be accepted by the firefighters.

The QFES has established a significant respiratory protection program to address the needs of firefighters at wildland fires. This has included the provision, servicing, and maintenance of air-purifying respirators, canisters, and detection equipment. In addition, the QFES recalculated the relevant Occupation Exposure Limit (OEL) values to account for respiration, work, duration etc. These corrected values are summarised in the guidance documents provided to the firefighters.

This program has also included doctrine, education, and guidance materials for the responders.

The presentation will highlight the scale of the program undertaken by the QFES, some issues that need to be resolved that may be global in nature and others that are unique to Queensland that impact on the program’s rollout and success. It will also highlight the risk-based approach that has been adopted, and how the exposure characterisation was applied to

inform the program. Whilst the QFES has made significant progress, it remains a journey that is still been undertaken as we strive to protect our responders.

Submission ID: 128

Comparison Study of In-Market Filtering Facepiece Respirators using ASTM F3407-20 RFC Standard to Evaluate Design and Component Impact on Overall Fit Capabilities

Authors

Mr. James Wyner, Mark Holbrow, Larry Weldon, Don Seeto - Shawmut Corporation

Abstract

Background. The purpose of the study was multi-fold: to assess the ability of the ASTM F3407-20 Respirator Fit Capability Standard to compare the fit capability performance of a range of commercial N95 filtering face piece respirator (FFR) designs; to understand how FFR design and construction factors may impact fit performance; and to assess the relative performance of the KN95 FFR design compared to N95 FFR designs. The scope of ASTM F3407-20 testing performed was the evaluation of 20 current commercially available FFR models. A list of 14 N95 FFRs tested was comprised of molded-cup, duckbill, tri-fold and vertical flat fold designs. Additionally, five KN95 models and one KF94 were evaluated.

Methods. The Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators, ASTM F3407-20, provides detailed instructions for evaluating the respirator fit capability of filtering facepiece respirators. The standard uses the NIOSH Bivariate Test Panel and specifies that at least 13 of the 25 subjects (> 50%) must achieve a respirator fit capability (RFC) result of ≥ 100 for a one-size respirator.

Using the parameters of the ASTM F3407-20 RFC standard test procedures, the study involved 575 individual subject tests, conducted in a controlled environment at Shawmut Corporation's West Bridgewater, MA offices. Panel subjects were volunteers from the employee population in Shawmut's corporate offices and adjacent manufacturing plant, covering the spectrum of facial sizes required in ASTM F3407-20, and included 44% male and 56% female subjects across the 10 bivariate panel cells. Over 4,600 interior air samples were evaluated and recorded. All test equipment was calibrated and traceable to NIST standards. Equipment included a TSI PortaCount Plus® model 8048 with applicable software, two (2) TSI Particle Generators with NaCl solution, a Hexagon digital caliper, and a small fan to evenly distribute particles in the enclosed area.

Results. Of the 14 N95 FFR models tested, only 4 achieved a passing score based on the ASTM F3407-20 standard. Those that passed recorded percentages of 93%, 79%, 64%, and 73% of test panelists achieved an RFC score ≥ 100. Results for N95 FFR design forms showed cup designs performed better than duckbills, tri-folds and flat-folds, but highly variable results were seen within all styles. None of the KN95 or KF94 design forms passed.

Conclusions. Fit capability is essential to understanding filtering facepiece respirator performance. Fit variability may be an important metric for general consumer use. Although each N95 FFR has been evaluated and approved by NIOSH for filtration efficiency and breathability, the study found that fit performance varied dramatically across individual N95 models, which would impact each model's probability of protecting a wide swath of its user populations. Among the form factors of molded-cup, duckbill, tri-fold and flat-fold, the molded-cup form factor offered a higher probability of fit capability than the others. Additionally, the design of KN95 FFRs do not deliver comparable fit capability and safety performance to NIOSH-approved N95 FFRs. Adoption of the ASTM F3407 standard would have public health benefits and also lead to improvements in respirator design.

Submission ID: 130

NIOSH Respirator Approval Program 2020 to present, we have been busy!

Authors

Colleen Miller - NIOSH NPPTL

Abstract

The National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) certifies conformance of respirators in the United States to requirements codified in federal regulations. ***Title 42, Code of Federal Regulations, Part 84*** (42 CFR 84) includes requirements for atmosphere-supplying and air-purifying respirators. NIOSH NPPTL uses established Standard Operating Procedures, policies, guidance documents such as the Standard Application Procedures, and Standard Test Procedures to ensure NIOSH-approved respirators meet the minimum requirements described in 42 CFR 84. This presentation will provide an overview of the NIOSH Respirator Approval Program, including an update about recent activities:

- Summary of approval decisions
- Prioritization Guidance offered since February 2020
- Public Health Emergency Approvals for filtering facepiece respirators and powered air-purifying respirators
- U.S. Food and Drug Administration's Emergency Use Authorizations and NIOSH approved respirators
- Reviewing approval applications virtually and keeping the laboratory open
- Managing unprecedented numbers of inquiries and new approval applicants
- Conducting virtual site qualification visits
- Certified Equipment List Quick Searches and Respirator Trusted Source Pages
- Rulemaking activities

Submission ID: 131

An Update on Achieving NIOSH Surgical N95 Approval

Authors

Heidi Sewchok - NIOSH

Abstract

A poster was presented at the Denver ISRP conference in 2018 about the new consolidated process for achieving surgical N95 filtering facepiece respirator (SN95s) approval under the Memorandum of Understanding (MOU) between NIOSH and the Food and Drug Administration (FDA). NIOSH did not receive any applications in 2018-2019 and in 2020, provided updated guidance for applicants and approval holders. Since then, NIOSH has approved over 25 new SN95s.

When the information on the MOU between NIOSH and the FDA was originally presented in 2018, NIOSH had plans to call respirators approved under this process N95-F respirators. Since then, it was made clear that to avoid confusion, the terminology used to describe them should be consistent with what was used for respirators approved under the prior process. Therefore, the respirators approved under the MOU are now called Surgical N95s.

Respirators approved under the MOU are disposable filtering facepiece respirators (FFRs) that are tested to meet the additional criteria for biocompatibility, flammability, and fluid resistance. The NIOSH approval labels includes the protection surgical N95 and are easily identified on the NIOSH Certified Equipment List.

Following the guidance and the consolidated process has been challenging for some applicants, especially those more familiar with the medical device industry, rather than respiratory protection. This presentation will discuss several of the common issues encountered and explain NIOSH expectations, including the data demonstrating biocompatibility, flammability, and fluid resistance, labeling and packaging requirements.

NIOSH Conformity Assessment Letter to Manufacturers, NIOSH CA 2018-1010R1.0, was revised in 2020 and provides information for approval holders and applicants.

Submission ID: 132

COVID-19, Dogma, Hubris, and the Forgotten Lessons of SARS-1

Authors

Mario Possamai - Retired

Abstract

The presentation will be in two parts.

The first part will focus on the key lessons of SARS-1, the 2003 outbreak widely seen as a dress rehearsal for the COVID-19 pandemic. The most important lesson was the precautionary principle — that it's vital to err on the side of caution when facing a new pathogen whose transmission dynamics, including its potential airborne characteristics, are not known. The lessons of SARS-1 also:

- Called into question the adequacy of the large droplet model of disease transmission, based on 1930s research which lacked the technology to detect and study aerosols;
- Highlighted the importance of taking a multidisciplinary approach to pandemic containment, including ensuring that all relevant disciplines, including engineers, are at the table when containment strategies are developed and implemented; and
- Underscored the importance in pandemic preparation of having a safe, reliable supply of N95 respirators and other PPE.

The second part will look at the COVID-19 pandemic through the lens of SARS-1, and focus on the failure of public health organizations and leaders to heed both the lessons of SARS-1, and of the cutting-edge research into aerosols between SARS-1 and the dawn of COVID-19. The possibility of airborne transmission was categorically dismissed at the start of the pandemic, even though COVID-19's transmission dynamics were little understood, and its cousins, SARS-1 and MERS, both had airborne characteristics. The large droplet theory, despite its well-documented deficiencies, remained the cornerstone of the pandemic response. Mounting evidence of COVID-19's airborne characteristics was dismissed. Acknowledgements of airborne transmission were made grudgingly and without political and scientific commitment. The engineers, physicists and other professionals who were most knowledgeable on aerosols and aerosol mitigation measures were largely kept on the sidelines, when their expertise could have saved lives. Tragically, the failure to heed the lessons of SARS-1 led to preventable deaths, infections, and lockdowns.

Submission ID: 133

Case Study – Radiological RPE Requirements in Decommissioning – Particulate Hazards

Authors

Peter Hiller - National Nuclear Laboratory

Abstract

Work within the nuclear environment presents a wide range of unique and challenging radiological hazards that need to be managed if the risks associated with the work are to be kept to acceptable levels. In the UK, as the industry has transferred from power generation through to an increasing amount of decommissioning, the hazards associated with individual tasks become more challenging to address and often unique to the individual situation.

Management of these hazards is particularly important when considering the dose uptake of radiation workers undertaking proposed tasks. Managing these hazards through the hierarchy of hazards controls is essential if the work is to be undertaken safely and compliance with legislation is to be maintained. However, adopting an overly cautious approach to hazards management can result in unacceptable increases in cost and time scales and therefore striking the correct balance is crucial to the successful delivery of tasks.

This presentation introduces the radiation hazards associated with direct and inhaled/ingested dose and the basic principles in place within a UK context to manage these hazards (Health and Safety at Work Act and the associated ALARP principle). The hierarchy of hazard control will be introduced and specifically, how this hierarch is used to manage inhaled dose. Inhaled dose can be a particularly significant hazard when considering decommissioning activities. Often, these activities disturb resuspend materials that have been undisturbed for many years and as well as having little or no provenance data associated with them, are often dry and can represent an increased airborne/inhalation hazard.

Methods for the management of these hazards will be discussed and a practical case study presented. This will demonstrate how the hazards can be practically managed, in this case with simple innovations, to deliver a programme of work safely without incurring significant cost and time delays associated with alternative more onerous hazard management approaches. The session will conclude with a brief look at future R&D planning in this area with a collaboration, currently in the early stages between the National Nuclear Laboratory and the UK Health and Safety Laboratory.

Submission ID: 134

Digital Transformation of Droplet/Aerosol Infection Risk Assessment and Evaluation of Countermeasures Realized on the Supercomputer “Fugaku”

Authors

Prof. Makoto Tsubokura - Kobe University

Abstract

Virus droplet infection caused by sneezing, coughing, or talking is strongly influenced by the flow, temperature and humidity of the air around an infected person and potential victims. Especially in the case of COVID-19, possibility of aerosol infection by atomized droplets is suggested, in addition to the usual direct droplet infection. Because smaller aerosol particles drift in the air for a longer time, it is imperative for the precise infection risk assessment to predict their scattering route and to estimate how surrounding airflow affects the infection. This is also the case when proposing countermeasures to reduce the infection risk. The fastest supercomputer in 2020, “Fugaku”, has not only achieved digital transformation of epidemiology in allowing end-to-end, detailed quantitative modeling of COVID-19 transmissions for the first time, but also transformed the behavior of the entire Japanese public through its detailed analysis of transmission risks in multitudes of societal situations entailing heavy risks. A novel aerosol simulation methodology was synthesized out of a combination of a new computational fluid dynamics methods meeting industrial demands, “CUBE”. This method not only allowed the simulations to scale massively with high resolution required for micrometer virus-containing aerosol particles, but also extremely rapid time-to-solution due to its ability to generate results representing multitudes of societal situations in minutes not weeks, attaining true overall application high performance. Such simulations have been running for the past 1.5 years on “Fugaku”, cumulatively consuming top supercomputer-class resources and the result communicated by the media as well as becoming official public policies. In this talk, the details of the digital transformation of virus droplet/aerosol infection risk assessment and countermeasure proposal realized by the collaboration of “Fugaku” and “CUBE” will be introduced, with special emphasis on the effect of face masks on reducing the infection risk for the fight against COVID-19.

Submission ID: 135

Prisoners of mental models: a tale of two diseases

Authors

Prof. Trish Greenhalgh - University of Oxford

Abstract

There is overwhelming scientific evidence that COVID-19 is transmitted predominantly through the air and that its prevention depends on indoor air quality and respirator-grade facial protection. In March 2020, the World Health Organisation spectacularly shot itself in the foot with an announcement on social media that this fact was "fake news", and that the newly-named coronavirus was *not* airborne. Indeed, the narrative that COVID-19 was spread by droplets (and therefore required assiduous handwashing and cleaning of surfaces) was mobilised with extraordinary speed and enthusiasm, given the lack of scientific evidence to support it. Face coverings were depicted by WHO officials and national public health leaders as potentially dangerous fomites, carrying a risk of self-inoculation through "touching the face". In the words of one scathing critic, "the precautionary principle was abandoned like an orphan on the Silk Road". Mask mandates were introduced in most countries half-heartedly, and too late to prevent the huge peak of first-wave deaths. Two years on, the false narrative persists: sanitising hands is now a near-universal ritual on entering a building, and our classrooms and open-plan offices are being uselessly fortified with anti-droplet Perspex screens. Indoor air quality and high-grade facial protection remains low on most policymakers' and institutions' priority lists.

How did we get to this absurd situation? The short answer is that key decision-makers were drawing on the wrong mental models. This has happened before—in 19th century London when physician John Snow presented evidence that cholera (then assumed to be an airborne "miasma") was actually waterborne. Officials of the day collected only certain kinds of data (to do with the quality of the air) and then claimed that there was "no evidence" that cholera was waterborne. Despite Snow's famous act of removing the handle from the Broad St water pump, it was more than ten years (and several more waves of deaths) before the health authorities accepted that cholera is transmitted through water. In a contemporary reversal of that situation, in 2020 WHO and the scientists advising them collected only certain kinds of evidence (this time relating to droplet-borne transmission), refused to contemplate evidence from aerosol science, and then concluded that there was "no evidence" that SARS-CoV-2 was airborne. In both cases—cholera and SARS-CoV-2—prevailing mental models that were assumed by some to transcend theory but were actually heavily theory-laden, powerfully shaped both science and policy, with fatal consequences for some. The evidence-based medicine movement (whose 'hierarchy of evidence' was never designed to accommodate the study designs used by aerosol scientists) and infectious disease clinicians (whose stock in trade is randomised controlled trials of handwashing interventions) emerge as rigid and unimaginative defenders of the false droplet narrative.

Submission ID: 136