SOCIEDADE BRASILEIRA DE BIOSSEGURANÇA E BIOPROTEÇÃO

SB3 Technical Note No. 3

Use of N95/KN95/FFP2/PFF2/P2 Respirators and Powered Air-Purifying Respirators (PAPRs) in Microbiology Laboratories, High Biological Containment Environments / Laboratories (NB3, NBA3), and Health Care Services

Technical Guidelines and Biosafety Requirements

1. Concept and Importance

Respirators are essential Personal Protective Equipment (PPE) for safe work in microbiology laboratories, high biological containment[1] environments/laboratories, and hospital areas with a risk of airborne transmission. Their use aims to reduce the risk of occupational exposure to aerosols containing high-consequence biological agents. Among the most commonly used models are the N95/KN95/FFP2/PFF2/P2 [2] [3] [4]

[1] – In this document, as in others from the Brazilian Society for Biosafety and Biosecurity (SB3), the term "high biological containment environments/laboratories" is used as a replacement for NB3 or NBA3, as recommended by the *World Health Organization (WHO) Laboratory Biosafety Manual*, 4th edition, 2020.

[2] The designations N95, KN95, FFP2, PFF2, and P2 represent internationally equivalent standards of filtration efficiency for 0.3 µm particles (94–95%), established respectively by NIOSH (USA), GB2626 (China), EN 149 (EU), ABNT (Brazil), and AS/NZS (Australia/New Zealand).

[3] The N95 (NIOSH, USA), KN95 (GB2626-2019, China), FFP2 (EN 149, Europe), PFF2 (ABNT/EN, Brazil/Europe), and P2 (AS/NZS 1716:2012, Australia and New Zealand) respirators belong to the class 2 group, with a minimum filtration efficiency between 94% and 95% for 0.3 µm particles, according to standardized test methodologies. In theoretical terms, all these certifications are considered equivalent regarding the capacity to retain solid and liquid particles, including biological aerosols. However, there are construction and quality control differences that influence practical performance and facial seal stability.
N95, FFP2, PFF2, and P2 models have, by standard, headstraps (elastic bands crossed behind the head), which provide greater sealing pressure and reduce the risk of lateral leakage. The standard for KN95 respirators does not specify the type of attachment, allowing versions both with headstraps and earloops (elastic bands behind the ears). In practice, most KN95 models available on the market have the earloop design, which, although more comfortable, reduces stability and facial sealing effectiveness.
Studies conducted by NIOSH and Health Canada/CSA have shown that KN95 respirators with earloops often fail facial fit tests, even when maintaining laboratory filtration efficiency above 95%. KN95 models with headstraps, when properly certified and approved under the same conditions, may offer performance similar to N95/FFP2/PFF2/P2 certifications; however, due to variability among manufacturers and lack of construction standardization, they are not recommended for use in high biological containment environments/laboratories (NB-3/BSL-3), where facial sealing and respirator stability are crucial for occupational safety.

[4] Filtration efficiency tests for class 2 respirators (N95, KN95, FFP2, PFF2, and P2) are carried out under controlled conditions using standardized aerosols to simulate solid and liquid particles. Sodium chloride (NaCl) is used to assess retention of solid particles, representing dust and dry biological aerosols, while glycerin or paraffin oil is used to test efficiency against liquid and oily particles. These tests measure the filtering material's capacity to retain at least 94–95% of 0.3 µm

respirators and powered air-purifying respirators (PAPRs), each with specific characteristics, limitations, and usage requirements.
The selection and correct use of respirators must be integrated into the Institutional Respiratory Protection Program (RPP), including training for selecting the appropriate model for each situation and use, facial seal evaluation, and periodic inspection of PPEs.

respiradores motorizados (PAPRs – Powered Air-Purifying Respirators), cada qual com características, limitações e requisitos de uso específicos.

A seleção e o uso correto do respirador devem integrar o Programa Institucional de Proteção Respiratória (PPR), incluindo treinamento para seleção do modelo adequado a cada situação e uso, avaliação de vedação facial e inspeção periódica dos EPIs.

2. Facial Fit Test (Fit Test): Mandatory Nature and Conditions

The facial fit test[5] for N95/KN95/FFP2/PFF2/P2 respirators is an individual procedure that must be performed—by the institution's occupational safety department or the person responsible for biosafety—individually on each professional who performs activities in environments that require respiratory protection against biological agents, prior to the start of their activities, and must be repeated at least once a year.
It is emphasized that different respirator models fit differently on each person; therefore, it is not possible to ensure individual and collective protection without conducting individualized facial fit testing.
The facial fit test is an individual, mandatory, and non-transferable[6] procedure that must be carried out: (a) upon the worker's entry into risk activities; (b) annually; (c) whenever there is a change in model, batch, or brand of respirator; and (d) whenever the user presents craniofacial changes that result in modification of the facial structure and,

particles, considered the most difficult to capture (most penetrating particle size). The choice of test agents follows international standards—such as NIOSH 42 CFR Part 84 (USA), ABNT NBR 13698:2011 (Brazil), EN 149:2001 (Europe), GB2626-2019 (China), and AS/NZS 1716:2012 (Australia and New Zealand)—and allows verification that the respirator maintains adequate performance both under laboratory conditions and during prolonged use. This knowledge is essential for biosafety professionals and public procurement managers, who must consider certification and test type before institutional acquisition of respirators.

[5] Filtration efficiency tests use sodium chloride aerosols (for hydrophilic particles) and glycerin or paraffin oil (for hydrophobic particles), evaluating maximum penetration of 5 to 6% at 0.3 µm, according to NIOSH and EN 149 methods.

[6] The fit test or fit testing procedure is also provided for in item f, section IX, paragraph 1, article 44 of Chapter II – *Technical Regulation on the Use of Equipment for Respiratory Protection*, of Ordinance MT No. 672, dated November 8, 2021, which regulates procedures, programs, and conditions for occupational safety and health and other related provisions.

therefore, of the PPE seal (e.g., weight loss or gain, surgeries, among others). There are two types of facial fit tests accepted internationally:
a – **Qualitative Fit Test:** uses substances such as saccharin, Bitrex, or irritant smoke to verify whether unfiltered air passes through. Suitable only for respirators up to N95/KN95/FFP2/PFF2/P2, it is a low-cost test that does not require advanced qualification from those applying it. This test only identifies success or failure in the respirator's fit to the user's face.
b – **Quantitative Fit Test:** requires specific particle-counting equipment (e.g., PortaCount) that measures the ratio of particles outside/inside the respirator, adapted to different respirator models N95/KN95/FFP2/PFF2/P2. It is more accurate and requires adequately qualified professionals and is recommended for operators of high biological containment environments/laboratories handling high-consequence and/or exotic pathogens in highly aerosol-generating procedures (for example, high-containment environments/laboratories working with high-consequence pathogens involving animal models, antigen production, and aerobiology assays), when the risk assessment classifies the risk as high or very high[7].
Without performing the individual facial fit test, N95/KN95/FFP2/PFF2/P2 respirators are ineffective, creating a false sense of security and lack of real protection, and must not be used in laboratory or hospital activities with respiratory risk.
Annual repetition of the facial fit test is mandatory due to anatomical changes in the face, which may compromise the seal and efficacy of the respirator.

3. N95/KN95/FFP2/PFF2/P2 Respirators

N95/KN95/FFP2/PFF2/P2 respirators have as their main function protecting the user against biological agents transmitted via aerosols such as viruses, bacteria, and airborne fungi, providing 95% filtration. Their effectiveness critically depends on the facial seal achieved between the respirator and the user's face; without this, the protection offered by the filter is nullified. These are low-cost PPEs, allowing high user protection when the appropriate model for each user is selected through facial fit testing, requiring minimal training for their use, donning, removal, and decontamination for disposal, facilitating work routine and installation sustainability.
These N95/KN95/FFP2/PFF2/P2 respirators may be constructed with headstraps (elastic bands crossed behind the head) or with earloops (elastic bands behind the ears).

[7] As described in the *WHO Laboratory Biosafety Manual, 4th Edition (2020)* — Monograph 3: *Risk Assessment*, section *Risk Evaluation Matrix* (pp. 11–13) — the biological risk assessment process uses a four-level classification matrix: Low, Moderate, High, and Very High. These levels result from the combination of the probability of occurrence (Likelihood) and the severity of consequences (Consequence). Activities involving high-consequence pathogens, aerosol-generating procedures, use of animal models, or manipulation of large culture volumes are typically classified as high or very high risk, reflecting the possibility of significant exposure or dissemination in the event of containment failure.

Respirators with headstraps offer better stability and sealing and are strongly recommended for high-risk environments. Those with earloops are generally less stable and more prone to seal failures and are not recommended for high biological containment environments/laboratories.
Regarding construction, N95/KN95/FFP2/PFF2/P2 respirators may or may not have an exhalation valve (lateral or front). N95/KN95/FFP2/PFF2/P2 respirators with an exhaust valve, although they facilitate breathing, do not filter exhaled air. Thus, they may represent a risk of environmental contamination and, therefore, are not recommended for use in microbiology laboratories, high biological containment environments/laboratories, or hospital settings. Non-valved N95/KN95/FFP2/PFF2/P2 respirators should be prioritized in high biological containment environments/laboratories, as they ensure filtration of both inhaled and exhaled air. Users who have a beard, mustache, or goatee cannot use N95/KN95/FFP2/PFF2/P2 respirators, as facial hair prevents adequate sealing, nullifying the respirator's expected efficacy and safety.

4. Powered Air-Purifying Respirators – PAPR

PAPRs (Powered Air-Purifying Respirators) are motorized devices with HEPA filters that create positive pressure inside the hood, reducing respiratory resistance and providing simultaneous eye and face protection. Powered respirators (PAPRs) provide air filtration efficiency above 99.97%, provided they are properly positioned considering the dimensions of the sealing system and the user's head, without gaps or spaces between the face, neck, and the elastic sealing area of the hood.
PAPRs are classified into two main groups—tight-fitting and loose-fitting—according to their construction characteristics and sealing method. Tight-fitting models have direct sealing to the face, similar to N95/KN95/FFP2/PFF2/P2 respirators, requiring mandatory facial fit testing before use and periodically. These models cannot be used by people with beards, mustaches, or goatees, as any interference in the facial sealing area compromises protection effectiveness. Loose-fitting models, on the other hand, use positive-pressure hoods or helmets, eliminating the need for facial fit testing and allowing use by users with facial hair or other conditions that prevent sealed respirator use. Although loose-fitting PAPRs provide greater comfort and easier breathing, they have a lower protection factor compared to tight-fitting models and require proper air flow maintenance, filter integrity, and strict battery charge management to ensure their effectiveness in high-containment laboratory and hospital environments.
They are high-cost PPEs requiring greater training for use, from system verification and assembly to donning and doffing. It is recommended that donning and doffing be carried out with the assistance of a second trained professional to ensure user safety, involving detailed procedures for immediate decontamination and subsequent cleaning and

disinfection for reuse.
Use of powered respirators requires, as with all PPE selection procedures in such facilities, a prior detailed and exhaustive risk assessment performed by professional(s) fully experienced in biosafety for high-containment installations handling high-consequence pathogens, considering each pathogen and procedure individually to justify their indication or use. These respirators are indicated for cases of intolerance to prolonged use of N95/KN95/FFP2/PFF2/P2, facial deformities, or periods of continuous and significant weight loss (e.g., GLP-1 agonist use).
In high-containment environments and/or work with high-consequence pathogens, where risk assessment justifies the use of PAPRs, cleaning, decontamination, and disposal procedures must follow specific institutional protocols developed according to local biosafety guidance and manufacturer instructions.
PAPRs must be certified according to NIOSH recommendations or equivalent authority and used exclusively in environments where maintenance, decontamination, and traceability can be ensured through validated institutional SOPs, and only after a biological risk assessment specific to each institution/environment, pathogen, and procedure justifying their use.
Although PAPRs offer high levels of protection and user comfort, their use implies substantially higher initial and operational costs than conventional filtering respirators (N95/KN95/FFP2/PFF2/P2). Indiscriminate adoption of these devices can compromise the financial and operational sustainability of high-containment facilities, especially in public or research institutions with limited budgets. According to WHO (LBM4, Monograph 5 – Biological Risk Management) and ISO 35001:2019, mitigation measures must be proportional to the identified level of risk and financially sustainable to ensure operational continuity of high-containment facilities. Thus, it is recommended that their implementation be based on a detailed, technically justified risk assessment, prioritizing PAPR use only in situations where the residual risk, after primary and secondary containment measures, remains high or very high, in accordance with WHO (LBM4, 2020) and ISO 35001:2019 guidelines.
Routine use of PAPRs in NB-2 laboratories is not recommended, except for high-risk aerosolization procedures or operators with medical restrictions preventing the use of tight-fitting respirators.

5. Procedures for Removal and Decontamination of Powered Air-Purifying Respirators

The doffing and decontamination of powered air-purifying respirators (PAPRs) are critical steps for preventing cross-contamination and must be performed according to a Standard Operating Procedure (SOP) validated by the institutional biosafety department. It is recommended to use a double glove barrier and the assistance of a second operator

during the removal and decontamination of the equipment, following the guidelines of NIH/CDC manuals.

5.1. Removal of the Powered Air-Purifying Respirator (PAPR)

The removal process should ideally involve a second trained professional as an assistant to help remove the hood and the motor mounted on the belt. This assistant will disconnect the hose from the motor blower. Next, the assistant will hold the belt unit while the user loosens the belt. The hood and belt-mounted unit are then placed in a designated “dirty” area or container for later disinfection. After the powered unit is turned off, the user removes other PPE items, such as the inner glove pair, and performs hand hygiene.

5.2. Decontamination of the Powered Air-Purifying Respirator (PAPR)

The decontamination and cleaning of powered air-purifying respirators (PAPRs) must follow validated institutional protocols, developed in accordance with the manufacturer’s instructions and the recommendations of the local biosafety team, considering the chemical compatibility of materials and the biological agent handled.
The definition of the decontamination method and product, as well as its concentration and contact time, must be based on biological risk assessment, pathogen characteristics, and equipment usage conditions, ensuring microbiological efficacy and component integrity.
After successful disinfection, the motor and blower should be transferred to a designated “clean” area, where they can be safely stored until next use.
In exceptional high-risk situations, some high biological containment facilities (NB-3/BSL-3 or higher) may subject disposable components (such as hoods and breathing hoses) to terminal autoclaving for inactivation prior to final disposal of these parts.

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6. Guidelines for Institutional Procurement

The institutional procurement of respirators intended for use in laboratories, health care services, and high biological containment environments/laboratories must follow strict technical criteria, based on internationally recognized certification standards (ABNT NBR 13698:2011, EN 149:2001, NIOSH 42 CFR Part 84, and GB2626-2019).
Purchased products must have a valid Approval Certificate (CA), issued by the competent authority, in accordance with NR-6 (MTP Ordinance No. 672/2021), which establishes the legal requirements for certification and use of Personal Protective Equipment (PPE) in Brazil.
Public bidding documents and terms of reference must specify that respirators have a

minimum filtration efficiency of 94–95% for 0.3 µm particles, proven through standardized laboratory testing, and a headstrap system (elastic bands crossed behind the head) ensuring adequate stability and facial seal.
It is essential that models intended for biological protection have no exhalation valve, in order to prevent the release of potentially contaminated aerosols into the environment, and that they have passed individual facial fit testing performed periodically according to institutional respiratory protection programs.
Models with earloops—even if certified—should not be considered equivalent in sealing performance to N95, PFF2, FFP2, or P2 respirators and therefore are not recommended for use in critical or high-containment areas.
SB3 recommends that public and private institutions incorporate these criteria into their procurement, supplier approval, and quality control processes, ensuring responsible and technically sound acquisition of Respiratory Protective Equipment, in accordance with biosafety best practices and applicable national and international regulatory requirements.

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7. SB3 Recommendations

Based on technical evidence and national and international standards of biosafety and respiratory protection, the **Brazilian Society for Biosafety and Biosecurity (SB3)** recommends that public and private institutions adopt the following measures:
a) Conduct individual facial fit testing for all users of N95/KN95/PFF2/FFP2/P2 respirators upon initiation of laboratory activities and periodically (at least once a year), as well as whenever there is a change in model, manufacturer, batch, or relevant anatomical alteration (e.g., weight gain/loss, facial surgery).
b) Ensure user training on proper use, inspection, storage, and disposal of respirators, including instructions about the impossibility of using N95/KN95/FFP2/PFF2/P2 respirators in the presence of beards, mustaches, or goatees, which compromise facial sealing.
c) Institutionally record fit test results under the responsibility of the Respiratory Protection Program (RPP) or equivalent body, ensuring traceability, technical oversight, and periodic compliance auditing.
d) Avoid the procurement and use of respirators with earloops, prioritizing models with headstraps, which provide better stability and sealing.
e) Replace conventional respirators with powered air-purifying respirators (PAPRs) in cases where the user does not achieve satisfactory sealing in successive fit tests or presents facial characteristics (including facial hair) that prevent the safe use of filtering facepiece respirators.
f) Require, in procurement and institutional approval processes, the presentation of a

valid Approval Certificate (CA), filtration efficiency test reports, and compliance with applicable international standards (ABNT NBR 13698, EN 149, NIOSH 42 CFR Part 84, GB2626-2019).

g) Include the biosafety officer and the RPP manager in the stages of selection, procurement, and implementation of respiratory protective equipment, ensuring that choices are based on technical criteria and aligned with the biological risk level of the facility.

h) Base the adoption of powered respirators (PAPRs) on criteria of proportionality and operational sustainability, considering that, although they provide greater comfort and protection, they involve higher acquisition, maintenance, and training costs. Their indication must be technically justified in the biological risk assessment and integrated into the institutional biorisk management plan to ensure rational use of resources without compromising operator safety or operational feasibility.

i) Promote internal audits and periodic reviews of respiratory protection practices, focusing on compliance with standards, the effectiveness of training programs, and the adequacy of equipment in use.

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8. Conclusion

The use of N95/KN95/FFP2/PFF2/P2 respirators in microbiology laboratories, high biological containment environments/laboratories, and health care services is only safe and effective when associated with individual proof of sealing through facial fit testing. SB3 recommends the immediate and mandatory adoption of this procedure in all institutions where there is a risk of respiratory exposure to biological agents, aligning national practices with international biosafety standards and ensuring effective protection for professionals.

The use of powered air-purifying respirators (PAPRs) should only be indicated after detailed and documented biological risk assessment, considering individually the pathogens handled and the procedures performed. If this assessment determines that a powered respirator is the most appropriate model, its use must be integrated into the training program and individual evaluation of professionals authorized to access such facilities, ensuring high technical proficiency and operational safety.

It is also recommended that donning and doffing be performed with the assistance of a second trained professional, especially in high biological containment environments/laboratories (NB-3/BSL-3), where the complexity of procedures requires strict control and supervised monitoring.

For the selection and use of PPE intended to provide respiratory protection for professionals operating inside high-containment facilities and/or working with high-consequence pathogens, the procedures to be carried out and the associated risks must

necessarily be considered, among other factors. In this context, it is necessary to evaluate the characteristics of the facility, the level of user training, and the reliability of the institutional biosafety culture, aiming for sustainability of such installations, which are known to have very high operational costs.

The use of respirators represents a critical component of institutional biosafety. Without individual verification of facial sealing for models that require it, respirators completely lose their effectiveness, exposing the user to biological risk.

SB3 recommends that the selection and use of respirators be based on detailed biological risk assessment, proven training, and adherence to structured respiratory protection programs, with the Respiratory Protection Program (RPP) documenting the individual history of facial fit tests, ensuring traceability and compliance with the institutional standard adopted.

The use of powered air-purifying respirators (PAPRs) must be restricted to technically justified situations, after risk assessment and formal training, ensuring rational and safe use of these high-cost, operationally complex devices.

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