

BioProtect Tool: a Control Banding Method for Respirator Selection against Bioaerosols

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ABSTRACT

Selecting the right respirator to protect workers against occupational exposure to bioaerosols is complicated by the lack of occupational exposure limits, the limits of current sampling methods, the diversity of bioaerosols and the inconsistency among experts' recommendations. Thus, qualitative methods such as control banding offer a more practical alternative for risk assessment and management of bioaerosols. The objective of this project was to develop a control banding approach, the BioProtect Tool, for respirator selection against both infectious and non-infectious bioaerosols applicable to all workplaces. A committee including occupational hygienists, microbiologists and physicians, as well as experts in the fields of control banding, respiratory protection, ventilation and aerosol physics was formed to develop and validate the model. A 4 x 5 selection matrix was developed, with four biosafety risk groups and five exposure level bands. Each exposure level band is the sum of a control level band and a generation rate band. A minimum protection factor is assigned to each risk group-exposure level pair, allowing the user to identify an appropriate respirator. A validation of the model using nineteen case studies showed that the assigned protection factors obtained with the control banding approach matched or exceeded the assigned protection factors retrieved from the literature in fifteen cases out of nineteen. Comparison with the Canadian Standard Association's control banding model also showed that the control banding approach presented in this publication is more sensitive to slight changes in workplace conditions and tends to give more conservative results. Overall, the control banding approach developed is a simple and useful tool for assessing the risk of occupational exposure to infectious and non-infectious bioaerosols, providing recommendations for respirator selection and identifying activities that present the most risk. It could be easily integrated into the assessment and management of occupational risks wherever workers are exposed to bioaerosols.

Keywords: Control banding, bioaerosols, respiratory protection, risk assessment

INTRODUCTION

Health risks associated to occupational exposure to bioaerosols are relatively well known and the importance of properly protecting workers against these agents cannot be understated. However, selection of appropriate respirators to protect workers against bioaerosols is complicated by the lack of occupational exposure limit (OEL) values, limits of current sampling methods, the diversity of bioaerosols and the inconsistency among experts' recommendations (Eduard, Heederik, Duchaine, & Green, 2012).

In 2007, the Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) published the Guide on Respiratory Protection against Bioaerosols (Lavoie, Cloutier, Lara, & Marchand, 2007), in which it was advised to follow experts' recommendations for the selection of respiratory protection against infectious bioaerosols. However, these recommendations may vary significantly from one source to another for similar risk situations, and over time as new knowledge is acquired. It was also advised to select respirators against non-infectious bioaerosols according to the risk coefficient (RC) method, by measuring the concentration of bioaerosols in the workers' breathing zone and comparing this concentration to tolerated background levels. Application of the RC method may be confounded by a lack of consensus regarding tolerated background levels and both the low reproducibility and poor reliability of sampling methods. Considering the limitations of the currently available approaches to the selection of respiratory protection against bioaerosols, the development of novel tools such as the control banding (CB) BioProtect Tool is justified.

An initial CB approach to be applied to respiratory protection against bioaerosols was recently proposed as part of the update of the Canadian Standard Association (CSA) Z94.4-11 standard for the Selection, Use and Care of Respirators (2011). This approach is partly based on a mathematical model proposed by McCullough and Brosseau as a part of their research on respirator selection for controlling workers' exposure to infectious aerosols in healthcare settings (Canadian Standards Association, 2011; McCullough & Brosseau, 1999). The CSA Z94.4-11 discriminates between the healthcare work environment and general workplaces, which may lead in some instances to different levels of protection despite similar levels of risk.

In order to circumvent the weaknesses mentioned above, a new CB approach, the BioProtect Tool, which is based on a system of bands rather than on a mathematical model and which does not discriminate between different workplaces, was developed in close collaboration with experts from different fields.

METHODS

Methods can be divided into two parts: 1) the development, in collaboration with an experts committee, of the BioProtect Tool and 2) the validation of the BioProtect Tool via case studies and comparison with the CSA model.

Development of the BioProtect Tool

The model was inspired by CB models applied to chemicals and nanoparticles (Paik, Zalk, & Swuste, 2008; Russell, Maidment, Brooke, & Topping, 1998), the research works of McCullough and Brosseau (1999) and the newly updated CSA standard for the Selection, Use and Care of Respirators (2011). A selection matrix was developed, with four rows corresponding to four biosafety risk groups and five columns corresponding to specific exposure level bands. Each exposure level band is associated with a score which is the weighted sum of a control level score and a generation rate score. A minimum assigned protection factor (APF) is associated with each risk group-exposure level pair, allowing the user

to identify an appropriate respirator. The bands and scores were validated by a committee composed of occupational hygienists, microbiologists and physicians, as well as experts in the fields of control banding, respiratory protection, ventilation and aerosol behavior.

Description of the bands

A) Risk groups: bioaerosols are defined in this article as airborne particles containing live organisms including viruses, bacteria, molds, protozoa, and substances or products of these organisms (e.g.: toxins, dead microorganisms or fragments of microorganisms) (American Conference of Governmental Industrial Hygienists, 1999). Bioaerosols are similar to their non-biological counterparts in that their behavior in the air and their deposition pattern depend on their physical characteristics, primarily their aerodynamic size and shape (Brosseau, McCullough, & Vesley, 1997). Bioaerosols are divided into four risk groups, following the classification of microorganisms used in biosafety and based on their pathogenicity (Canadian Standards Association, 2011; Centers for Disease Control and Prevention & National Institutes of Health, 2009; Health Canada, 2004; National Institutes of Health, 2011; Parlement européen et Conseil de l'union européenne, 2000; World Health Organization, 2004). In addition to pathogenicity, this classification takes into account the infective dose, mode of transmission, the host and the availability of preventive measures and effective treatment (Health Canada, 2004). There are three infectious risk groups (RG 2 to RG 4) and one non-infectious (RG 1). The four risk groups are in the BioProtect Tool the equivalent of hazard bands used in other CB approaches (Paik et al., 2008; Russell et al., 1998). Long-term exposure to high levels of RG 1 bioaerosols may also, despite their non-infectious nature, cause serious and irreversible health problems such as sensitization and the development of occupational diseases (e.g.: asthma, organic dust toxicity syndrome (ODTS), farmer's lung, etc.) (Burge, 1995; Eduard, 1997; Eduard et al., 2012; Goyer, Lavoie, Lazure, & Marchand, 2001; Lacey, 1991; Lacey & Dutkiewicz, 1994; Lavoie et al., 2007). The BioProtect Tool was developed with the aim of protecting workers against risks associated with RG 1 bioaerosols as much as RG 2, 3 and 4 bioaerosols. Table I presents the four risk groups with their definition as well as a few examples. One or more of the databases cited below must be consulted for a more exhaustive and up-to-date list (American Biological Safety Association; National Institutes of Health, 2011; Parlement européen et Conseil de l'union européenne, 2000; Public Health Agency of Canada, 2012).

Table I. Classification of Microorganisms into the Four Risk Groups

Risk Group	Definition and Examples
1	Def.: Agents that are not associated with disease in healthy adult humans (No or low risk for individuals and communities) Ex.: <i>Bacillus subtilis</i> , <i>Escherichia coli</i> K12, the majority of molds
2	Def.: Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available (Moderate risk for individuals, low for communities) Ex.: Bacteria: <i>Salmonella</i> spp., <i>Legionella</i> spp., <i>Chlamydia</i> spp., <i>Clostridium</i> spp., <i>Vibrio cholerae</i> , <i>Listeria</i> spp., <i>Streptococcus</i> spp., <i>Helicobacter pylori</i> Fungi: <i>Blastomyces dermatitidis</i> , <i>Cladosporium bantianum</i> , <i>Cryptococcus neoformans</i> , <i>Microsporum</i> , <i>Penicillium marneffeii</i> Endoparasites: <i>Entamoeba histolytica</i> , <i>Giardia lamblia</i> , <i>Leishmania</i> spp., <i>Plasmodium</i> spp., <i>Schistosoma</i> spp., <i>Toxoplasma</i> , <i>Trypanosoma</i> Viruses: Hepatitis A, B, C, D and E, Epstein Barr, types A, B and C influenza, human papillomavirus, mumps, measles, polio (all types)
3	Def.: Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions <i>may be</i> available (High risk for individuals, low for communities) Ex.: Bacteria: <i>Mycobacterium tuberculosis</i> , <i>Brucella</i> spp., <i>Yersinia pestis</i> Fungi: <i>Coccidioides immitis</i> , <i>Histoplasma capsulatum</i> Viruses: Hantavirus, Rift Valley fever, Japanese encephalitis, Yellow fever, types 1 and 2 HIV Prions: Creutzfeldt-Jacob disease, kuru agents
4	Def.: Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are <i>not usually</i> available (High risk for individuals and communities). This group comprises viruses only. Ex.: Crimean-Congo hemorrhagic fever, Ebola, Marburg, Lassa, Herpes B (Monkey B), Hemorrhagic fever agents and undefined viruses.

B) Exposure level: the exposure level is a function of the control level and the generation rate. The control level (Q) corresponds mainly to the type and rate of ventilation present in the workplace (indoor versus outdoor, number of air changes per hour (ACH), etc.). Table II presents the control level bands and the corresponding scores.

Table II. Control Level (Q)

Score	Control level band
2.0	$ACH \leq 2$; no ventilation or confined spaces
1.5	$2 < ACH \leq 6$; general ventilation or open windows
1.0	$6 < ACH \leq 12$; negative pressure room; laboratory ventilation; isolation room; displacement ventilation
0.5	$ACH > 12$; mechanized operations; operations in a laboratory hood; some hospitals departments (bronchoscopy, surgery room, etc.); outdoor work
0	operations in a laminar flow hood; closed circuit sources

ACH: number of air changes per hour

The generation rate (G) corresponds to the aerosolization (suspension) potential of the biological contaminant. It depends on the type of activity, the process and the proximity to the emission source. Table III presents the generation rate bands and corresponding scores as well as a few examples for each.

Table III. Generation Rate (G)

Score	Generation rate band	Examples
8.0	Very high aerosolization and probability of inhalation	Proximity to emission sources; work within the emission plume; medical activities producing aerosols (bronchoscopy, etc.)
6.0	High aerosolization and probability of inhalation	Decontamination work; care given to an infected patient coughing or sneezing with mouth uncovered; dry sweeping
4.0	Moderate aerosolization and probability of inhalation	Long distance from the source; infected patient coughing or sneezing with mouth covered; wet sweeping
2.0	Low aerosolization and probability of inhalation	Sampling; inspecting with manipulation of contaminated material
0	Very low aerosolization and probability of inhalation	Careful manipulation, inspecting without manipulation of contaminated material

The exposure level (E) is the result of the weighted sum of the control level (Q) (Table II) and the generation rate (G) (Table III) scores for a maximum of 10. The weighting factors are 20 % of the score from the control level and 80 % from the generation rate. The weighting factors are already included into the scores shown in tables II and III. This 20 %-80 % weighting system is empirical and was chosen in order to avoid underestimating workers' exposure in situations where they are in close proximity to the contamination source (i.e. where the generation rate is effectively the main contributor of exposure).

A total score between 0 and 2 (first band) is considered a very low exposure level, from 2.5 to 5 (second band) is a low level, from 5.5 to 7 (third band) is a medium level, from 7.5 to 9 (fourth band) is a high level, and from 9.5 to 10 (fifth band) is a very high exposure level (Table IV).

Table IV. Exposure Level (E)

Score	Exposure level band
9.5 – 10	5 (very high)
7.5 – 9	4 (high)
5.5 – 7	3 (medium)
2.5 – 5	2 (low)
0 – 2	1 (very low)

Selection Matrix

A minimum APF is associated to each risk group-exposure level pair, from which a respirator with the right APF may then be selected. Table V shows the selection matrix that synthesizes the model.

Table V. Selection Matrix for the Choice of the Assigned Protection Factor (APF)

		Exposure Level Band				
		1	2	3	4	5
Risk Group	1	None	10	10	10	25
	2	None	10	10	25	50
	3	None	10	25	50	1000
	4	1000	1000	1000	1000	1000

Each number corresponds to a minimum assigned protection factor (APF)

According to the National Institute for Occupational Safety and Health (NIOSH), the APF is “the minimum level of protection expected for a substantial proportion (usually 95%) of properly fitted and trained respirator users” (Lenhart, Schafer, Singal, & Hajjeh, 2004). It is the ratio of the concentration of contaminant outside the respirator over the concentration of contaminant inside the respirator, measured on tightly fitted respirators in a controlled laboratory environment or in the workplace (Lenhart et al., 2004). An APF of 10 means that, in ideal conditions, the concentration of contaminant is ten times lower inside the respirator than outside. A worker wearing a properly used, well fitted and well maintained respirator with an APF of 10, such as a N95 half-mask, is therefore exposed to 10 times less contaminant than if he did not wear any respiratory protection. Users of the BioProtect Tool may choose a respirator with a higher APF than the minimum recommended APF. Choosing a respirator with a lower APF, however, might put workers’ health at risk.

Validation of the BioProtect Tool

Validation of the BioProtect Tool was performed through the study of nineteen cases retrieved from the literature. Two cases pertain to a potential exposure to the severe acute respiratory syndrome (SARS) virus in a healthcare setting (Ministerial Committee on Precautionary Measures against Severe Acute Respiratory Syndrome (SARS), 2004), three to potential exposure to tuberculosis (Centers for Disease Control and Prevention, 2005; McCullough & Brosseau, 1999; Nolte, Taylor, & Richmond, 2002), two to hantavirus (Centers for Disease Control and Prevention, 2002a), two to potential exposure to anthrax in a post office (Centers for Disease Control and Prevention, 2001, 2002b), one to legionellosis in a spa (McCullough & Brosseau, 1999), three to histoplasmosis (Lenhart et al., 2004), one to H1N1 influenza virus (Centers for Disease Control and Prevention, 2010), one to exposure to psittacosis in a poultry slaughterhouse (Noone, 2012), and four to non-infectious bioaerosols in a peat moss packaging plant (Duchaine et al., 2010), agricultural farms (Lee et al., 2005), a water treatment plant (Lavoie, 2000) and a waste recycling plant (Lavoie & Guertin, 2001). A comparative analysis was performed between the

APFs obtained with the BioProtect Tool and those previously recommended by independent authors, experts or working groups retrieved from the literature (Table VI). This validation method has been recognized as a method of choice for the evaluation of CB approaches (Brouwer, 2012; Jones & Nicas, 2006). The nineteen cases were also analyzed using the CB approach of the CSA (Canadian Standards Association, 2011) and the APFs obtained with the two approaches were then compared (Table VI).

RESULTS AND DISCUSSION

From the analysis of Table VI, it can be observed that the APFs obtained with the BioProtect Tool are the same as the APFs recommended by authors in thirteen cases out of nineteen (cases 1, 3, 4, 7, 8, 10, 11, 12, 13, 14, 15, 16 and 17). There are three cases for which no APF was specifically recommended (cases 6, 18 and 19) and thus a comparison with the BioProtect Tool could not be made. By eliminating the latter three cases, the BioProtect Tool gave the same result in thirteen out of sixteen cases. For case 2 (SARS), the APF obtained with the BioProtect Tool (APF of 25) is between the two options given by the Ministerial Committee on Precautionary Measures against SARS (APF of 10 or APF of 50 to 1000). In case 5 (tuberculosis), three recommendations were found by three different authors, each recommending a different APF, which made the comparison complicated. This example shows the disparity among experts' recommendations and the need for more objective methods. The APF of 25 obtained with the BioProtect Tool in this case is equal to the APF of 25 recommended by McCullough and Brosseau (1999), higher than the APF of 10 recommended by Nolte et al. (2002) and equal to the lowest possible APF recommended by the CDC (2005). For case 9 (anthrax), the APF obtained with the BioProtect Tool is lower than the recommended APF (25 compared to 1000). This can be explained by the fact that anthrax was, and is still considered a biological weapon by the CDC, hence the APF of 1000 (National Institute for Occupational Safety and Health, 2009). However, the BioProtect Tool treats anthrax as any other RG 3 organism, therefore leading to an APF much lower than what is recommended for biological weapons. This indicates that the BioProtect Tool might not be suited for the choice of respiratory protection against bioaerosols that can be used as biological weapons. In the same way, the CSA's CB approach is not applicable in this case and it clearly states that its Z94.4-11 standard "is not intended to address the requirements for protection for first responders during CBRN (chemical, biological, radiological, and nuclear) events" (Canadian Standards Association, 2011).

Overall, it can be stated that the APFs obtained with the BioProtect Tool were equal, higher or within the range of the recommended APFs in fifteen cases out of sixteen (excluding the three cases discussed above where no APF was recommended), the remaining case (9) being the only one where the BioProtect Tool leads to a lower APF than what is recommended, for the above-mentioned reasons. In comparison to the CSA approach, the BioProtect Tool seems more sensitive to slight changes in the conditions (i.e. control level and/or generation rate) and generally more conservative. Indeed, fourteen APFs of 10, one APF of 25 and two APFs of 50 were obtained with the CSA approach, compared to eleven, five and three, respectively, with the BioProtect Tool. This can be explained in part by the 20 %-80 % weighting system which is absent from the CSA approach. As mentioned earlier, the 20 %-80 % weighting system was chosen in order to avoid underestimating workers' exposure in situations where they are in close proximity to the contamination source. By not taking this factor into account, the CSA approach may lead to the underestimation of workers' exposure, which might eventually put workers' health at risk.

Table VI. Assigned Protection Factors (APFs) Obtained with the BioProtect Tool and the CSA Approach, and from Existing Recommendations in the Literature

Bioaerosol	#	Case	Evaluation with the BioProtect Tool				Recommendations found in the literature	CSA APF
			Q	G	E (Q+G)	A P F		
SARS virus (RG 3)	1	ER staff sorting potentially infected patients	1.5 (general ventilation)	2 (low aerosolization)	3.5 (low)	10	N95 half face piece (APF 10)	10
	2	Care given to an infected patient	1 ($6 < ACH \leq 12$)	6 (patient coughing/sneezing with mouth uncovered)	7 (medium)	25	N95 half face piece only (APF 10) or N95 under PAPR with disposable hood (APF 50 to 1000)	10
Tuberculosis (<i>M. tuberculosis</i>) (RG 3)	3	Entry in the room of an infected patient	1 (negative pressure)	4 (patient coughing/sneezing with mouth covered)	5 (low)	10	N95 minimum (APF 10)	10
	4	Bronchoscopy performed on infected patient	0.5 (bronchoscopy)	8 (medical activity producing aerosols)	8.5 (high)	50	Full face piece (APF 50) or PAPR (APF 25 to 1000, depending on face piece)	10
	5	Autopsy on a person deceased from tuberculosis	1 ($6 < CAH \leq 12$)	6 (high aerosolization)	7 (medium)	25	CDC: Full face piece (APF 50) or PAPR (APF 25 to 1000, depending on face piece); Nolte <i>et al.</i> : N95 minimum (APF 10); McCullough & Brosseau: APF 25	10
Hantavirus (RG 3)	6	Potential contact with rodents (electricians, plumbers, etc.)	2 (no ventilation)	2 (low probability of contact with contaminant)	4 (low)	10	No general recommendation. Employer must determine level of risk and implement appropriate protective measures	10
	7	Frequent exposure to wild rodents (zoologists, exterminators, etc.)	2 (no ventilation)	6 (high probability of inhalation)	8 (high)	50	N100 half face piece (APF 10) or PAPR with half face piece (APF 50)	50
Anthrax (<i>B. anthracis</i>) (RG 3)	8	Mail handling	1.5 (general ventilation)	2 (low probability of contact with the bioaerosol)	3.5 (low)	10	N95 half face piece (APF 10)	N/A
	9	Collecting <i>B. anthracis</i> samples in a post office	1.5 (general ventilation)	4 (moderate probability of contact with the bioaerosol)	5.5 (medium)	25	PAPR with full face piece (APF 1000)	N/A

Legionellosis (<i>L. pneumophila</i>) (RG 2)	10	Cleaning a spa	1.5 (general ventilation)	4 (contact with the bioaerosol)	5.5 (medium)	10	APF 10	10
Histoplasmosis (<i>H. capsulatum</i>) (RG 3)	11	Inspection, sampling, etc.	0.5 (outdoor work)	2 (low aerosolization)	2.5 (low)	10	N95 half face piece (APF 10)	10
	12	Outdoor work and cleaning	0.5 (outdoor work)	4 (moderate aerosolization)	4.5 (low)	10	APF 10 minimum	10
	13	Chimney cleaning, work in attics or henhouses	2 (no ventilation)	6 (high aerosolization)	8 (high)	50	APF 50 minimum	50
Bioaerosols in agricultural farms (RG 1)	14		2 (no ventilation)	8 (very high aerosolization)	10 (very high)	25	APF 25	25
Bioaerosols in a waste recycling plant (RG 1)	15		1.5 (general ventilation)	6 (high aerosolization)	7.5 (high)	10	APF 10	10
Bioaerosols in a water treatment plant (RG 1)	16		1.5 (general ventilation)	6 (high aerosolization)	7.5 (high)	10	APF 10	10
H1N1 Influenza virus (RG 3)	17	Workers cleaning up an infected patient's isolation room in a hospital	1 (negative pressure)	4 (long distance from the source, moderate aerosolization)	5 (low)	10	N95 minimum (APF 10)	10
Peat moss (RG 1)	18	Peat moss packaging	1.5 (general ventilation)	8 (out-of-control aerosolization)	9.5 (very high)	25	Respiratory protection recommended without specifying an APF	10
Psittacosis (<i>C. psittaci</i>) (RG 2)	19	Poultry slaughterhouse	1.5 (general ventilation)	2 (low probability of inhalation)	3.5 (low)	10	Respiratory protection recommended without specifying an APF	10

Legend: RG=risk group; CB=control banding; Q=control level; G=generation rate; E=exposure level; APF=assigned protection factor; ER=Emergency room

CONCLUSIONS

Knowing that bioaerosols are present in many workplaces and knowing the adverse health effects they may cause, the importance of identifying situations most at risk and providing the right protection to workers is obvious. Considering the limitations of existing sampling methods and lack of OELs for bioaerosols, control banding constitutes a good alternative or complement to quantitative industrial hygiene methods. The BioProtect Tool presented here was developed in order to fill in the gap and provide a simple and user-friendly tool for the selection of respiratory protection against bioaerosols applicable to all workplaces. It is a useful tool for assessing the risk of exposure to infectious and non-infectious bioaerosols, providing recommendations for appropriate respirator selection and identifying activities that are most at risk; it could be easily integrated in the assessment and management of occupational risks wherever workers are exposed to bioaerosols. Validation using case studies showed that there exists a good concordance between APFs obtained using the BioProtect Tool and those retrieved from the literature, and that it is a more sensitive and more conservative approach than the CSA's CB approach. However, the BioProtect Tool does not seem suited for selecting respiratory protection against bioaerosols that might be used as biological weapons, as seen with the study of the anthrax case.

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