



Government
— of —
Saskatchewan

Ministry of Labour Relations and Workplace Safety
300 - 1870 Albert Street
Regina, Canada S4P 4W1

November 23, 2020

Kevin Siebert
Director – Patient and Staff Safety - Quality and Safety
Saskatchewan Health Authority
4211 Albert Street, 4th Floor
REGINA SK S4S 3R6

Dear Kevin Siebert:

**Re: Exemption from Clause 88(1)(a) of
The Occupational Health and Safety Regulations, 1996
Pursuant to Section 3-85 of *The Saskatchewan Employment Act***

Further to your correspondence regarding the above, an extension to this exemption will be granted subject to the conditions stated on the attached exemption form.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Ray Anthony".

M. Ray Anthony
Executive Director
Occupational Health and Safety Division

Attachment

EXEMPTION FROM REGULATIONS

BY VIRTUE OF THE PROVISION MADE IN SECTION 3-85 OF THE SASKATCHEWAN EMPLOYMENT ACT, AND IN CONSIDERATION OF THE FACT THAT THE SAFETY OR HEALTH OF PERSONS WORKING AT THE PLACE OF EMPLOYMENT OF:

Saskatchewan Health Authority
various locations

WILL NOT BE MATERIALLY AFFECTED AND THAT INTERESTED PERSONS HAVE BEEN CONSULTED, I HEREBY DIRECT:

Saskatchewan Health Authority (“SHA”) is permitted to utilize its stock of The National Institute for Occupational Safety and Health (“NIOSH”) approved tight fitting N95 respirators (the “Respirators”) although the requirements of clause 88(1)(a) of *The Occupational Health and Safety Regulations, 1996* (the “regulations”) may not be met due to the Respirators exceeding their manufacturer designated shelf life (“Expired N95 Respirators”).

SUBJECT TO THESE CONDITIONS:

1. This exemption only applies to the following types of Expired N95 Respirators:
 - 3M 1860;
 - 3M 1860s;
 - 3M 1870;
 - 3M 8210;
 - Kimberly Clark 46727; and
 - Kimberly Clark 46827.
2. This exemption only applies to Saskatchewan Health Authority (SHA) workers who may be required to wear these Expired N95 Respirators.
3. This exemption does not exempt SHA from other respiratory protective devices requirements as prescribed within section 88 of the regulations. The SHA must comply with all other legislative requirements concerning the respiratory protection of workers, as well as any other relevant guidance from Saskatchewan Public Health concerning the respiratory protection of workers.
4. Expired N95 Respirators used in accordance with this exemption may only be utilized if they are not damaged, and have been stored in accordance with the storage requirements listed in the *CAN/CSA standard Z94.4 -18* titled “*Selection, use and care of respirators*” under section 11.5.1 and as per the manufacturers’ storage conditions and recommendations.
5. The Expired N95 Respirators may only be utilized, if respirators that have not exceeded their manufacturer designated shelf life are not available to the SHA.

6. Before it may rely on this exemption, the SHA must establish a provincial committee (the “Committee”) made up of physicians, relevant SHA operational leaders, and representatives from the Ministry of Health to provide leadership, enable assets, and establish processes to ensure the safe and effective management of respiratory protection resources and other related protective measures through the hierarchy of hazard control, and pandemic planning and operations. The functions of the Committee will include, but not be limited to, the following:
 - a. The Committee will ensure there is support for the critical and emerging needs of effected front-line workers, SHA staff, physicians, and partners in the community, as well as make available to these entities relevant evidence and guidance of national and international bodies.
 - b. The Committee will consult with competent persons as needed, depending on the decisions or recommendations being developed.
 - c. Before the SHA may rely on this exemption, the Committee must establish a PPE Framework which will provide guidance for clinical, ethical, and operational structures and principles that must be applied to effectively manage respiratory protection and associated PPE in the context of a pandemic and anticipated critical supply shortages. In addition, this Framework will provide detailed guidance on required actions broken down by multiple settings, personnel, and PPE risk assessment level.
 - d. As the guidance provided by the Committee is subject to change based on evidence and the progression of the pandemic, the decisions and recommendations from the Committee will be regularly reassessed and updated as required.
 - e. As the SHA has other uses and needs for respiratory protection, whether it be for chemical, contaminant or other biological exposure protection, the Committee must consider the broader implications of their decisions and recommendations.
7. The SHA must ensure that workers using the Expired N95 Respirators are notified that these devices have exceeded their manufacturer designated shelf life.
8. The SHA must ensure that workers using these Expired N95 Respirators have been provided with any additional training required to ensure safe use of the Respirators.
9. The SHA must comply with all other manufacturer guidance on the appropriate use and limitations on use of the Expired N95 Respirators.
10. The SHA must ensure that workers visually inspect any subject Respirator prior to its use. The purpose of this inspection is to determine if the integrity and functionality of the subject Respirator has not been compromised, specifically focusing on the straps, nose bridge, and nose foam material. The SHA must ensure that any respirator failing this inspection is returned to the worker’s Supervisor or other designated individual for proper disposal and tracking.

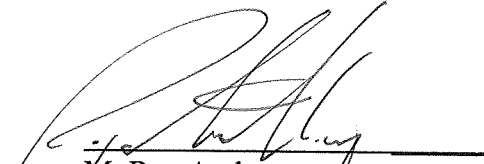
11. The SHA must ensure that workers report any concerns or adverse events regarding the use of Expired N95 Respirators, such as concerns regarding the integrity or functionality of the Respirators, failure of seal checks, or difficulty fit testing. The SHA must ensure that any such issues are recorded, tracked, and addressed in a timely manner.
12. The SHA will ensure that any records associated with this exemption, such as rationale for recommendations, decisions made by the Committee, or Respirator tracking, are maintained until otherwise notified by the Occupational Health and Safety (“OHS”) Division. Such records will be made immediately available to the OHS Division upon its request.
13. The SHA will ensure that, if the Expired N95 Respirators are utilized in a setting where there is a risk of high velocity fluid spray, effective controls are put in place to mitigate the risk of fluid splashes and release of other contaminants into the air. These effective controls for fluid resistance shall be in place until such time that the SHA performs sufficient fluid resistance testing of the Expired N95 Respirators to ensure that they meet appropriate quality standards, and provide the OHS Division with results of the testing.
14. Prior to relying on this exemption, the SHA performs sufficient filtration efficiency testing, and inhalation/exhalation resistance testing of the Expired N95 Respirators to ensure that they meet appropriate quality standards, and provide the OHS Division with results of the testing. The SHA will ensure that any Expired N95 Respirators that fail any of the testing namely filtration efficiency, inhalation/exhalation resistance, and fluid resistance will not be used as respiratory protective devices for workers.
15. Further to condition 14, the SHA submitted three test results conducted to assess the filtration efficiency, inhalation/exhalation resistance, and fluid resistance of the stockpiled Expired N95 Respirators that the SHA holds. These tests were conducted by Nelson Labs, an accredited laboratory in Salt Lake City, Utah that performs pre-certification testing for companies applying for NIOSH certification. Any of the following lots of Respirators that failed any test must not be used as respiratory protective devices for workers.
 - Test results were submitted dated April 15, 2020, and all the samples from the 3M and Kimberley Clark makes and models passed the inhalation/exhalation resistance testing.
 - Kimberley Clark 46727 respirators from Lot #AM9235C84, and Kimberley Clark 46827 respirators from Lot #AM7233A84 and Lot #AM7229C81 failed the filtration efficiency test based on the test results submitted dated April 20, 2020.
 - Synthetic blood penetration resistance test results submitted dated May 21, 2020, had few samples of the Kimberly Clark Model 46827 respirators from Lot # AM7232B84 that failed the synthetic blood penetration test.
16. SHA must ensure to perform retesting (i.e., filtration efficiency, inhalation/exhalation resistance, and fluid resistance tests) of the Expired N95 Respirators at least every six months.
17. The SHA shall promptly report any failure to comply with any conditions of this exemption to the Executive Director of the Occupational Health and Safety Division.
18. The SHA must post a copy of this exemption in two conspicuous places at each location where workers affected by the exemption are employed.

AND FOR THESE REASONS:

1. The Centers for Disease Control and Prevention (“CDC”) in the United States is one of the major operating components of the Department of Health and Human Services and serves as their nation’s health protection agency. NIOSH operates under the CDC, as a federal agency in the United States that provides a testing, approval, and certification program assuring respirators used in the workplace meet appropriate standards. The Executive Director of the Occupational Health and Safety Division accepts the CDC and NIOSH as an agency acceptable for approval of respiratory protective devices under conditions prescribed by the agency pursuant to section 88 of the regulations.
2. On March 2, 2020, based on a request by the CDC, the Food and Drug Administration (“FDA”) issued a letter authorizing emergency use of: (1) all disposable filtering facepiece respirators (“FFRs”) approved by NIOSH as non-powered air-purifying particulate FFRs; and (2) FFRs that were NIOSH-approved but have since passed the manufacturers’ recommended shelf-life, for use in healthcare settings by healthcare personnel to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (“COVID-19”) outbreak.
3. The CDC has evaluated stockpiled N95s that have exceeded their manufacturer-designated shelf life from 10 geographically dispersed facilities with a range of storage conditions. The results have concluded that the evaluated respirators remain mostly effective. The testing was conducted in accordance with the NIOSH performance standards for filtration efficiency, and inhalation/exhalation resistance. All test samples of the 3M 1860, 8210, and 1870 respirators passed the test. It is anticipated that 3M 1860S will perform similar to the 1860 as they only differ in size.
4. Health Canada published on its website under “COVID-19 medical masks and respirators: Information for health professionals” referenced November 6, 2020, that “in times of increased demand and decreased supply, health care providers may consider using expired respirators. An expired respirator can still be effective at protecting health care providers if: it can be fit-tested; the straps are intact; there are no visible signs of damage. Health care providers should inspect the respirator and perform a seal check. It is unknown how long after the expiry date the respirator would be considered suitable for use.”
5. The SHA published in their PPE Bulletin of April 17, 2020 advising that “We are supplementing existing supplies with N95 respirators available from provincial pandemic supplies. The SHA and the Saskatchewan Association for Safe Workplaces in Health (SASWH) have been using these beyond normal shelf life N95 respirators in fit testing throughout the SHA with no reported issues. As well, Canadian guidance and international research completed on testing of beyond normal shelf life respirators further support the use of these supplies.”
6. The standard of health and safety of any worker will not be materially affected by this exemption.

EXPIRY & REVOCATION:

This exemption may be revoked by the Director at any time without notice. Unless sooner revoked, this exemption will expire on November 5, 2021.



M. Ray Anthony
Executive Director
Occupational Health and Safety Division

Date: November 23, 2020