TSI® INSTRUMENTATION FOR MEASURING SUBMICRON PARTICLE FILTRATION OF BARRIER FACE COVERINGS TO ASTM F3502

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APPLICATION NOTE AFT-008 (A4)

What are Barrier Face Coverings?

The COVID-19 pandemic has seen an enormous increase in the demand for respirators[1] and medical masks. To satisfy this increased demand, homemade and commercially-available fabric face coverings have begun to be used widely in public spaces. There was precedent for doing so in earlier health crises, but this time the use of such face coverings is at a global scale. As prevention of the spread of disease became a focal point of discussion, much confusion has been revealed on behalf of the public on the proper terminology, level of protection, and proper usage of respiratory protective devices.

To address some of these concerns, ASTM International has developed a quantitative performance specification for these devices. These common-use devices will be called "Barrier Face Coverings" (BFCs), and their performance will be tested according to a newly-released standard, ASTM F3502-21.

Although the term "mask" is commonly used for all face coverings, ASTM F3502 explicitly seeks to clarify the definitions of facial coverings. According to ASTM F3502 BFCs are **NOT** considered masks. The purpose of this differentiation is to avoid confusing barrier face coverings with respirators and medical masks, and, therefore, misunderstanding the levels of protection provided by (and appropriate use scenarios for) each of the device types. The following describes the differences in purpose and testing of respirators, medical masks, and barrier face coverings.

[1] Respirators have many classes and categories. For the purposes of this document, "respirator" is understood to mean non-powered air-purifying particulate respirators that have the half facepiece form; i.e., half filtering facepiece respirators (FFRs)

How do Barrier Face Coverings Differ from Respirators and Medical Masks?

While barrier face coverings have become very prevalent during the COVID-19 pandemic, they do not perform identically to other types of respiratory protection devices. Table 1 provides a summary of each device type, including the names of the standards to which each device type is tested.

Table 1: Standards for several types of respiratory protection (and barrier) devices.

Device type		Test method			Selected device characteristics (TSI® solution)
		42 CFR part 84 subpart K	ASTM F2100[2]	ASTM F3502	
Filtering facepiece respirators (FFRs)		X			Filtration efficiency (Model 8130A)
Surgical respirators [A]		X	X		
Medical masks	**Procedure masks / isolation masks**		X		Filtration efficiency (Model 8130A[2])
	Surgical masks		X		
Barrier face coverings				X	Filtration efficiency, breathability (resistance) (Model 8130A) Fit/Inward Leakage, quantitative measurement (PortaCount® Models 8040/8048/8030/8038)

[A] Since surgical respirators are respirators and also are intended for use in a medical space, they must meet the requirements of both the respirator standard and the medical mask standard.

Respirators and Surgical Respirators

The best protection for the wearer of the listed devices in terms of filtration is provided by respirators, (e.g., N95). Surgical respirators offer equivalent filtration performance for particles, but since they are intended for use in medical settings, they are not necessarily widely available for public use. Since a tight fit to the face is required to minimize leaks, fit testing for respirators is required by Occupational Safety and Health Administration (in medical or industrial applications) in the United States.

Respirators were originally designed to protect workers in industrial, construction, and mineral extraction applications; for example, where a high filtration performance is required (at or above the 95% efficiency level). In their original context, protection of the user from particles in the environment is the primary goal, rather than protection of the environment from the user. This is why inward rather than outward leakage is assessed through fit testing, and why features such as exhalation valves are permitted for certain classes (to facilitate easier breathing).

Surgical respirators can be used to protect healthcare workers in settings such as caring for patients with highly infectious diseases (e.g. tuberculosis), or in situations where particles can be generated (e.g. during surgeries where cauterization or machining of bone occurs). Surgical respirators have additional performance requirements in common with medical masks, described below.

[2] As of early 2021, ASTM F2100 specifies that ASTM F2299 (with 0.1 um PSL) must be followed for filtration efficiency testing of medical mask material. An anticipated upcoming change to ASTM F2100 will eliminate the ASTM F2299 requirement, and will replace it with the test procedure in ASTM F3502. If this change to ASTM F2100 does occur, the Model 8130A can be used to test to ASTM F2100. There is no change to the requirements for surgical respirator testing.

Medical Masks

Medical masks (which includes "procedure masks," "isolation masks," and "surgical masks") offer some level of protection to both the wearer and those around them, but are primarily designed to prevent transmission of inhalable droplets and aerosols from the wearer. They are often worn by healthcare professionals during many different types of healthcare procedures.

These devices can come in a variety of configurations, such as how they are attached to the wearer. However, these devices do not usually fit tightly to the face. This means that while fit testing is not required, the level of protection offered to the wearer is reduced relative to respirators that are properly selected and fit-tested. Additionally, they are often made from materials that do not have as high filtration performance as respirators. As such, they are not suitable for protecting the wearer from very fine particles from industrial processes.

Understanding Product Differences

Respirators	Medical Face Masks	Barrier Face Coverings
"3.1.8. *respirator, n*—Personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous atmospheres."	"3.1.7 *medical face mask, n*—an item of protective clothing designed to protect portions of the wearer's face, including the mucous membrane areas of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures."	"3.1.3 *barrier face covering, n*—a product worn on the face specifically covering at least the wearer's nose and mouth with the primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter."

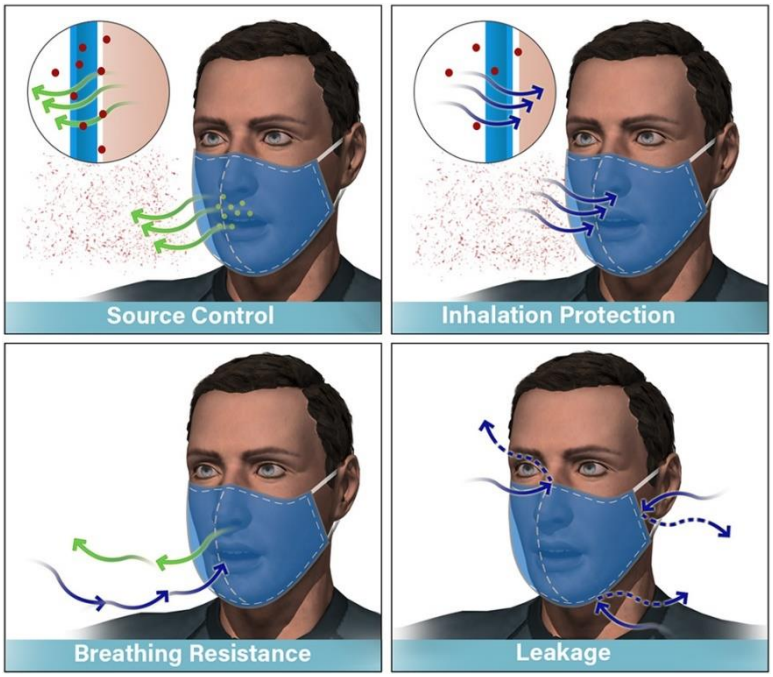
***Source**: CDC website – cdc.gov.*

In addition to particle filtration performance and breathability, medical masks (including surgical respirators) are assessed for properties such as biocompatibility, resistance to bodily fluids, flammability resistance, and bacterial filtration performance. Unlike respirators[3], medical masks are tested at the material stage of production, rather than the finished product, consistent with the lack of a fit testing requirement.

[3] Surgical respirators must meet the filtration and breathing resistance requirements of normal respirators as finished devices, as well as the additional requirements for medical mask materials.

In general, barrier face coverings are significantly less efficient in filtering submicrometer-sized particles than are respirators, and in many cases are less efficient than medical masks. BFCs also may not fit the user's face as well as the other classes of protective devices. While BFCs do have these shortcomings, they do have the benefits of lower expense, greater availability, and in many cases, reusability with washing.

From a filtration perspective, the efficacy of a BFC depends upon the filtration efficiency and the fit to the wearer's face. No aspect of the design or assessment of BFCs had been formally standardized before 2021; the new ASTM F3502-21 standard is the first standard method introduced for the purposes of testing commercially-produced barrier face coverings.



Source: *International Personal Protection, Inc.*

Barrier Face Coverings (BFCs)

Barrier face coverings are the latest class of protective devices for the general population that are being used very commonly in public spaces during the COVID-19 pandemic. Barrier face coverings can be made of a wide variety of different materials, and can have many different designs. These devices are intended to provide protection to those around them (i.e., source control for sick or infectious individuals), as well as some degree of protection to the wearer (respiratory protection from inhaled particles in the environment).

How will Barrier Face Coverings be tested under the new standard, ASTM F3502?

Tested Properties

As shown in Table 3, two "performance properties" of barrier face coverings are required to be tested under the new ASTM F3502 standard: initial filtration efficiency and breathability.

Filtration efficiency pertains to the capture of submicron particles by the mask, and is expressed as a percentage. Breathability (air flow resistance) pertains to how easy it is to breathe while wearing the mask, and is measured as the pressure drop across the mask. This pressure drop is expressed in units of mm H_2O.

Performance Categories

As per Table 2, there are only two performance levels specified for filtration efficiency (i.e., ≥ 20% or ≥ 50% for filtration efficiency), and two performance levels specified for flow resistance (i.e., ≤ 15 mm H_2O or ≤ 5 mm H_2O). Barrier face coverings must be tested for both filtration efficiency and flow resistance, and the performance of a BFC in each of these properties is measured independently. A particular barrier face covering may have any combination of the performance characteristics. This creates four categories:

- ≥ 20% filtration efficiency and ≤ 15 mm H_2O air flow resistance
- ≥ 20% filtration efficiency and ≤ 5 mm H_2O air flow resistance
- ≥ 50% filtration efficiency and ≤ 15 mm H_2O air flow resistance
- ≥ 50% filtration efficiency and ≤ 5 mm H_2O air flow resistance

If a manufacturer chooses, they may report the actual filtration efficiency along with the actual air flow resistance (breathability)[4]; both measurements must rounded to the nearest integer value.

Table 2: Criteria set for barrier face covering performance according to ASTM F3502.

Performance Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)
Submicron particulate filtration efficiency (Effectiveness of barrier face covering for capturing small particles from wearer; larger percentages indicate higher performance)	≥ 20%	≥ 50%
Air flow resistance (Indicative of ease of breathing while wearing barrier face covering; lower resistances indicate more breathable products)	≤15 mm H_2O	≤ 5 mm H_2O

How Does Barrier Face Covering Testing Compare to the Testing of Other Respiratory Protection Devices?

The test procedure in ASTM F3502 is heavily based on specifications in a US federal regulation, 42 CFR part 84 subpart K. This regulation is used by NIOSH to certify respirators in the US. Key commonalities, as well as several differences between normal respirator testing and BFC testing, are summarized in Table 3 and are further described below.

[4] More specifically, the lowest values resulting from testing of 10 samples, rounded down to the nearest integer.

Filtration Efficiency

In barrier face covering testing, only the *initial* filtration efficiency is measured (the test procedure limits the test to 30 seconds in length, at maximum). For respirators, however, a loading test is conducted where the filter efficiency is measured at regular time intervals until a certain mass of aerosol is accumulated on the filter. This accounts for changes in performance during use.

Composition of Test Aerosol

In accordance with 42 CFR part 84, some respirators undergo testing with only NaCl, or some with only oil. Barrier face coverings will only be tested with NaCl according to ASTM F3502. The size distribution of that NaCl aerosol is the same as what is specified in 42 CFR part 84 (subpart K, salt test).

Air flow Resistance

In barrier face covering testing, the inhalation air flow resistance (breathability, or breathing resistance) can be measured either simultaneous with, or prior to, the filtration efficiency measurement. For respirators, however, unloaded devices are tested for both inhalation resistance and exhalation resistance.

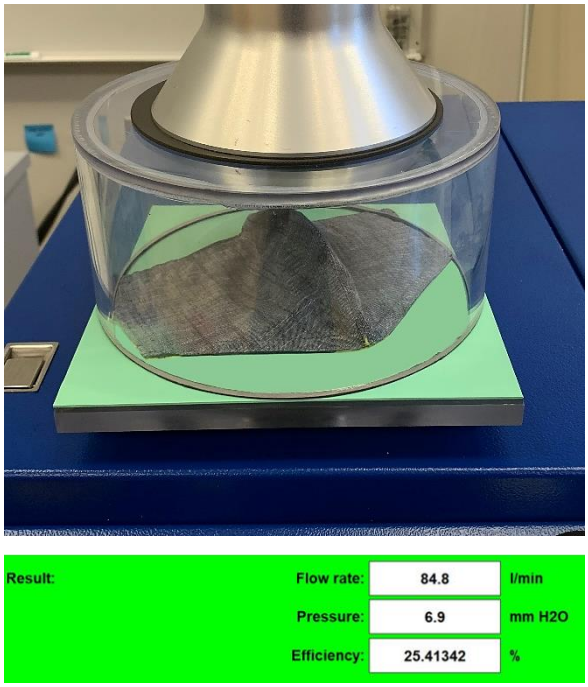


Figure 1: Performing a BFC filtration efficiency test on a TSI® 8130A Automated Filter Tester. The green box shows the "Results" screen of a passing BFC (Level 1, Level 1; see Performance Criteria in Table 2).

Table 3: Comparison of test requirements between respirator testing (filtering facepiece respirators) according to 42 CFR part 84 and Barrier Face Covering testing according to ASTM F3502.

Element of test procedure		42 CFR part 84 [A]	ASTM F3502
Test article (filter) conditioning		Identical between these two standards	
Aerosol testing	Initial efficiency measurement	Not required	Required
	Loading	Required	Not required
Air flow resistance pressure drop)	Inhalation	Required	
	Exhalation	Required	Not required
Aerosol characteristics	Aerosol composition	Salt or oil [B]	Salt only
	Size distribution (NaCl only)	Identical between these two standards	

[A] Specific types of respirators may have additional testing requirements under 42 CFR part 84 that are not shown in this table.

[B] Aerosol composition in respirator testing is determined by the series of respirator. For example, salt (NaCl) is used for N-series respirators (such as N95), while oil is used for the P- and R-series respirators. See 42 CFR part 84 for details.

Fit/Inward Leakage Assessment

Within respiratory protection and barrier devices generally (i.e. all types of "masks" taken together), the topic of leakage can be looked at in two ways: inward leakage or outward leakage. Specifically, inward leakage means that the wearer may be exposed to particles coming from outside, while outward leakage means that others may be exposed to particles generated by the wearer. In either case, leakage bypasses the device, reducing overall effectiveness. The purpose of the leakage (fit) assessment is to determine the level of leakage and to decide if it is acceptable.

Historically, the concepts of "fit" and "fit testing" were associated with respirators. Since the goal of a respirator is to protect the wearer, *inward leakage* is the relevant concept. Since BFC are intended as barrier devices, their primary purpose is to act as source control, thus protecting others from particles generated by the wearer. For BFCs, then, *outward leakage* is the more relevant concept. A leakage assessment of a BFC is required by Section 5.4 of ASTM F3502-21; also refer to Section 3.1.6.

As specified in ASTM F3502-21, the leakage assessment of a BFC must consist of a design analysis, with an option to supplement that design analysis with a quantitative fit assessment.

Design Analysis

Design analysis is a process, with a goal of representing the coverage and potential leakage pathways in (around) a BFC. The design analysis requirement in F3502 is to develop BFCs that fit well to the face, or more specifically, to minimize inward leakage.

Generally speaking, the test methods and devices for measuring inward leakage are more accessible than for outward leakage. Because of this, the inward leakage approach is used within ASTM F3502.

Inward Leakage Assessment

While BFCs are meant as barrier devices (i.e. to protect others from particles produced by the wearer), as mentioned above there are more test methods and devices for measuring inward leakage than outward leakage.

A leakage assessment represents the total inward leakage likely to occur during wear. A leakage assessment may be qualitative or quantitative. The quantitative inward leakage assessment that is optional within ASTM F3502-21 is described in ASTM F3407. This optional test may be used to supplement the design analysis.

TSI® Solutions for Testing of Barrier Face Coverings

Filtration Efficiency and Pressure Drop

The Model 8130A[5] Automated Filter Tester is a globally established solution for respirator testing. Because of this, and the similarity between the requirements of respirator testing and barrier face covering testing as required by ASTM F3502, the Model 8130A is also a complete solution for barrier face covering testing. Figure 2 shows the 8130A as well as its schematic.

The Model 8130A[6] generates NaCl polydisperse aerosol that is detected with two solid-state photometers. Photometers are used for their excellent sensitivity and dynamic range, as well as their ability to measure the large mass concentrations required for the loading testing of respirators. The 8130A can support flow rates of 10 to 110 L/min and can measure very high total filtration efficiencies during initial penetration and loading tests. Differential pressure can be measured as part of the filtration test, or alone with the aerosol generator turned off.

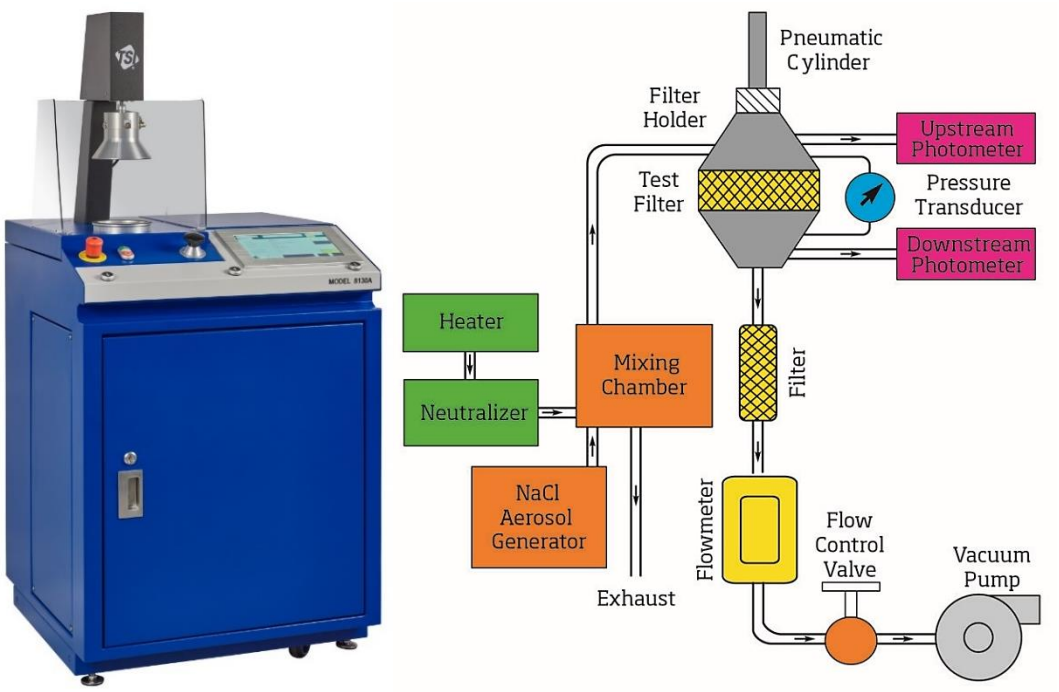


Figure 2: The Model 8130A Automated Filter Tester.
Left: The tester when viewed from the front.
Right: a schematic of the internal components of the tester.

[5] The Model 8130A-EN cannot be used for barrier face covering testing according to ASTM F3502 unless the Model 8118A salt generator is used. Contact TSI for further details.
[6] The Model 8130A can generate oil and NaCl aerosol. For the requirements of this standard only the NaCl measurement is described.

Quantitative Inward Leakage Assessment

Quantitative inward leakage assessment may be conducted for BFCs (or for occupational-use respirators, in which case it is called "fit testing") with the TSI® PortaCount® Respirator Fit Tester Models 8040/8048/8030/8038. The PortaCount® fit tester is a condensation nuclei counter-based quantitative respirator fit testing instrument, as called out in both ASTM F3502 (BFC) and F3407 (Respirator Fit Capability) standards. When being used for testing to F3502, a PortaCount® fit tester should be operated in N99 Mode with a minimum ambient aerosol concentration of 2,000 particles/cm^3. For more guidance on the topics of fit in general and inward leakage see TSI® Application Note RFT-036, ASTM F3407 Respirator Fit Capability, or contact TSI® Incorporated.

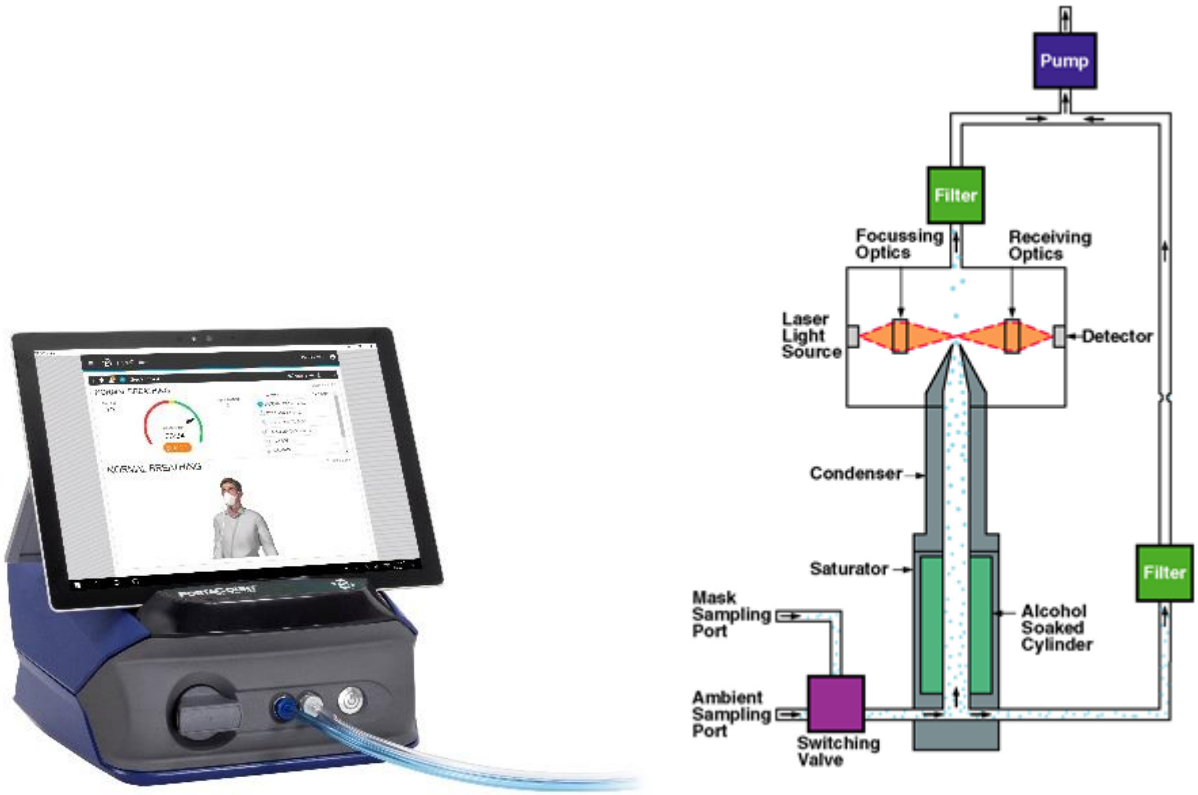


Figure 3: The PortaCount® Respirator Fit Testers.
Left: The tester when viewed from the front.
Right: a schematic of the internal components of the tester.

Summary

ASTM F3502 seeks to provide a level of standardization for nontraditional respiratory protective devices, as well as a clarification of terminology. TSI® testing experts have been actively participating in and following the developments of the new standard, and are ready to help support your BFC testing needs moving forward with the Model 8130A and the PortaCount® Respirator Fit Tester Models 8040/8048/8030/8038.

References

1. ASTM F3502: Standard specification for barrier face coverings. https://www.astm.org/Standards/F3502.htm
2. CertiTest® Automated Filter Tester Model 8130A specification sheet. A4 and US.
3. 42 CFR part 84: Approval of respiratory protective devices. https://www.ecfr.gov/cgi-bin/text-idx?SID=6b0b69703a73ccc1c57f3084ae6a29b7&mc=true&node=pt42.1.84&rgn=div5
4. "42 CFR part 84 Standard." Application note AFT-001, US.
5. "42 CFR part 84 Testing Modes." Application note AFT-002, US.
6. ASTM F2100: Standard specification for performance of materials used in medical face masks. https://www.astm.org/Standards/F2100.htm
7. "Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators" https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf

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