NATO STANDARD

AEP-71

FIT AND PROTECTION TESTING METHODS FOR NEGATIVE-PRESSURE RESPIRATORS

Edition A Version 2

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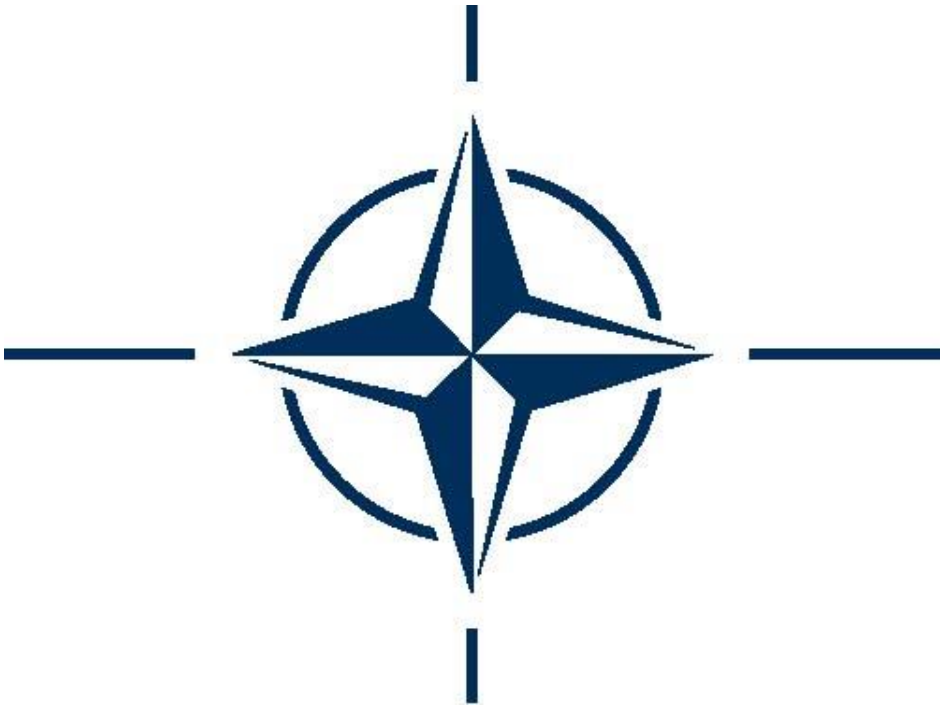

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NORTH ATLANTIC TREATY ORGANIZATION (NATO)

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NATO LETTER OF PROMULGATION

21 November 2019

1. The enclosed Allied Engineering Publication AEP-71, Edition A, Version 2, FIT AND PROTECTION TESTING METHODS FOR NEGATIVE-PRESSURE RESPIRATORS, which has been approved by the nations in the NATO ARMY ARMAMENTS GROUP (NAAG), is promulgated herewith. The agreement of nations to use this publication is recorded in STANREC 4725.

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Zoltán GULYÁS
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RECORD OF RESERVATIONS

CHAPTER	RECORD OF RESERVATION BY NATIONS

Note: The reservations listed on this page include only those that were recorded at time of promulgation and may not be complete. Refer to the NATO Standardization Document Database for the complete list of existing reservations.

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RECORD OF SPECIFIC RESERVATIONS

[nation]	[detail of reservation]

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CHAPTER 1 INTRODUCTION

1.1 AIM

This document provides guidance on methods, procedures, and documentation for assessing the fit and protection levels of negative-pressure respirators used by NATO armed forces. Assessment will be done through various evaluation approaches, thereby achieving common understanding between NATO armed forces whenever fit and protection factors are discussed. This will serve as an indicator on the protection afforded by a properly selected, fit-tested, and functioning respirator when properly worn and used in an environment where the oxygen content is not less than 20%.

This document is prepared for negative-pressure respirators, sometimes referred to as air purifying respirators (APR). However, some of the information may apply to other types of respirators such as positive-pressure respirators, including powered air-purifying respirators (PAPR), supplied-air respirators (SAR) and self-contained breathing apparatus (SCBA), or other types of respirators such as an "escape hood" with suitable modifications and adapters.

1.2 AGREEMENT

Participants agree to implement approved methods, procedures, and documentation practices whenever determining the fit and protection level of a negative-pressure respirator, or other types of respirators operating at a negative-pressure mode that will be used in NATO operations.

1.3 TERMS AND DEFINITIONS

The terms and definitions used for the purpose of this agreement only are listed within the Lexicon at the end of the document.

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CHAPTER 2 METHODS AND PROCEDURES

2.1 QUALITATIVE METHODS

QLFT should be administered using a test substance within a contained area or in a manner so that test substances cannot be easily dissipated. One common example is a shroud worn over the individual's head and shoulders.

The test substance is dissipated in a vaporized/sprayed/aerosolised form (depending on test substance) within the contained area/shroud.

All individuals must be pre-tested to assess whether they are sensitive to the test medium.

It is agreed that during the performance of static QLFT, suitable test media (substances) have to meet the following requirements:

a. Non-toxic in the amount and concentration that may occur in the inhaled air,
b. Detectable in the range of relevant concentrations,
c. Have a known lung retention (preferably zero), and
d. Free from tendency to be adsorbed or deposited on solid surfaces whether humid or dry.

Some suggested Static QLFT test substances that meet the requirements above are:

a. Isoamyl acetate, also known as banana oil, which is detected as a sweet smell.
b. Dentatonium benzoate (Bitrex), which is detected as a bitter taste.
c. Saccharin, which is detected as a sweet taste.

2.2 QUANTITATIVE METHODS

It is agreed that one of the following methods will be used to perform QNFT and SWPF Testing:

a. Laser Photometry. A test aerosol is used. Laser photometers are used to measure the mass concentration of test substance within the respirator and the test chamber. Suitable test substances include sodium chloride (NaCl), and Di-Ethyl-Hexyl-Sebacate (DEHS).

b. Condensation Nucleus Counting (CNC). A test aerosol is used. A single device capable of measuring particle number concentrations by CNC within the respirator and the test chamber (alternately) is usually used for QNFT. Two separate devices can be used for SWPF to permit continuous monitoring and they must be calibrated against one another. Typically, alcohol is used as a condensation medium to collect all particles and to increase particle size, thereby ensuring an accurate particle count. Suitable test substances include sodium chloride (NaCl) and polyalphaolefin oils (e.g. emery oil).

c. Fourier Transform Infrared Spectroscopy (FTIR). This method uses measurement equipment to identify and quantify concentrations of test gases (e.g. sulphur hexafluoride (SF_6)) based upon spectral transmission.

d. Flame Photometry. This method uses NaCl as the test substance for detection of sodium within the respirator and the test chamber.

Note: QNFT values are not always directly comparable between test methods. Differences between challenges, detecting methods, and evaluation procedures can provide a variance in the numerical results.

2.3 GENERAL FIT TEST PROCEDURES

Test substance generation. Care shall be taken that the characteristics of the challenge test substance are well understood and that the response of the measurement instrumentation at the chosen range of concentrations is linear. For example, at high aerosol concentration particle size distribution may change; or counting instruments may under-respond due to coincidence errors, requiring the use of a calibrated diluter on the challenge sampling line. Some test substances at the high challenge concentrations required for high PF measurements may foul the instrumentation, requiring dilution or more frequent routine maintenance.

The individual shall be properly trained in donning and shall then don the respirator without any assistance from test administrative personnel. However, the test administrator shall closely monitor the donning process to ensure the individual has correctly donned their respirator. A low fit factor value could be the result of improper donning and may be mitigated through a re-don and retest.

Prior to testing, test subjects should refrain from activities that could compromise the integrity of the test (depending on the test method used; for example: eating, smoking,

or chewing gum, may affect a number of methods) for a minimum of 30 minutes (national standards may dictate a longer period) prior to QLFT, QNFT, and SWPF Testing, as these activities will increase aerosol released by the test subjects, or de-sensitize them during the tests.

Test subjects must ensure that the facepiece of the respirator adheres to the skin and the harness fits properly without any impediments (e.g., they shall be clean-shaven or have a moustache properly trimmed, no piercing, hair pulled back and buns or hair ties outside the harness, etc.).

Test subjects should remain at rest while wearing a respirator for a minimum of 5 minutes (national standards may dictate a longer period) prior to the QNFT measurement.

Test subjects shall be trained in proper procedures to connect to the sampling instrumentation, open and close valves, and prevent kinking of sampling lines during activities.

Users shall perform the following exercises during all fit and PF testing. Member nations may specify a particular subset or combination of these exercises that is required during testing when time is a constraint.

a. Normal breathing. The individual will inspire and expire as the individual would under normal conditions in accordance with national test standard requirements.

b. Deep breathing. The individual will inspire and expire as the individual would under strenuous or abnormal conditions in accordance with national standard requirement.

c. Looking Left, Looking Right. The individual will perform normal breathing while turning their head right to left and left to right repeatedly.

d. Looking Up, Looking Down. The individual will perform normal breathing while turning their head upward and then downward repeatedly.

e. Bend over and reach for the floor. The individual will perform normal breathing while bending over, keeping knees straight, and reaching for the floor repeatedly.

f. Facial Expressions. The individual will perform normal breathing cycling through several facial expressions including yawning, smiling, frowning, and rotating the jaw.

g. Speaking or Silent Speaking. The individual will perform normal breathing whilst speaking or mouthing the words from a selected passage in a language in which the individual is proficient in reading and speaking.

Note: Speaking at an audible level produces particles that interfere with accurate condensation nucleus counting measurements when measuring high PF's; hence speaking may be simulated instead.

More exercises representative of realistic user activities and work rates shall be added for SWPF testing by each member nation.

Note: Strenuous activity will increase the generation of background particles within the mask that will be measured by CNC devices. This may result in an apparent reduction of PF. Measuring the particle generation in a completely particle-free environment under the same conditions, or preferably increasing the outside concentration, will permit differentiation of this effect.

Each exercise shall be performed for the duration of sampling, which shall be as long as necessary to gain statistical confidence in results. Often, the sampling duration is fixed per manufacture specifications or is specified by instructions which may accompany the test equipment. When specific values for what defines statistical confidence are not known, and manufacturer instructions are not provided, the default setting of the equipment shall be used or sampling shall be conducted for a minimum of 30 seconds for each exercise.

Individual users shall attain a fit factor not less than 10,000 when being fitted in a negative-pressure respirator by QNFT. National standards may require higher values. In order for a respirator to be deemed NATO-compliant, the distribution of protection factor values obtained during SWPF for a realistic selection of properly fitted wearers shall provide most wearers a PF that exceeds this same value, with the specifics of the distribution to be set by national standards.

Note that FF and PF can be measured by sampling either within the nose-cup of the respirator or within the eye-space, and that these two locations may yield significantly different results depending on the respirator design; care should be taken to assure that the location of measurement is relevant to the specific requirement.

Each member nation may have different occupational health and safety regulations pertaining to the use of respirators and test media. As such, it is the responsibility of each nation to ensure appropriate regulations are met when choosing to adopt workplace QLFT and QNFT standards and methods.

ANNEX A

CAPABILITIES AND SPECIFICATIONS FOR QUANTITATIVE LEAK TEST EQUIPMENT FOR NEGATIVE PRESSURE RESPIRATORS

(HEADFORM INWARD LEAKAGE)

A.1 *INTRODUCTION*

The aim of this annex is to provide guidance on the conduct of Quantitative Leak Testing for Negative-Pressure Respirators (quantitative leak testing equipment), referred to here as QLTE. QLTE will provide a serviceability or function test, that is, an approach to assess the proper functioning and levels of protection of CBRN military respirators under field and laboratory conditions. It should be compatible with all NATO forces, enabled through a variety of mechanisms or components, in order to achieve common interoperability. The same general approaches may be used as in QNFT, but with a universal head form based system on which to mount the respirator, ensuring that normal face-seal leakage is absent during testing.

A.2 *DEFINITION*

The QLTE primary function is to test for leaks in respirators. The QLTE is designed to verify and provide the user with a visual indicator that a respirator is in perfect operating condition. The use of a QLTE facilitates the troubleshooting of defective respirators and provides a rapid and effective method to pinpoint leaks, repair them if possible, and re-test.

A.3 CONCEPT OF OPERATIONS

The following represents the defining aspects of the concept of operations for the QLTE:

a. Employed as a portable tool to aid military units in determining leakage and fit of protective respirators.

b. Used to maintain respirators in a high state of readiness.

c. Tool to determine the effectiveness of a unit’s maintenance program.

d. Home and deployed operations.

e. Peacetime, wartime, military operations other than war, homeland training and field exercises.

f. Supports CBRN capabilities, especially CBRN individual protection, in low, medium and high CBRN threat areas.

The following compares fit testing against serviceability testing:

a. A comprehensive respirator testing program will include both Serviceability (Function) as well as Fit Testing.

b. Fit Testing will ensure that a specific respirator will fit on a specific person.

c. Function Testing will verify the integrity of the overall respirator and its components.

d. Individuals should only be Fit Tested with a fully functioning respirator.

e. Function testing can be done more quickly, does not require the respirator user to be present, and can pinpoint leaks or bad components easily.

A.4 TEST CAPABILITY

The following identifies the desired testing capability of the QLTE:

a. Ability to locate leaks so repair or replacement decisions can be made.

b. Overall respirator integrity test (IL, PF, and leakage rate).

c. Outlet valve test.

d. Drink System tests.

A.5 BASIC SPECIFICATIONS

The following identifies the basic desirable specifications of the QLTE:

a. Fully deployable by military organizations worldwide.

b. Essential components can be easily replaced in the field.

c. Easy to use with minimal training.

d. Quick setup/close down.

e. Up to 12 respirators per hour throughput.

f. Portable in a self-contained carrying case, packaged for ease of use and ease of transport.

g. Powered RS-232 serial and USB ports for data logging on the user's computer.

h. User-friendly software package. The easy-to-read display on the QLTE prompts the operator through the intuitive step-by-step test sequence. The operators interface comprises a streamlined menu structure and simple keypad to facilitate ease of use.

i. Universal power supply for worldwide usage (100 to 240 VAC, 50/60Hz).

j. Test head appropriate for testing of relevant respirator sizes and types. The head form provides a tight seal for most gas respirator and respirator types and sizes. Respirators attach to the head form using their head harness. An inflatable rubber sealing surface is often used to accommodate 'universal sizing'.

k. Desirable accessory for testing respirators with hoses.

l. Respirator leakage measurement using a poly-dispersed oil (PAO) or equivalent.

A.6 QLTE ADAPTORS

The following identifies the requirement and reason for QLTE adaptors.

Respirator designs vary greatly:

a. Sealing surface (shape, face/neck),

b. Valve Configurations,

c. Canister Connections/openings,

d. Drink tube Connections, and

e. Sizes.

It may be necessary to be able to close off or seal various orifices in order to identify unusual sources of leakage, and various connectors or sealing options need to be provided, customized to the respirator.

QLTE will be required to be easily adaptable. Adaptors will provide the most cost-effective interface solution for different respirators. Additionally, more than one design of mounting head may assist in providing more universality of fit.

LEXICON

SECTION I – TERMS AND DEFINITIONS

Negative-Pressure Respirators. In a negative-pressure respiratory protective device (commonly referred to as a negative-pressure air purifying respirator), one or more air purifying cartridge or canisters, containing an air purifying element, such as a combination of activated carbon and high efficiency particulate arresting (HEPA) filter, are attached via an inhalation valve to a tight-fitting rubber facepiece. The negative air pressure created by inhalation draws contaminated air through the air purifying filters to the wearer. Due to this, a leak-proof seal between the face seal and the wearer is essential for high levels of respiratory protection.
Leaks at the seal may be caused by improper fit or the presence of facial hair and foreign substances under the sealing surface, or elsewhere in the respirator by cracked or damaged seals, valves and cartridges.

Filter Efficiency. The ability of a filter to remove particulate contaminants from the outside environment during respiration through a respirator.
The efficiency is the ratio of particles trapped by the filter over the total number of particles upstream from the filter.
Specific particle sizes or the total number of particles of all sizes may be used in the calculation. The result of filter efficiency should be expressed by specifying the parameters of particles used (i.e. – particle size distribution, test substance type, etc.).

Fit Test (FT). A test method, qualitative or quantitative, to determine if the respirator is providing an adequate face seal for the individual user.

Seal Check. A pass/fail test that assesses the adequacy of respirator fit through the judgement of whether air is leaking past the face seal when the wearer maintains, for several seconds, a constant negative pressure via inhalation with the filter port(s) blocked. The assessment is subjective on the part of the wearer, possibly aided by an observer. Its sensitivity is lower than that of a qualitative fit test.

Seal checking is an essential first step for ensuring correct donning and is useful as a confidence building exercise in training. There is as yet no alternative in the field. Nevertheless, it must be recognized that it will only identify gross seal leaks / donning issues and cannot be deemed a substitute for a variety of other fit testing types, as it is not adequate to detect relatively smaller issues that still might constitute ‘failing’ performance.

Qualitative Fit Test (QLFT). A pass/fail test that assesses the adequacy of respirator fit through means of the user’s sensations and response (taste, smell, irritation) to a test substance introduced into surrounding areas of the user. Such a

test is inadequate to determine the high levels of protection required in a CBRN environment but can be used as an alternative to a seal check or tear gas training in order to validate good donning practices during training. Its sensitivity is lower than that of a quantitative fit test.

The QLFT method employs the use of a particular test substance outside the respirator that will cause a physiological reaction when the wearer is exposed. The substance is introduced (often into a small hood around the wearer's head) after the individual has donned the respirator. The individual will typically perform standard test exercises in a sitting or standing position with limited movement and indicate whether or not test substance is detected through user sensations such as smell, taste, or irritation.

If test substance is detected, the respirator has failed fit testing, requiring re-donning of the respirator or a new size respirator to be selected and the fit testing to be repeated. This methodology is not sufficiently sensitive to assess the protection factor (PF) performance levels required to meet AEP-73 but it may have some relevance as a quick screening method.

Quantitative Fit Test (QNFT). An assessment of a respirator's fit by performing a numerical measurement of the amount of leakage into the respirator.

The QNFT method is the gold standard, capable of meeting requirements within AEP-73 for PF performance. The same test substance generation and detection instrumentation that can be used for QNFT, with the methods suitably modified, can often be applied to Inward Leakage (see 1.3.10 below) and simulated workplace protection factor (SWPF) tests.
In all cases the detection instrumentation must be tethered to the individual, although the results may be data-logged or transmitted remotely to limit the amount of equipment involved.

The QNFT is to be used to validate the selection of the correct size of respirator for an individual, on initial issue, and that the fit and performance of the system has not degraded, prior to an active deployment where the item might be used.

Note: At very high levels of protection, other leakage routes aside from leakage at the face seal, such as penetration through the filter or the exhalation valve, may contribute to the overall result.

Fit Factor (FF). This term is used to express the results of a quantitative fit test performed under controlled conditions where the best fitting size for the wearer is being selected. A fit factor is the ratio of the test substance concentration outside the respirator to the test substance concentration inside the respirator and the information is collected over the course of a relatively static activity routine. A

numerical expression is shown below in paragraph 1.3.9 below. Test substances used include oil mist, salt particles, ambient dust particles, sulphur hexafluoride gas and particulate in ambient air. Test parameters (temperature, activity routine, choice of gas or particles, particle size and humidity) used for the evaluation of fit factor are specified in AEP-73.

Protection Factor (PF). A numerical estimate of the anticipated protection provided by a respirator, under somewhat more realistic conditions than those used to generate a FF. This factor is generated from the ratio of test substance (challenge) concentration outside the respirator to test substance concentration inside the respirator, measured under a specified set of test conditions. PF will take both filter efficiency and respirator performance into account, during defined physical activities. When repeated trials are performed on numerous individuals, PF may be expressed as a distribution rather than a single value.

Calculation of Protection Factor. The PF of the system under test (or alternately the FF) is the quotient of the test substance concentration (C) outside the respirator and the test substance concentration within the respirator, as given in the equation below, with the test substance concentrations averaged over the time of the measurement (up to and including an entire activity routine):

$$PF = \frac{C_{outside}}{C_{inside}}$$

The minimum possible PF is 1 (when the outer and inner concentrations are identical), and the theoretical maximum possible PF is infinite (when CBRN substance is not penetrating inside the respirator).

A mathematically equivalent calculation for calculating the PF over a series of activities in a routine uses the harmonic mean of the individual activity PFs (PF_i) as given in the equation below, where n is the total number of activities (provided the individual activities are each of the same duration):

$$PF = \frac{n}{\sum_1^n \frac{1}{PF_i}}$$

Note: The PF becomes equivalent to the FF when the subject performs only a limited series of movements, and penetration through the filter is negligible compared to leakage. When measuring very high PF's, penetration through the filter can be a significant contribution.

Inward Leakage (IL). Inward leakage is mathematically the inverse calculation from that of a PF. It is often used when a wearer is not involved, for example a head form

test, or where only a sub-set of leakage routes is examined (for example, IL at the exhalation valve); the maximum IL is 1 and the minimum is zero. It is also often expressed as a percentage.

Head form IL is to be used to validate certain aspects of the performance of a respirator where the face-seal is not the primary focus of the investigation; in general, in this case, one hopes for a relatively leak-free seal to the head form, with other potential sources of leakage being investigated. This approach can be applied in order to understand the performance of the item in general, or to diagnose leakage problems and perform maintenance on an individual item. The more sensitive methods used for QNFT are appropriate, but simple measurement of leakage rates based on pressure loss when the respirator is placed under constant negative pressure on a head form may also be used.

Simulated Workplace Protection Factor (SWPF). A measure of respirator performance that is obtained using test activities designed to simulate work, and test substances chosen to simulate the hazard substances in terms of how they penetrate the respirator. The respirator must be properly selected, fit-tested, worn, and used, along with associated equipment as relevant. The activities and environmental conditions should be chosen to simulate actual work conditions to the extent possible.

If obtained in the field, rather than a laboratory setting, this can be termed a field SWPF. A distribution of SWPF values obtained using a large number of representative individuals can also be given.

Nations may elect to use the SWPF to validate the selection of the correct respirator for the user population in question at the time of procurement, as each specific user population can have significantly different facial characteristics or possess different integrating equipment. It is also used to assess potential sealing issues caused by integrating equipment (e.g. hoods, headgear, sights) or by specific exposure conditions or activities, in order to assist in mitigating or managing these issues through alterations in equipment or procedures.

It is usual for SWPF to be performed in a contained indoor environment in which high concentrations of test substance can be generated and various confounding factors can be controlled.

However a field SWPF that uses ambient particles (e.g. dust, pollen) as test substance, while much less sensitive and perhaps more difficult to interpret, has the advantage
of realism that may be harder to achieve indoors, particularly when looking for gross problems caused by adverse environments or issues with, as examples, vehicle

sights or weapons firing. In either case, the measurement equipment must either be worn by the individual e.g. in a backpack or carried by a handler.

Note: As well as the type of information collected for a PF/FF determination, any equipment worn by the test subject during the test, in particular potentially interfering equipment such as hoods, ballistic helmets, night vision goggles etc. as well as the environmental exposure conditions and the activity routine used should be noted with the final SWPF value.

SECTION II – ACRONYMS AND ABBREVIATIONS

AEP	allied engineering publication
APR	air purifying respirator
C	concentration
CBRN	chemical, biological, radiological, and nuclear
CNC	condensation nucleus counting
DEHS	di-ethyl-hexyl-sebacate
FF	fit factor
FT	fit test
FTIR	Fourier transform infrared spectroscopy
HEPA	high efficiency particulate arresting
Hz	Hertz
IL	Inward Leakage
n	number of activities
NaCl	sodium chloride
PAO	poly-*alpha*-olefin
PAPR	powered air-purifying respirator
PF	protection factor
QLFT	qualitative fit test
QLTE	quantitative leak testing equipment
QNFT	quantitative fit test
SAR	supplied-air respirator
SCBA	self-contained breathing apparatus
SF_6	sulphur hexafluoride
STANREC	standardization recommendation
SWPF	simulated workplace protection factor
USB	universal serial bus
VAC	volts of alternating current

AEP-71(A)(2)