

Long-Term Field Evaluation Program Concept

Background:

The Long-Term Field Evaluation (LTFE) program for self-contained self-rescuers (SCSRs) for miners was initiated more than 20 years ago by the U.S. Bureau of Mines. The objective for the LTFE program is to obtain data to determine the expected performance characteristics of SCSRs used in the mining industry. LTFE program results based on scientific principles can provide useful information to monitor expected SCSR performance and assess possible degradation due to the physical stresses of in-mine use. Of utmost concern is the successful performance of any SCSR that passes its inspection criteria specified by the manufacturer. It is such apparatus that must be relied upon in an emergency.

The information gathered in the first 20 years of this program has been very useful. Improvements have been initiated in SCSRs and some models of SCSRs have been recalled or removed from service. However, experience gained in the original LTFE program suggests modification to certain program aspects may increase the utility of the program for verifying that SCSRs passing inspection criteria will perform reliably in the event of an emergency.

The original SCSR program relied on a sampling program designed to collect SCSRs in proportion to their deployed prevalence in underground coal mining; sample size was based on market share. Sampling locations were directed at sampling the full range of underground coal mining activities, for example; large mines and small mines, high coal seams and low coal seams. The number of new units tested in the LTFE program was limited and consequently the statistical power relative to the performance of new units was limited. Much of the work being undertaken was needed to properly establish the breathing and metabolic simulator as a valid test instrument. Since that time, operation of the automated breathing and metabolic simulator (BMS) has been improved and the correlation to human performance established: further development of the correlation to human test subjects as part of the LTFE is no longer required. We have reached a point where we can determine SCSR performance to be acceptable or unacceptable based on BMS testing.

NIOSH has utilized a standardized reporting format for the LTFE results. This format has been deemed appropriate for health and safety professionals familiar with the BMS and the characteristics of SCSR devices; however, this is one area in which improvements could be achieved through the simple application of defined levels of acceptable performance. By applying defined levels of acceptable and unacceptable results into the reporting format it should be easier to understand and thus more useful for persons concerned with underground coal mine escape equipment and miner safety but not expert in the BMS or in closed circuit self contained escape respirators.

This document describes a redesigned LTFE program that:

- identifies an improved sampling plan,
- documents all pertinent evaluation procedures,
- defines evaluation criteria, and
- establishes new standard reporting procedures.

This document does not describe in detail planned changes to the standard product audit program as applied to SCSRs. The product audit program evaluates new respirators to assure continued compliance with certification testing requirements. NIOSH plans to expand the product audits of SCSRs to involve sampling 10 to 20 new units of each approved SCSR respirator type every year. These units will be subjected to certification testing, including man test 4, and a limited number of units will be BMS tested to establish the relationship between these two test methods and their associated performance criteria.

Sampling plan and statistical issues for the Long Term Field Evaluations Program:

The LTFE sampling plan will utilize an MSHA-generated and maintained inventory of SCSRs used by the mining industry. The MSHA list represents an inventory of SCSRs from each mine collected into a single master listing of all SCSRs. The list will be randomly sorted to select respirators for the LTFE program. The sampling plan will identify 400 SCSRs for evaluation testing, 100 each from the four current approvals. The selected sample size will give a high probability (95.2%) of detecting at least one failure in any approval if the true failure prevalence is 3% or higher in the first year of testing using an evaluation criterion that treats evaluation of LTFE Critical Parameters on a pass/fail basis.

NIOSH/MSHA approval requires the approval holder to implement a quality system that includes processes and procedures for product configuration management. A condition of the NIOSH/MSHA approval is that any changes to the respirator require NIOSH/MSHA approval. Changes made to any respirator are evaluated on the basis of change to form, fit and function. Because of the system of configuration management required for initial and continued NIOSH/MSHA respirator approval, SCSRs manufactured over time bearing the same NIOSH/MSHA approval are considered to be the same configuration. Thus, over time (several years of testing) the LTFE sampling plan design will achieve even greater statistical significance relative to all in-mine SCSRs.

In the second year of testing, the 400 additional samples will give an overall sample size of 800 resulting in a 98% probability of detecting at least one failure if the true failure prevalence is 1.5% or higher. Continued testing will increase the probability of detecting true failures in field-deployed SCSRs. A detailed discussion of the statistical analysis is provided in Attachment # 1, Sample Size Considerations for the Long-Term Field Evaluation Program.

The identified sampling strategy will enable the evaluation data to be used to detect failures in specific subgroups or strata by accumulating data over multiple years. Potential subgroups include the following strata:

Deployment Type: Carried, Cached

Age of Unit: < 1 year, 1 – 5 years, > 5 years

Type of Mine: Seam Height

SCSR Collection Procedure

The SCSR collection procedure is intended to collect units from the field that are within the respirator manufacturer's criteria for visible damage, temperature exposure and other manufacturer prescribed inspection criteria. The LTFE program is not designed to evaluate the performance of damaged units not being removed from use. For this reason, NIOSH will only accept units that appear to meet all of the manufacturer's inspection criteria for evaluation. NIOSH will endeavor to coordinate site visits to collect SCSR units with the MSHA district office involved and have an MSHA official in attendance when the inspection and collection takes place. NIOSH will report to MSHA the number of units evaluated and the number of units accepted into the LTFE program. The difference in these numbers will be an indication of how well that mine is inspecting their SCSRs.

NIOSH will notify the mine owner at least 24 hours in advance of the unit collection and the notification will include the number of units to be collected and the serial numbers of those units.

NIOSH will inspect units until the required number of units acceptable for LTFE use is obtained. The serial number of each unit inspected will be noted along with whether it passed or failed the inspection criteria as stringently applied by NIOSH. The mine owner will be notified of all units failing the visual inspection and the miners will be notified of all belt-worn units that fail the visual inspection pursuant to the provisions of 42 CFR 85a.

NIOSH will furnish a new SCSR of the same approved type for each SCSR taken into the LTFE program. If the SCSR being evaluated is an obsolete approved type it will be replaced with an approved SCSR of a type determined to be appropriate by NIOSH given due consideration to the mine operator's requests.

SCSR Evaluation Procedure:

LTFE program testing is different from testing used for certification of SCSRs to the requirements of 42 Code of Federal Regulations, Part 84 (42CFR84). SCSR evaluation testing for certification relies on a series of bench tests and human subject tests (man tests) to establish conformance with the requirements specified in 42 CFR, Part 84. Current LTFE program evaluations are based on laboratory testing to evaluate SCSR performance using machine tests (90%) and human-subject tests (10%) at the same, constant metabolic work rate. For the machine tests, a metabolic breathing simulator (BMS) is used to test SCSRs to an end point determined by oxygen depletion in the SCSR. The BMS operational parameters are selected to provide a constant and repeatable physiological work rate. BMS testing at a constant rate to obtain an operational end point provides a reliable and repeatable means of evaluation. The revised LTFE will rely on BMS testing. Limited human treadmill testing will be employed to establish a baseline correlation between certification testing, LTFE BMS testing and LTFE Human subject testing.

For SCSR LTFE evaluation testing the BMS is operated at the following conditions:

Oxygen Consumption Rate, $VO_2 = 1.35$ lpm
Carbon Dioxide Production Rate, $VCO_2 = 1.15$ lpm
Ventilation Rate, $V_e = 30$ lpm
Respiratory Frequency, 18 breaths per minute

A detailed test protocol is included in Attachment #2, LTFE Test Protocol.

SCSR Evaluation Criteria:

For the LTFE program Critical LTFE Parameters used for evaluating SCSR test results are defined as the ability of the device to provide life support in a hazardous environment. Life support is further defined as an acceptable concentration for oxygen and carbon dioxide for a specified capacity (quantity of usable oxygen and associated duration). The Critical LTFE Parameters also include a requirement for breathing circuit integrity. Breathing circuit integrity means no breach (no rips, tears or holes; no chemical migration, no foreign particles) in the breathing circuit.

The Critical LTFE Parameters used for evaluation are:

$O_2 \geq 15\%$ [Average O_2 values less than 15% over a 1 minute period are considered a failure]
 $CO_2 \leq 4\%$ [Average CO_2 values over 4% for a 1 minute period are considered a failure]
Capacity \geq NIOSH approval rated capacity
Breathing Circuit Integrity = No compromise of the breathing circuit such as: no rips, tears or.; no chemical migration allowing user exposure to chemicals, no foreign particles exceeding 5mg total measured from the mouthpiece and breathing tube

During the course of evaluation testing it is expected that performance observations other than the Critical LTFE Parameters will be made. Examples of these include breathing resistance or inhalation temperature that exceeds 42 CFR 84 requirements. Criteria used to determine the classifications of these observed performance parameters are as follows:

Major Parameter Classification: A non-critical parameter that results in reduced protection for an individual using the SCSR.

Minor Parameter Classification: A parameter that is not likely to reduce the usability of the SCSR.

Classification of the observed parameter using the above criteria will be determined by the test engineer. In the case of a Major Parameter Classification, the test engineer will consult with other NIOSH experts. The NIOSH/NPPTL Branch Chief responsible for the LTFE program through consultation with the NIOSH/NPPTL Director will have final authority to determine the classification. In the case of Critical LTFE Parameters (O_2 , CO_2 , Capacity and breathing circuit integrity), no consultation is required.

The LTFE BMS testing will also note SCSR units that demonstrate significant performance deviations from new units of the same approval or from the historical database. These observations will be noted in the annual report and may be discussed with the manufacturer.

LTFE Evaluation Baseline Testing New SCSRs:

- a. SCSRs tested at specified VO₂, VCO₂, ventilation rate and respiratory frequency.
- b. Assess Critical LTFE Parameters through the approved rated duration:
 - O₂ ≥ 15%
 - CO₂ ≤ 4%
 - Capacity ≥ NIOSH approval rated capacity
 - Breathing Circuit Integrity = No compromise of the breathing circuit such as: no rips, tears or holes; no chemical migration, no foreign particles.
- c. Assess other Major and Minor non-critical parameters.

LTFE Evaluation Testing of Sampled SCSRs:

- a. SCSRs tested at specified VO₂, VCO₂, ventilation rate and respiratory frequency.
- b. Assess Critical LTFE Parameters through the approved rated duration:
 - O₂ ≥ 15%
 - CO₂ ≤ 4%
 - Capacity ≥ NIOSH approval rated capacity
 - Breathing Circuit Integrity = No compromise of the breathing circuit such as: no rips, tears or holes; no chemical migration, no foreign particles.
- c. Assess other Major and Minor non critical parameters:

Further detail on data analysis is provided at Attachment 3, Data Analysis.

LTFE Evaluation Action Levels:

In the case of observed deviations, the following guidelines are used to determine corrective actions.

- a. For Critical LTFE Parameters not meeting established limits for Critical LTFE Parameters, 100% immediate corrective action (fix, user notice, recall, or rescind approval) is required. Units will be considered to fail when one failure is observed.
- b. For Major Parameters not meeting 42CFR84 requirements, 100% corrective action (repair, user notice, recall, or rescind approval). In cases where an observed deviation for the same Major Parameter is observed for more than 3% of the yearly test quantity the deviation will be treated as a Critical LTFE Parameter.
- c. Minor Parameter: No corrective action is required on deployed units but the problem should be addressed in manufacturing new units.

Follow-through actions will be processed as part of the NIOSH/NPPTL Certified Product Investigation Program (CPIP).

LTFE Program Reporting:

The LTFE reports will have 3 components. An initial report will be generated when the units are collected from the mine. Units not accepted for LTFE evaluation because of NIOSH inspection failure will be noted and the mine operator, the miner in case of belt worn units, and the appropriate regulatory authority will be notified Attachment 4(a). An interim report will be issued to individual mines when the units from that mine are tested. This report will note any problems observed in the tested units Attachment 4(b). A consolidated report on all approval types tested will be issued annually. This LTFE annual report will include results of evaluation testing, follow-through corrective actions to address issues observed during evaluation, and verification of manufacturer site quality audits. NPPTL will prepare an annual NIOSH Report of Investigation (RI) presenting results. An outline for the RI is provided at Attachment 4(c). LTFE Report of Investigation Outline.

Additional technical information on the technical aspects of the LTFE performance requirements and a useful bibliography may be found in the NIOSH Self-Contained Self-Rescuer Long Term Field Evaluation: Combined Eighth and Ninth Phase Results. NIOSH Publication No. 2007-103, October 2006. This is available electronically at <http://www.cdc.gov/niosh/mining/pubs/pubreference/outputid2120.htm>

Attachments:

- Attachment 1: Sampling plan and statistical issues for the Long Term Field Evaluations Program
Note: The sampling plan is the statistical analysis work.
- Attachment 2: Determination of Capacity and Performance of a Self Contained Self Rescuer:
Standard Test Protocol
Note: STP for BMS testing of SCSR
- Attachment 3: Data Analysis
Note: Procedure for handling test data
- Attachment 4(a) Initial Report
4(b) Interim Report
4(c) Annual LTFE Report of Investigations Outline