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## **Protocol for Sampling, Testing and Analyzing Oxygen-Starter Performance of the CSE SR-100 Self-Contained Self-Rescuer**

### **Purpose:**

The purpose of this protocol is to establish procedures to sample, test, and analyze the CSE SR-100 Self-Contained Self-Rescuer (SCSR) oxygen starter performance in mine-deployed respirators.

### **Background:**

The primary oxygen supply of the CSE, SR-100 SCSR is stored chemically. Upon activation, the SR-100 oxygen starter is designed to provide approximately 9 liters of gaseous oxygen into the breathing circuit of the SCSR. The injection of gaseous starter oxygen provides initial oxygen for breathing to allow time for the reaction in the chemical bed to activate and begin producing oxygen for the user. Tests performed as part of the National Institute for Occupational Safety and Health (NIOSH) Long Term Field Evaluation audit program in December 2009 and by the manufacturer as part of their quality assurance program, in February 2010, revealed failures of oxygen starters on some units. CSE has calculated that the oxygen-starter failure rate on new units is less than one percent. CSE further reported to NIOSH and the Mine Safety and Health Administration (MSHA) that the oxygen starter failure is related to application of thread sealant and thread dimensions at the starter oxygen high pressure valve connection and the valve connection assembly process is not traceable to a manufacturing lot or manufacturing date. The actual oxygen-starter failure rate in field-deployed units is not well characterized at this time.

Based on certification performance requirements established at Title 42, Code of Federal Regulations, Part 84, (42 CFR, Part 84), NIOSH and MSHA have determined that only a fully functioning oxygen starter enables performance of the SR-100 to be operationally compliant. Starter oxygen is required for proper function in the first several minutes of use and to ensure a complete oxygen supply. The 42 CFR, Part 84, sampling plans for addressing quality characteristics and the associated manufacturing process accepted quality levels (AQLs) are found at 42 CFR 84.41:

§ 84.41 Quality control plans; contents.

(c) The sampling procedure shall include a list of the characteristics to be tested by the applicant or his agent.

(d) The characteristics listed in accordance with paragraph (c) of this section shall be classified according to the potential effect of such defect and grouped into the following classes:

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- (1) *Critical*. A defect that judgment and experience indicate is likely to result in a condition immediately hazardous to life or health for individuals using or depending upon the respirator;
  - (2) *Major A*. A defect, other than critical, that is likely to result in failure to the degree that the respirator does not provide any respiratory protection or a defect that reduces protection and is not detectable by the user;
  - (3) *Major B*. A defect, other than Major A or critical, that is likely to result in reduced respiratory protection, and is detectable by the user; and
  - (4) *Minor*. A defect that is not likely to materially reduce the usability of the respirator for its intended purpose, or a defect that is a departure from established standards and has little bearing on the effective use or operation of the respirator.
- (e) The quality control inspection test method to be used by the applicant or his agent for each characteristic required to be tested shall be described in detail.
- (f) Each item manufactured shall be 100 percent inspected for defects in all critical characteristics and all defective items shall be rejected.
- (g) The Acceptable Quality Level (AQL) for each major or minor defect so classified by the applicant shall be:
- (1) *Major A*. 1.0 percent;
  - (2) *Major B*. 2.5 percent; and
  - (3) *Minor*. 4.0 percent.

According to the NIOSH/MSHA approved quality plan, CSE defines the supply of starter oxygen for the SR-100 as a critical attribute. The expected failure rate of critical attributes is zero. Test data provided by CSE indicate the actual failure rate to be around one percent.

Redundancy in deployment of SCSR's required under Title 30, Code of Federal Regulations, Part 75.1714-4, promulgated under the Mine Improvement and New Emergency Response Act of 2006 PL 109-236 (S 2803), Section 2 (3)(C)(iii)(II), helps to offset any negative impact from unexpected performance problems and, in this situation is being relied upon as a temporary solution. In a user notice offered by CSE on May 10, 2010, CSE acknowledged the benefit of redundancy in the event of oxygen starter failure advising, "If for any reason a unit does not inflate the breathing bag, the user should don another unit if one is readily available. If a second unit is not readily available, the manual start should be used." If an additional SCSR is readily available, the existing data showing a 1 in 100 (1%) failure rate would yield a 1 in 10,000 chance of having both units fail in any sequence of two SCSRs.

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As a permanent solution, CSE has proposed a redesign of the SR-100, but as of the date of this protocol, has not submitted plans to NIOSH and MSHA for approval test and evaluation. However, none of the improvements proposed thus far will address units currently deployed. Both NIOSH and MSHA expect that currently deployed SR-100s will ultimately need to be replaced, and that the pace of the replacement needs to be driven by the actual oxygen-starter failure rate. To that end, a sampling of field-deployed SR-100s is proposed to determine the prevalence of failed oxygen starters in the CSE SR-100 respirators.

### **Approach**

In order to properly establish the actual prevalence of failed oxygen starters among field-deployed SR-100s, NIOSH proposes using a quality assurance (QA) approach. Operation of the oxygen starter is a single quality attribute. Defined in this manner, standard QA sampling methods may be relied upon to yield a statistically significant characterization of the overall number of failures by the number of failures observed in a reasonably small sample. The total mine-deployed population of SR-100s currently exceeds 70,000 units, thus it is crucially important to draw upon widely recognized sampling techniques and statistical methods. While the method proposed is not designed to find the actual proportion of failed starters, it will with great certainty establish important limits. For example, it will not be possible to state the failure rate is 0.8%, but it will be possible to state the failure rate does not exceed 1.25%, at a 95% confidence interval. The criteria selected are based around limits of 1.25%, 5%, 8%, and 12.5%.

### **Criteria**

The SR-100 sample selection plan is based on American National Standards (ANSI)/American Society of Quality (ASQC) Q3-1988, Sampling Procedures and Tables for Inspection of Isolated Lots by Attributes (Q3-1988). NIOSH 42 CFR 84.43 lists Mil Std 105D as an acceptable sampling plan. Mil STD 105D, as well as the now more widely used ANSI Z1.4, provides for sampling by Limiting Quality (LQ) levels when the actual consumer risk is at issue. The Q3-1988 is a recognized standard for LQ sampling plans. The Q3-1988 plan offers LQ rates for 0.5%, 0.8% and 1.25% nominal limiting quality. It also offers higher LQ rates up to 32%. An LQ rate of 1.25% represents a 95% confidence level that the lot will have less than 1.25% for the tested characteristic. Thus, a LQ value of 1.25% is a reasonable approximation of a 1% consumer risk defect level.

To evaluate deployed SR-100 units for sufficient starter oxygen, NIOSH proposes to use Q3-1988 Limiting Quality (LQ) values. As noted, Q3-1988 lists standard tables of LQ quality levels ranging from 0.05 to 32 percent for various lot sizes. For a quantity of 35,000 to 100,000 deployed SR-100 respirators and LQ's ranging from 1.25 to 12.5, the proposed sampling criteria are:

For LQ 1.25 the sample size is 500 pieces, accept on 3 defects, reject on 4 defects.  $D=0.27$

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For LQ 5.0 the sample size is 500 pieces, accept on 18 defects, reject on 19 defects.  $D=2.5$

For LQ 8.0 the sample size is 315 pieces, accept on 18 defects, reject on 19 defects.  $D=3.9$

For LQ 12.5 the sample size is 200 pieces, accept on 18 defects, reject on 19 defects.  $D=6.3$

Where  $D$  = process average percent nonconforming.

Accept means that the lot is determined to be within the LQ, reject means that the lot defect rate exceeds the LQ.

LQ means that there is a 95% probability that the actual lot quality is equal or better than the stated requirement (1.25%). The process average ( $D$ ), which corresponds to an AQL value, must be significantly better than the LQ in order to have a 95% probability of acceptance.

With the Q3-1988 plan and a 500-piece SR-100 sample size information at LQs of 2.0 and 3.15 can also be obtained. For LQ 2.0 accept criteria is not more than 5 defects and for LQ 3.15 accept criteria is not more than 10 defects.

### **Sample Collection**

NIOSH will use the current MSHA SCSR inventory of all mine-deployed SR-100 units to randomize units manufactured after October 2003. The significance of October 2003 relates to similarity in design and construction. This is the date when the threads on the SR-100 starter-oxygen bottle were modified to the current design. The heat-exposure indicator was also added to the SR-100 in that time frame. (Fewer than 4700 of the currently-deployed SR-100s in service in mines are older than this cut off.)

Using the MSHA inventory, and the unit serial number as a unique identifier, all in-service SR-100s newer than October 2003, will be randomized. As defined in Q3-1988, a sample size of 500 is needed to ascertain the target LQ values at the stated level of confidence (95%). Past experience collecting SCSRs from mine service indicates that more than 500 units will need to be assessed in order to obtain 500 recoverable units for testing. A recoverable unit is a unit that can be found and passes all manufacturer inspection criteria for use. There are numerous reasons that individual units may not be found. Foremost among the reasons is that a unit reported in the inventory can be damaged and removed from service between the time it is recorded and the time that it is searched for in the collection. NIOSH will tabulate and organize the randomly selected unit serial numbers by MSHA District and request each District to retrieve the SR-100s on their respective list. All units not recoverable shall be noted as such on the sample inventory list provided to the Districts, and the reason for which they are deemed to be unrecoverable shall also be made part of that record. NIOSH will then retrieve units from the MSHA Districts. Both agencies agree that surrender of the sought-after units by the owners will be on a voluntary basis. Units will not be taken from mine properties without the full consent of the owners. NIOSH will make arrangements to compensate owners of any devices that are tested.

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The ultimate goal of the collection is to assemble the lowest-ordered-500 randomly-listed, recoverable units available for testing. Since the logistics of sample collection and retrieval are not trivial, NIOSH proposes to accumulate these from the MSHA Districts in at least two forays to reduce the amount of over selection needed to obtain the required sample. Units retrieved by NIOSH from the MSHA district offices will be re-inspected in the NPPTL lab by a NIOSH technician and tested in an order that assures the goal of the collection, mentioned above, is met in full.

NIOSH also wishes to reserve the ability to evaluate the test results in the most efficient manner permitted under the QA sampling plan. For instance, if 19 defects were to be observed within the first 100 units tested, the sample collection, if it has not already been completed, and testing could be halted. In that event, the logic of the QA sample plan indicates the highest selected lot rejection criterion has been exceeded at the number of observations. We would not know what the actual prevalence is, but we would know that the QA percent defective exceeds 12.5%, and a replacement rate decision could be made on that basis. Appendix A, details some critical sampling plan decision points based on the number of defects observed.

### **Test Plan Outline**

1. Record the SR-100 unit serial number and date of manufacture.
2. Determine the minimum allowable volume of starter oxygen based on unit date of manufacturer and CSE maximum allowable leakage rate.
3. Open SR-100
  - a. If unable to open put the unit aside and do not use for this evaluation.
  - b. If the unit opens proceed to step 4.
4. Record serial number of oxygen starter cylinder.
5. Measure volume of starter oxygen available. The breathing bag will be removed from the unit and the unit connected to a spirometer and an electronic data recorder for the volume measurement.
6. Compare measured volume of starter oxygen available with the minimum allowable oxygen volume from step 2.
7. Test result:
  - a. If the volume of starter oxygen available is equal to or greater than ( $\geq$ ) the minimum allowable starter oxygen the unit is an accept (PASS);
  - b. If the volume of starter oxygen available is less than ( $<$ ) the minimum allowable starter oxygen the unit is a reject (FAIL).

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## Appendix A

### Strategy for Sampling Decisions Based on SCSR Sampling / Test Results

The sampling strategies are based upon ultimately obtaining a sample of 500 units and applying the Q3-1988 sample size and accept/reject criteria. The terminology used is standard for QA lot acceptance, i.e. accept the tested lot as meeting the stated quality level versus fail the tested lot as not meeting the stated quality level. For our purposes acceptance translates to a measured defect rate at or below the stated quality level, and reject means the measured defect rate exceeds the stated quality level. The selected LQ Level sampling criteria are listed below:

For LQ 1.25 the sample size is 500 pieces, accept on 3 defects, reject on 4 defects.

For LQ5.0 the sample size is 500 pieces, accept on 18 defects, reject on 19 defects.

For LQ 8.0 the sample size is 315 pieces, accept on 18 defects, reject on 19 defects.

For LQ 12.5 the sample size is 200 pieces, accept on 18 defects, reject on 19 defects.

With the sample size goal of 500 units there are several possible sample collection decision points based on the Limiting Quality (LQ) sampling criteria, the actual in-process number of units sampled and tested, and the number of defects found. Where  $N$  = the number of units sampled and tested and  $X$  = the number of defects detected, the decision points are:

A. While  $N \leq 200$  units:

- a. If  $X \leq 18$ , defect rate is less than 12.5%, sampling and testing continues.
- b. If  $X = 19$ , defect rate is at least 12.5%, test results will be evaluated and reported.

B. When  $201 \leq N \leq 315$ :

- a. If  $X \leq 18$ , defect rate is less than 8.0%, sampling and testing continues.
- b. If  $X = 19$ , defect rate is at least 8.0%, test results will be evaluated and reported.

C. While  $316 \leq N < 500$  units:

- a. If  $X \leq 18$ , defect rate is less than 5.0%, sampling and testing continues.
- b. If  $X = 19$ , defect rate is at least 5.0%, test results will be evaluated and reported.

D. When  $N = 500$  units:

- a.  $X \leq 3$ , defect rate is less than 1.25%.
- b.  $X \geq 4$ , defect rate is at least 1.25%.

The table in Attachment 1 provides a summary of the actual rate defective cut off points.

## Attachment 1

Condition	Measured Defect Rate, R	Effective Failure Rate w/redundancy
A	$R \leq 1.25\%$	less than 1 in 10,000
B	$R \leq 3.0\%^*$	less than 1 in 1000
C	$3.0\% < R < 5.0\%$	at least 1 in 1000
D	$R \geq 5.0\%$	at least 2 in 1000
E	$R \geq 8.0\%$	at least 6 in 1000
F	$R \geq 12.5\%$	at least 1 in 100

\*A measured defect rate of 3% represents the approximate point at which the effective failure rate in any sequential selection of two units rises above 1 in 1000.