

Reliability Assurance Standards for Certification of Self-Contained Self-Rescuers and Filter Self-Rescuers

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Introduction

Title 30, Code of Federal Regulations (CFR), Part II, specifies respirator certification standards. These standards include respirator performance criteria and quality assurance requirements, but they do not contain reliability engineering standards.

The current Part II standards had their origin in 1919 at the U.S. Bureau of Mines (BOM). These standards have been revised over the years, and the administrative responsibility for the certification program was transferred to the National Institute for Occupational Safety and Health (NIOSH) in 1972. Part II, however, has not been significantly modified in its technical standards since 1972. During this period, reliability engineering methodologies were still evolving and emerging as a distinct discipline. Today they are more well known and are experiencing more widespread acceptance and use.

In the late 1980s, several reports were received from within the mining industry that identified performance failures with a number of different filter self-rescuers (FSRs) and self contained self-rescuers (SCSRs). These reports prompted investigations that were jointly conducted by experts from

NIOSH, the Mine Safety and Health Administration (MSHA), and the BOM. The investigations provided governmental decision makers with information that indicated that the performance and quality assurance standards of Part II were insufficient to assure the reliable performance of field deployed FSR and SCSR respirators. The product designs were in conformance to standards and specifications. Additionally, the quality systems of the manufacturers appeared to be adequate. However, many of the performance failures were determined to be related to reliability issues associated with product design and performance, conditions-of-use and storage, and duration of use or product age.

As a result, reliability engineering philosophies were incorporated into the certification process. In May 1991, these were introduced as certification requirements by policy. This presentation defines reliability, describes the basic need for reliability engineering standards for certain classes of respirators, defines reliability certification guidelines (also called service-life plans), and identifies the future goal for incorporating reliability standards into Part II.

Definition of Reliability

Over the past 20 years, reliability has been defined in numerous text books and journals. Frank M. Gryna, *Juran's Quality Control Hand-*

book, fourth edition, 1988, defined reliability as the probability that an item will perform a required function under stated conditions for a

stated period of time. Another expert, Dimitri Kececioglu, *Reliability Engineering Handbook*, 1991, stated that "reliability is the probability that parts, components, products, or systems will perform their designed-for functions without failure in specified environments for desired periods at a given confidence level." These references are used here to underscore four common elements of reliability that were the focus of the reliability assurance or service-life guidelines of the respirator certification program. These elements are: probability, failure free performance of intended function, conditions-of-use, and duration. In establishing these guidelines it was also noted that Norbert Lloyd Enrick, *Quality Control and Reliability*, 1971, described that reliability assur-

ance goes a step beyond quality control by providing engineering proof of the performance capabilities of products. This proof became an important fifth element in defining the NIOSH reliability requirements. The need for reliability standards in the certification program was not known until the late 1980s. It became evident that performance and quality assurance standards were insufficient to assure the failure-free performance of certain classes of respirators. While the reliability engineering tools are applicable to all types of parts, components, products and systems as described by the quoted authors, they are an *absolute necessity* for certain types of personal protective equipment, such as respirators.

Basic Need for Reliability Engineering Standards

During the late 1980s there were nine performance-failures reported to governmental authorities that were significant in establishing the need for reliability engineering standards. All of these reports involved FSRs and SCSRs used by workers in the mining industry. These devices are used for respiratory protection during mine emergency evacuations. A few of these reports are used as examples and are briefly described below:

1. One SCSR design exhibited a closed breathing tube. The reports described that the sides of the breathing tube were stuck together. This condition prevented breathable oxygen from reaching the worker. The amount of tube sticking varied for each respirator. Prescribed donning procedures failed to open all closed tubes. The condition appeared on units that had been field deployed for a duration in excess of approximately 8 years. On units that functioned properly, the breathing tube air pathway opened after performing normal donning procedures. All field deployed units were subsequently recalled.
2. An SCSR design that had been field deployed for less than a year had several reports that the carrying case interfered with the respirator accessibility to the worker. After being carried on a mine worker's belt, some respirators could not be removed from the carrying pouch, or required extraordinary measures (compared to procedures in the instruction

manual) to gain access to the respirator. All field deployed units were retrofitted with a modified pouch.

3. One design, that was among the first units field deployed in 1981, was reported to provide oxygen for a duration much shorter than the performance specification. This design also was laboratory tested and exhibited excessively high CO₂ levels. All field deployed units were removed from service.

Each of these examples illustrate performance failures associated with conditions-of-use, age, design, or a combination of them. One common factor among all the examples was the need for more reliable respirators. Workers who experienced these failures had respirators that provided a diminished level of protection from that expected by performance standards and quality assurances related to the products.

The following rationale was applied in determining the need for FSR and SCSR reliability requirements. These are respirators that:

1. Are intended for use during mine emergency evacuations as life-saving devices.
2. Are complex devices, incorporating multiple components that age at different rates.
3. Cannot be adequately inspected or tested prior to use.

4. Are carried and/or stored in a harsh, uncontrolled mining environment.
5. Were most probably produced and sold without a prescribed expiration date.
6. Were certified without consideration of reliability.

Reliability Certification Guidelines

When the information from several different investigations was collectively considered, the solution to these performance-failures became apparent. NIOSH and MSHA, with the assistance of BOM, developed reliability certification requirements. These are also referred to as the Service-Life Program. The Service-Life Program is primarily the manufacturer's application of reliability engineering principles used to predict and manage the product throughout its useful life.

Guidelines were developed for consistent evaluations of the service-life plans by an intergovernmental agency team. A copy of the complete guidelines is attached. The major elements are discussed below.

1. **Reliability Engineering Methodology:** Manufacturers are required to submit service-life test data in their certification application. This information is needed to support their service-life periods.
2. **Service Action:** Service action is a general term used for describing such actions as refurbishment, part replacement, detailed inspections, etc. All service actions are the manufacturer's responsibility.
3. **Conditions-of-Use:** The manufacturers are required to specify the conditions-of-

use associated with their products' performance and service-life periods.

4. **Identification Date:** Identification dates are required on all FSRs and SCSRs. These dates specify when the unit has expired and should be removed from service.

There are two basic plans. These are called incremental and terminal.

1. **Incremental:** An incremental plan is one in which a service action is performed at a specified time between the manufacturing date and the final expiration date. This action normally would be to replace a "weak link" component. After completion of the service action, the unit is placed back in service and the life is extended from the service date to the final expiration or terminal date.
2. **Terminal:** A terminal plan is one in which there are no service actions in between the manufacturing date and the final expiration date. This date is determined by the age of the "weakest link" component of the respirator. The manufacturer places the terminal date on the unit at the time of production, and the unit is simply removed from service on the terminal date.

Future Part II Reliability Standards

Many of the performance standards for respirator certification are based upon obsolete technology. For example, the silica dust and silica mist tests of Part 11 have remained virtually unchanged for 60 years. Today, science and technology provide vastly improved methods and instruments for evaluating and determining a respirator's performance. The development of revised performance and quality standards is now being introduced in a new certification program

described in 42 CFR 84. This regulatory reform effort provides an opportunity to add reliability standards for additional respirator types such as, supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA). These are complex respirators commonly used in high-risk occupations. Part 84 also provides an opportunity to consider international standards including performance, quality, and reliability.