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History of U.S. Respirator Approval

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Abstract

This article is the second in a series of four articles on respirator history. The discussions presented in this article follow the history of respirator requirements, use, improvements, and certification in America. Included is a discussion of respirator evolution prior to American certification standards and discussion of the need, primarily from the mining industry, for government respirator certification. The reasons for government intervention and the origination of the American respirator certification program are discussed.

Keywords

respirator certification history; respiratory protection

INTRODUCTION

Mankind has always been plagued with atmospheric contamination, ranging from nuisance dusts, smoke, then later industrial toxic vapors and particulate matter. In modern times, respiratory protection has been required for radionuclides and most recently for nanoparticles (Ferber, 1966). Over the years, rudimentary equipment was developed in an attempt to protect the respiratory system. Initially different types of material or fabric (media) were used to filter particulates. Pliny the Elder (23 – 79 A. D.) made use of loose bladder skins to filter dust from crushing cinnabar, a mercuric sulfide mineral, which was a toxic reddish-orange vermilion pigment used in decorations (Schrenk, 1940).

There is a wealth of ancient history related to respiratory protection such as the use of animal bladders to protect against inhaling lead oxides in Roman mines (NIOSH, 1979). An improvement in animal bladders was achieved by attaching sackcloth filters to increase

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protection against mine dusts. Atmosphere-supplying respirators were also developed, such as the hoses or tubes used by ancient people to furnish fresh air to divers. These primitive diving hoses were improved by adding bellows in the seventeenth century as a source of positive pressure breathing air (Schrenk, 1940). Interestingly, today's respirators still function by the same two fundamental modes of operation used in ancient times to protect against inhalation hazards - air-purifying and atmosphere-supplying (Schrenk, 1940). Respirators started to evolve into more familiar devices in the 18th and 19th centuries. For additional information on the early history of respiratory protection, see Pre-World War I Firefighter Respirators and the U.S. Bureau of Mines Involvement in WW I, published by Spelce et al. (2017).

BUREAU OF MINES

When discussing the history of approved respirators (1919 to present), focus on the Department of Interior, United States Bureau of Mines (USBM) is essential because this is where respirator approval (i.e. conformity assessment) originated in the United States. The USBM came into existence because of hazardous conditions encountered in mining. In the early 1900s, thousands of miners were killed or seriously injured. From 1839 to 2010, 15,183 miners were killed in 716 mining disasters (NIOSH, 2018).

In Figure 1, mine rescuers are behind a barricade where surviving miners were located after a mine explosion in Briceville, TN on 9 December 1911 (MSHA, 2018). Modern gas analyzers were not available in these days, causing coal miners to turn to Mother Nature for assistance. Mice, but more commonly canaries, were used to warn miners of oxygen deficient atmospheres and toxic gas. The miners observe the canary's reaction to the atmosphere before proceeding into the mine. Primarily they were concerned with carbon monoxide, which lacks the warning signs of color, smell, and taste and can result in chemical asphyxiation, mine fire or mine explosion. Sadly, miners surviving the initial effects of a mine fire or explosion often succumbed to carbon monoxide asphyxia. Mine rescuers would enter the mine after fires or explosions equipped with canaries in small wooden or metal cages, referred to as "resuscitation cages." Canaries would be distressed and sway on their perches even in low concentrations of carbon monoxide and other gases before toppling over (MSHA, 2018). A canary showing any distress was a clear warning that the air was unsafe, triggering a hurried return to the surface by mine rescuers. Sidebar 1 below provides more history on mining disasters summarized by MSHA (2018).

It is not only mine explosions and roof falls that killed miners. Every year 1,500 miners die from "Black Lung" disease caused by the inhalation of coal dust. To help put this number in perspective, there were 1,500 lives lost as result of the sinking of the Titanic. Sadly, historically, adults were not the only casualties. Miners started to work as young as eight years old [Figure 2 and many of these youths lost their lives from mining disasters or became debilitated from black lung (MSHA, 2018).

Early in December 1907, more than 600 miners were killed in several coal mine explosions occurring in close succession. Thirty-four miners were killed in the Naomi Mine near Belle Vernon, PA, on 1 December 1907 as a result of a gas and dust explosion. Insufficient

ventilation and ignition from arcing electric wires were the causes of the explosion. Then, in the morning of 6 December, 1907, explosions occurred at the Number 6 and Number 8 mines in Monongahela, WV taking 362 lives. Only four miners emerged from the mines shortly after the explosions. Peter Urban, the only other survivor found during mine rescue efforts a few hours later was found underground next to the body of his brother.

A third major disaster occurred on December 19, 1907 from a gas and dust explosion killing 239 miners at the Darr Mine in southwestern Pennsylvania, many of whom were Hungarian immigrants. Some of the dead had just worked at the Naomi Mine that closed as result of the explosion just 18 days before. This explosion resulted from miners carrying open lamps in the mine. On November 13, 1909, at the Cherry Coal Mine in Cherry, IL 259 miners and rescuers died in the mine fire stated when a car full of hay brought down to feed the mules accidentally caught on fire by a portable kerosene lamp that was being used because of an electrical failure a few days earlier. The fire continued up the timbers and mine shaft stairs. There was much confusion during and right after the fire resulting in deaths of mine rescuers.

Figure 3 shows mine rescuers entering the mine wearing newly developed air supply apparatus. The appearance of the breathing apparatus resulted in the rescuers being nicknamed “helmet men.” In response to tragedies such as those at the Monongahela Mine and Cherry Coal Mine, public sentiment in favor of government regulation increased further leading Congress to pass an act (36 Stat. 369) that created the USBM within the Department of the Interior. The act that established the USBM was approved by Congress on May 16, 1910, and became effective on July 1, 1910. The goal of the Bureau under the original Act of 1910 was “*to increase health, safety, economy, and efficiency in the mining, quarrying, metallurgical, and miscellaneous mineral industries of the country.*” The words “safety” and “efficiency” were prominent on the seal of the USBM.

Public outcry was so great over mining tragedies that in 1907, the Secretary of the Interior established the Technologic Branch in the U.S. Geological Survey to aid the mineral industry with health and safety problems. In 1910, Congress removed the Technologic Branch from the U.S. Geological Survey and established the Bureau of Mines within the Department of the Interior. The mission of the USBM was to contend with an alarming number of fatalities and injuries in mines. As shown in Figure 4 (courtesy of NIOSH), the words “safety” and “efficiency” were prominently displayed on the Bureau’s emblem.

EARLY EVOLUTION OF APPROVED RESPIRATORS

The USBM developed technology to prevent injuries and fatalities, from flame resistant materials, permissible explosives, and explosion-proof equipment to prevent coal dust and methane gas explosions. It also promoted the development of respiratory protective devices. The mining equipment industry refined and marketed many of the technologies developed by the Bureau of Mines. Two former Bureau of Mines engineers (John Ryan and George Deike) created the Mine Safety Appliances Company in 1914 [Held, 1978]. The respirator shown in Figure 5 was advertised in the 1917 MSA catalog as a closed-circuit, self-contained breathing apparatus or SCBA developed for mine rescue (Held, 1978). This

product advertisement was two years prior to the first USBM approval granted in January 1920.

The Bureau applied a guiding principle establishing basic requirements for all types of respiratory equipment. These requirements were: (1) they must give adequate protection; (2) they must be reasonably comfortable and physically convenient to wear; (3) they must provide protection for an acceptable time period; and, (4) they must be constructed of durable materials (Schrenk, 1940). USBM-approved respirators, like other mining products and materials approved by the USBM, were considered permissible for specified uses, or considered safe for their intended use.

Breathing apparatus were eventually approved by the Bureau in accordance with Schedule 13 (May 5, 1919) which described the “Procedure for Establishing a List of Permissible Self-Contained Mine Rescue Breathing Apparatus,” and Schedule 14, “Procedure for Establishing a List of Permissible Gas Masks,” which went into effect in August 1919 (Pearce, 1958). However, the Bureau of Mines did not start approving particulate filtering respirators until 1934 under Schedule 21, and it wasn’t until 1944 that chemical cartridge respirators started being approved under schedule 23 (Pearce, 1958). At that time, there were no national requirements such as the Occupational Safety and Health Administration (OSHA, established in 1970) requiring the use of USBM-approved respiratory protection equipment in U.S. workplaces. Despite the absence of a regulatory requirement, reputable manufacturers voluntarily sought the Bureau’s approval.

There were many interesting designs during the early evolution of respirators as shown in figures 6 through 10 (Held, 1978). Figures 6 and 7 show a half mask and a full face particulate filtering respirator from the 1917 MSA Catalog. Figure 8 is a 1923 Wilson dust respirator which used a sponge for a filter. When it became dirty, it could be rinsed and reused. Figure 9 shows a picture of a 1929 American Optical vapor respirator. Can you imagine what kind of sound was produced from exhaling through this large rubber exhalation valve?

The USBM experimented with many respirator types and designs. Figure 10 is a 1924 USBM creation, called the Kilman’s cap-style dust respirator. The filter was worn on the top of the head providing a large surface area for the filtering media. For some reason this stylish design did not catch on with the public.

In addition to respirator testing and approval, the USBM was very active in mine safety in other ways. To support mine rescue operations, the USBM had mine rescue teams. Figure 11 shows two mine rescuers prepared for a mine rescue operation and equipped with a canary in a “resuscitation cage” (MSHA, 2018). Figure 12 is a picture of a 1926 Bureau of Mines device for demonstrating the effect of carbon monoxide on canaries (Held, 1978). Is this sort of like calibrating canaries?

USBM INVOLVEMENT IN DEVELOPING MILITARY GAS MASKS

In World War I, battlefield dangers came not only from enemy bullets but also from the extensive use of chemical warfare gases, such as chlorine, phosgene, and mustard gas. The

U.S. War Department called upon the science and engineering expertise of the USBM to develop standards for gas masks to prepare the U.S. armed services for this new and deadly type of warfare. To support the U.S. war effort the USBM took the lead to develop defensive equipment and offensive warfare gases. According to NIOSH (2010), in February 1917, as the U.S. was about to enter World War I, the Bureau assisted the War Department in studying poison gases and gas masks, until the effort was transferred to the Army in June 1918. For additional information on USBM gas mask approval schedules and approved respirators see the article Pre-World War I Firefighter Respirators and the U.S. Bureau of Mines Involvement in WW I, published by Spelce et al. (2017).

FIRST RESPIRATOR APPROVALS

Through the catalyst of World War I, the USBM became the guardian of workers in every U.S. industry (Held, 1978). Immediately after World War I, the USBM developed a series of respirator approval schedules (standards) and testing procedures setting forth the minimum requirements needed to be met to ensure respiratory equipment was permissible, safe for its intended use, and for specific hazardous conditions (Pearce, 1958). From their experience with mine rescue, USBM had played a critical role in developing self-contained breathing apparatus (SCBA) for the U.S. Navy fleet. Having gained all of this experience the USBM published the first approval schedule, Schedule 13, for SCBAs on 5 March 1919. Because of their experience in developing army gas masks for use in World War I, the Bureau issued Schedule 14 for gas masks on 22 May 1919.

Schedule 13, Self-Contained Breathing Apparatus + Teapot Dome Scandal

Before discussing USBM schedules (i.e., standards for various respirator types or classes), a brief mention of the Teapot Dome Scandal is described in Sidebar 2 (Wyoming State Historical Society, 2016).

Sidebar 2 Bureau of Mines Teapot Dome Scandal—In 1925, as result of the Teapot Dome Scandal (See Figure 13 - Courtesy of Library of Congress, 2018), the Bureau of Mines was transferred to the Department of Commerce. Albert Fall, the Secretary of the Department of Interior made a secret arrangement in which the U.S. naval petroleum reserve at Wyoming's Teapot Dome was leased without competitive bidding to a private oil company. Secretary Fall received \$400,000.00 in bribes and loans.

The American public was very upset over this long and drawn out investigation. Secretary Fall was found guilty of bribery; was fined \$100,000.00; and spent one year in jail. Through guilt by association, the Bureau of Mines also suffered. It was transferred to the Department of Commerce and its funding was progressively cut. After America's emotions cooled down over this incident, the Bureau of Mines was returned to the Department of the Interior in 1934. More information is available concerning this issue online (Wyoming State Historical Society, 2016).

The first USBM respirator approval was issued to the Gibbs breathing apparatus respirator on 15 January 1920, manufactured by the Mine Safety Appliance Company (MSA). The approval number was USBM-1300 approved under Schedule 13. The title page for the

original approval Schedule 13 for the earliest self-contained regenerating type of breathing apparatus is shown in Figure 14 (courtesy of NIOSH). The respirator, shown in Figure 15 in the report by Held (1978), was a closed-circuit SCBA which operated on compressed oxygen and a soda lime scrubber to remove carbon dioxide.

Figure 16, in the NIOSH report (2010) shows miners wearing the Gibbs respirator. Due to the passage of time and a devastating fire at the USBM, much of the USBM records on respirator approval schedules have been lost. A few original schedules and schedule updates have been found, from which we gain knowledge of the first testing procedures and the logic behind them.

When the compressed-air demand-type SCBA was developed, approval requirements were added to Schedule 13 and the revisions thereof (Ferber, 1966). The next oldest approval testing documentation for Schedule 13 is Schedule 13D (i.e., fourth revision) edition, grouping SCBA into logical categories of closed-circuit and open-circuit types. According to Ferber (1966), each SCBA category had provisions for 15 minute, 30 minute one hour, two hour, and four hour apparatus. The Schedule 13D revision also included provisions for a simplified five minute, escape SCBA, equipped with either a mouthpiece or half-mask facepiece. Other changes in the fourth revision of Schedule 13D requirements included a reduction in maximum weight of the apparatus from 40 to 35 pounds, use of stem gages, and more rigid specification of compressed air purity. There was also “...a requirement that accessories be available to permit the apparatus to function at temperatures down to -30°F , and the mandatory use of devices to warn the wearer when his oxygen or air supply has reached a predetermined low point. Many of these requirements will not apply to the escape apparatus.”

The USBM developed four additional approval schedules where it also tested and approved the following types of respiratory protective devices at its Central Experiment Station, in Pittsburgh, PA: Schedule 19, Supplied-air respirators on 28 April 1927, Schedule 21 Dust, fume, and mist (i.e. particulate) respirators on 21 August 1934, and Schedule 23 Nonemergency gas respirators (i.e. chemical cartridge respirators) on 13 November 1944.

The Bureau described important principles and aims of the approval program including the following (Schrenk, 1940):

1. Promote development and manufacture of respiratory equipment of known good quality, through minimum requirements for safe and durable equipment and methods for testing the devices for conformity to requirements.
2. Apply certain basic requirements to all types of respiratory equipment: (a) they must give adequate protection; (b) they must be reasonably comfortable and physically convenient to wear; (c) they must provide protection for an acceptable time period; and (d) they must be constructed of durable materials.
3. Suggest changes that will improve the comfort, safety, or efficiency of the apparatus by the Bureau's independent examination. These suggestions are usually followed by the manufacturer to improve his apparatus even though they may not be necessary to pass the prescribed schedule of tests.

4. Conduct laboratory and human subject inspections and testing to assess conformance to requirements. For example:
 - a. Dispersoid (dust, fume, mist and fog) respirators were tested against relatively high concentrations of quartz dust, lead dust, chromic acid mist, siliceous mist, lead paint mist, or lead fume, depending on the purpose for which the device was designed. The efficacy of a respirator was based not on the percentage efficiency but on the so-called permissible limits; that is, the leakage shall not exceed the amount considered safe to breathe. The device must have a reasonable service period before its resistance to a flow of 85 liters per minute exceeds 2 inches of water; so that the filter must be able to retain considerable dust without undue increase in resistance.
 - b. Supplied-air respirators were worn in one percent ammonia and a high concentration of dust. Abrasive blasting devices were worn during sand blasting. Samples of air were taken from the facepiece while it was being worn in the high concentration of dust or during sand blasting and the quantity of dust determined.

The laboratory tests yielded valuable empirical information, but the final decision depended on the performance of the device when worn by persons under actual conditions of use, and in maximum concentrations of contaminants for which the device was approved or concentrations that were considered to give an adequate test of the efficacy of the device. The man tests not only checked the efficiency of the apparatus but also gave information on comfort, freedom of movement, field of vision, and practicability.

The Bureau of Mine's established approval programs for a diverse range of products used in mining such as permissible brattice cloth, hydraulic fluids, explosives, explosion-proof products like motors, electrical enclosures and luminaires, cap lamps, intrinsically safe electronic instruments, and respiratory protective equipment. The USBM approval program was the robust independent third-party governmental program that linked standards and conformity assessment activities with identified workplace hazards. It was an underpinning of modern U.S. conformity assessment programs. Requirements of the current NIOSH approval program, Table I, had its roots at the USBM.

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Figure 1.
Miners Inspecting Canary’s Reaction During Mine Rescue in Briceville, TN, December 1911.



Figure 2.
Young Miner.



Figure 3.
"Helmet Men" Mine Rescuers at the Cherry Mine, November 1909



Figure 4.
USBM Emblem Symbol.

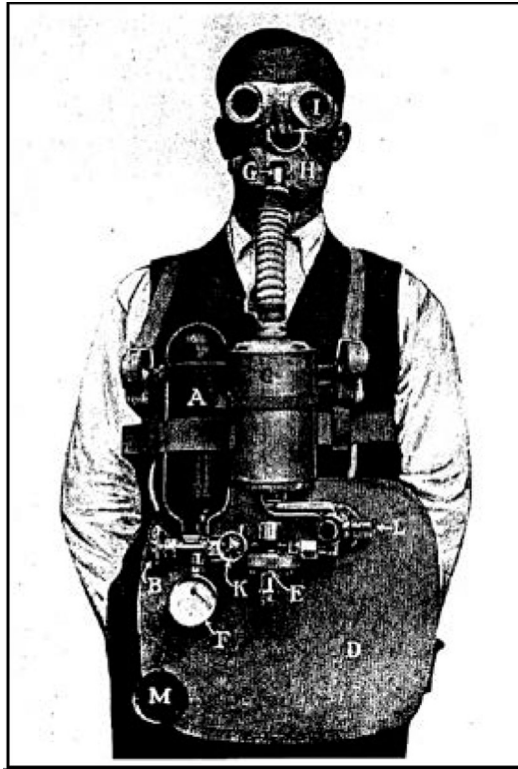


Figure 5.
Closed-Circuit Mine Rescue SCBA 1917 MSA Catalog.



Figure 6.
Half-Mask from 1917 MSA Catalog

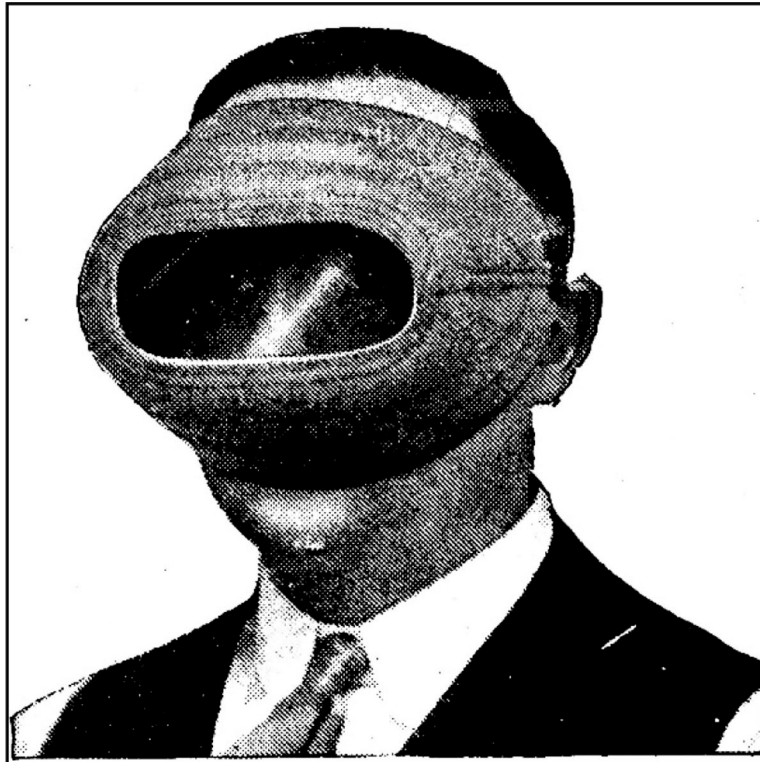


Figure 7.
Full Facepiece from 1917 MSA Catalog.

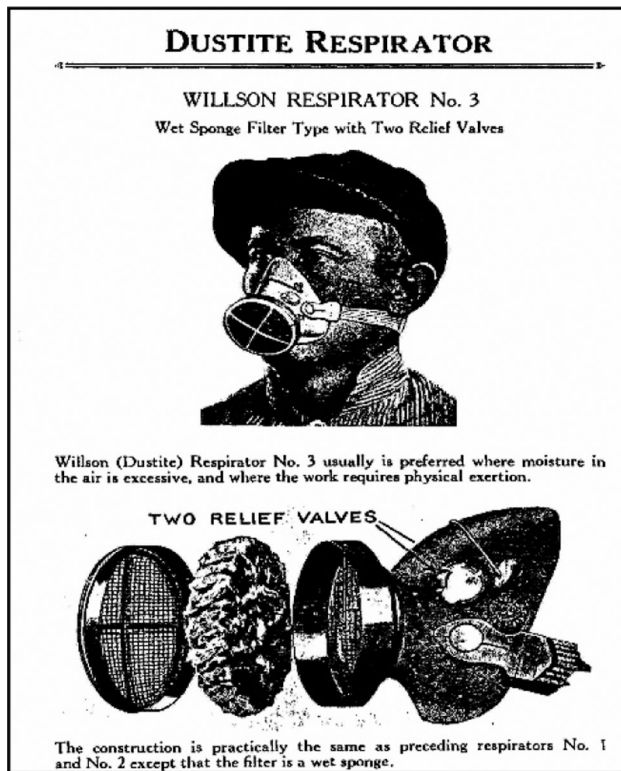


Figure 8.
1923 Wilson dust respirator.



Figure 9.
1929 American Optical vapor respirator.

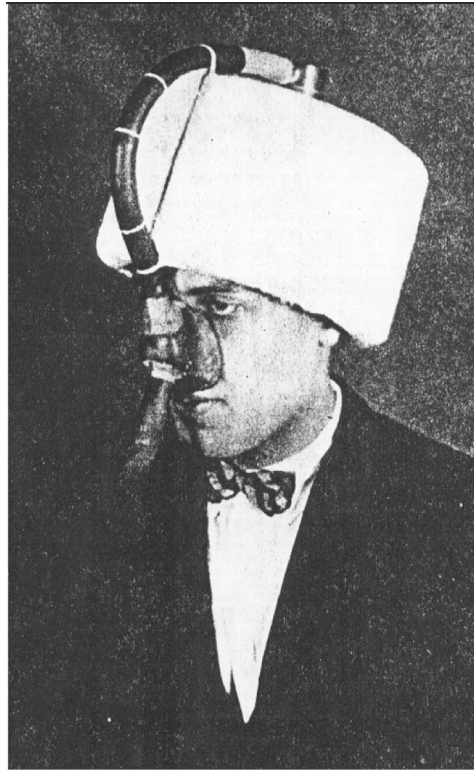


FIGURE 10.
1924 USBM Kilman's Cap-Style Dust Respirator.



FIGURE 11.
Mine Rescuers Equipped With a “Resuscitation Cage”.

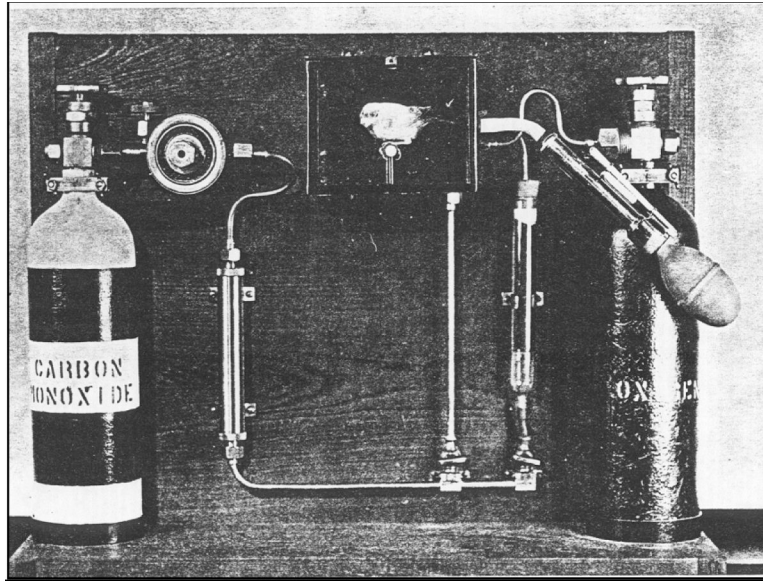


Figure 12.
1926 USBM Device Demonstrating Effect of Carbon Monoxide on Canaries.

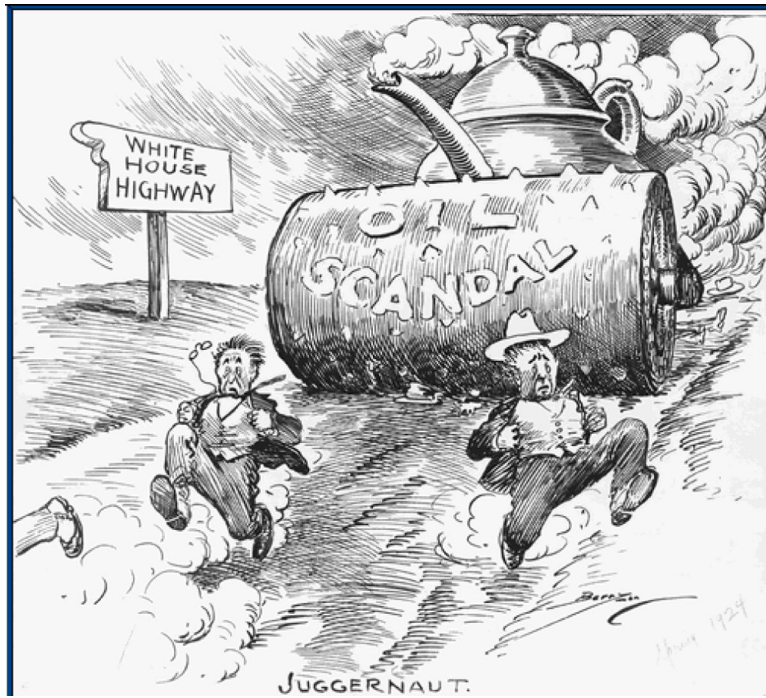


Figure 13.
Teapot Dome Scandal.

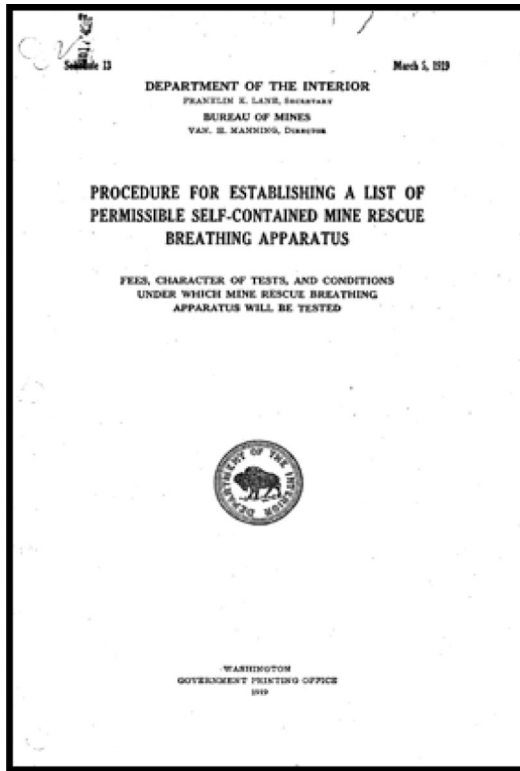


Figure 14.
Schedule 13 Cover.

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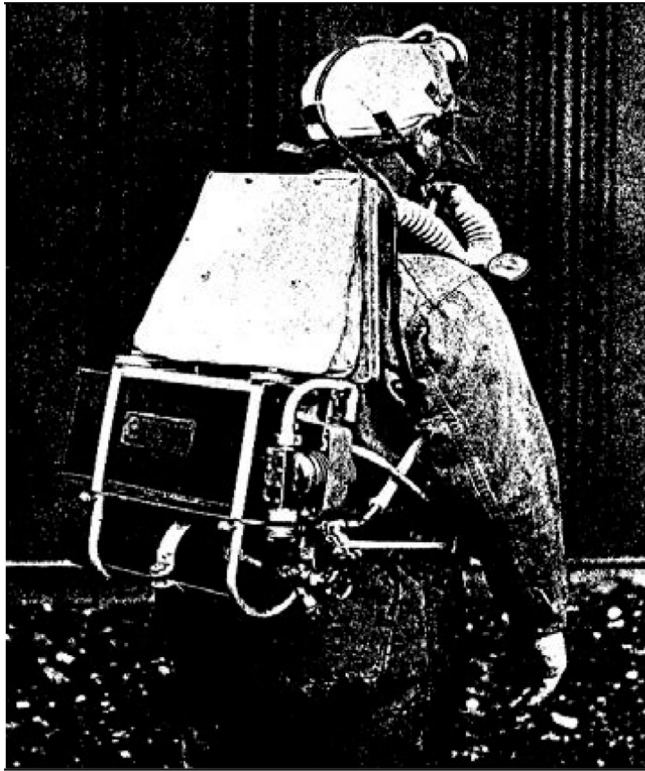


Figure 15.
Gibbs Respirator.



Figure 16.
Miners Wearing The Gibbs Respirator

Table I.

Summary of NIOSH Approval Program Requirements

The U.S. respirator approval program activities are comprehensive including:

- Evaluation of respirator design documents (engineering drawings, respirator specifications, performance test results)
- Evaluation of the applicant's manufacturing quality assurance system
- Evaluation of the applicant's respirator quality control plans
- Evaluation of applicant user instructions, packaging and component labels
- Inspection of the respirator and its components to confirm design specifications
- Testing to confirm performance conforms to Federal regulations and where applicable national standards
- Additional tests, cautions, and limitations of use as deemed appropriate to assess adequacy of protection for the intended use of the respirator
- On-going post-approval audit of manufacturing sites
- On-going post-market inspection and testing of approved respirators
- Issuance of public user notices
- Issuance of notices to manufacturers concerning policy or regarding stop sale, recall, or retrofit to approved products where investigations have identified non-conformance
- Revocation of the Certificate of Approval for cause