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Technical Bulletin
November 2024

Technical Report on X3 and X3 Pro Pressure Reducer

Initial Reports and Actions

In April 2024, 3M received a preliminary request for support through our field service team from Boca Raton Fire Department (BRFD) in Florida. The request claimed that one of their self-contained breathing apparatus (SCBA) did not perform as expected during the press-to-test portion of its inspection. This SCBA had been in service for approximately 10 years. This led the technician at BRFD to open and inspect the first-stage pressure reducer (reducer). They found damage to the transfer valve seat and noted the presence of a substance they could not identify that they referred to as “debris”. They sent the substance for analysis and shared the analysis with 3M, asking for our opinion on provenance of the substance, whether it may cause respirator malfunction, and if we believed any potential health effects were possible. We opened parallel investigations into both the dislodged seat and the substance.

While our investigation was underway, personnel at BRFD notified other local fire departments of their findings. These departments had not encountered any non-conforming respirator performance, but some decided to perform internal inspections of their reducers. We initially received a small number of reports (3-4) of dislodged seats and substance in some of those reducers. While no conclusions could yet be drawn from our investigation, we drafted a preliminary letter to address inquiries generated from the BRFD notification. At the time, given that some of the substance analysis revealed substances that are not known to be present in the aluminum alloy used to make 3M SCBA components, or in silicone seats, we felt it was possible some of the substance could have come from other sources. Our preliminary letter mentions this.

In June 2024, the International Association of Fire Fighters (IAFF) circulated a See "safety advisory", along with a See "Frequently Asked Question (FAQ) sheet", calling upon all their member locals to perform internal inspections, regardless of brand of SCBA. We note that the advisory refers to a non-conformance of a respirator during service. We had not been made aware of any such non-conformance from BRFD directly, however our understanding of the report is that the low-pressure alarm activated while cylinder pressure was above the 35% required alarm set-point. While this indicates that an inspection is required, this is a normal safety feature of the 3M Scott pressure reducers to warn respirator users of a possible malfunction. When this warning activates, the SCBA should be removed from use and submitted to an authorized technician for inspection. We do not deem it a malfunction of the respirator as the SCBA will continue to deliver breathing air to the user in this alarm state during egress.

We also note that the advisory contains inferences related to health effects of metals found in the lab analysis commissioned by BRFD. We will address these in a later section of this report. We have not received any reports of substances in the second-stage reducer (regulator), facepiece or nosecup. The advisory also does not factor in exposure amounts or exposure time, which are both important variables in determining health effects.

Having completed our own analysis, 3M will discuss and share findings with the IAFF senior leadership and Science and Research team.

METALLIC BUILDUP IN SCBA AIR PACKS

SAFETY ADVISORY • JUNE 2024

The International Association of Fire Fighters (IAFF) is issuing a safety alert to inform members of concerns about metal buildup in the air pack regulator of the Self-Contained Breathing Apparatus (SCBA).

The IAFF was recently contacted by a Local experiencing issues with SCBAs going into a low-air alert when the cylinder had adequate air remaining. An analysis initiated by the Local and conducted by the Department's certified SCBA technician identified a metallic substance on the O-Ring of the air pack.

After identifying the metallic substance, the Department conducted additional inspections and found metallic substances in a majority of units. Since this finding, other Locals have identified shaved pieces of metal in additional manufacturers' SCBAs.

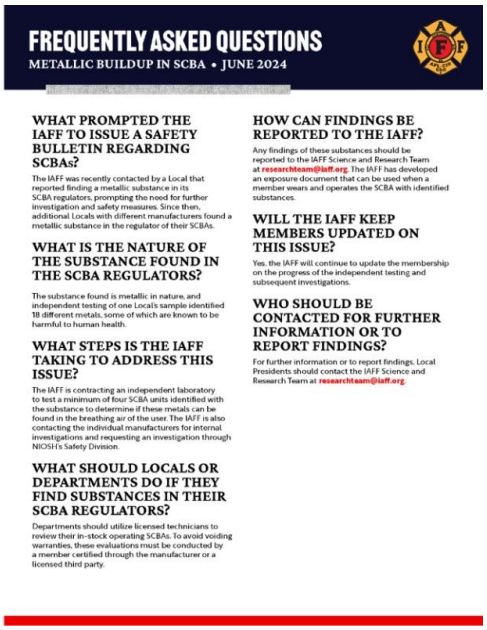
Samples of the metallic substance were collected and sent to a local independent laboratory for further analysis. Eighteen separate metals were found in the substance. These 18 metals are Aluminum, Barium, Boron, Cadmium, Calcium, Chromium, Copper, Iron, Magnesium, Manganese, Nickel, Potassium, Silicon, Sodium, Sulfur, Titanium, Vanadium, and Zinc.

Many of these metals may cause neurological, gastrointestinal, or respiratory issues, may result in lung and kidney damage, and may be potentially carcinogenic.

Due to the possible presence of these metals in SBCA units, the IAFF and our Subject Matter Experts are conducting independent analysis to identify if various manufacturers' SCBA units are experiencing metallic build-up in their air pack regulators and to assess corresponding potential air quality concerns.

The IAFF recommends that all SCBA units be inspected and evaluated by certified SCBA technicians for the presence of metal build-up in the air pack regulator. Additionally, all SCBAs should be thoroughly inspected to ensure proper maintenance and functionality.

If Locals identify any metallic substance build-up in their SBCA units or have additional questions, please contact the IAFF Science and Research Team at researchteam@iaff.org.



FREQUENTLY ASKED QUESTIONS

METALLIC BUILDUP IN SCBA • JUNE 2024

WHAT PROMPTED THE IAFF TO ISSUE A SAFETY BULLETIN REGARDING SCBAs?

The IAFF was recently contacted by a Local that reported finding a metallic substance in its SCBA regulators, prompting the need for further investigation and safety measures. Since then, additional Locals with different manufacturers found a metallic substance in the regulator of their SCBAs.

WHAT IS THE NATURE OF THE SUBSTANCE FOUND IN THE SCBA REGULATORS?

The substance found is metallic in nature, and independent testing of one Local's sample identified 18 different metals, some of which are known to be harmful to human health.

WHAT STEPS IS THE IAFF TAKING TO ADDRESS THIS ISSUE?

The IAFF is contracting an independent laboratory to test a minimum of four SCBA units identified with the substance to determine if these metals can be found in the breathing air of the user. The IAFF is also contacting the individual manufacturers for internal investigations and requesting an investigation through NIOSH's Safety Division.

WHAT SHOULD LOCALS OR DEPARTMENTS DO IF THEY FIND SUBSTANCES IN THEIR SCBA REGULATORS?

Departments should utilize licensed technicians to review their in-stock operating SCBAs. To avoid voiding warranties, these evaluations must be conducted by a member certified through the manufacturer or a licensed third party.

HOW CAN FINDINGS BE REPORTED TO THE IAFF?

Any findings of these substances should be reported to the IAFF Science and Research Team at researchteam@iaff.org. The IAFF has developed an exposure document that can be used when a member wears and operates the SCBA with identified substances.

WILL THE IAFF KEEP MEMBERS UPDATED ON THIS ISSUE?

Yes, the IAFF will continue to update the membership on the progress of the independent testing and subsequent investigations.

WHO SHOULD BE CONTACTED FOR FURTHER INFORMATION OR TO REPORT FINDINGS?

For further information or to report findings, Local Presidents should contact the IAFF Science and Research Team at researchteam@iaff.org.

Action Plan

After initial notification by BRFD an investigation was opened into the request for assistance. Our investigation was 3-fold:

1. Determining provenance of the substance, both internal and external to our first-stage pressure reducer. This includes a parallel investigation of the dislodged seats on our transfer valve, typically handled as a service repair.
2. Determining possibility of substance traveling from the pressure reducer along the inhalation path.
3. Determining health effects if inhalation is possible, including quantification of the substance and exposure time.

This report summarizes our current findings and conclusions.

Other Department Inquiries

3M subsequently received requests for support from other fire departments stemming from either the IAFF advisory and/or the local outreach by BRFD. They include fire departments in Texas, Florida, and Indiana. None of these departments had experienced any malfunctions of their SCBA but were seeking guidance on how to conduct inspections.

We contacted all these departments and addressed any questions pertaining to required inspections of their SCBA fleet. Over the course of the inspections, the service technicians discovered some SCBA that had the presence of a similar substance in the reducer areas noted in the original reports, while some did not. In some cases where small amounts of substance were identified it was not widespread throughout the fleets. There were no reports or evidence of any substance having migrated into the mask-mounted regulator (MMR) or nosecup area. There were also no reports of any SCBA having malfunctioned. The SCBA in question with presence of this substance varied in age between 2 and 11 years. In all cases where the SCBA were tested on the POSI breathing machines, they performed within standard parameters, taking into consideration their age and any normal adjustments that were required.

Correspondence with External Agencies

3M has been in contact with the National Institute for Occupational Safety and Health (NIOSH) throughout this investigation and provided details of the reports and the findings. We previously advised NIOSH of the request and the investigation we were conducting. Subsequent meetings were held, and a detailed action plan provided. In addition, as a requirement of our certifications, the Safety Equipment Institute (SEI) has also been notified and kept abreast of our investigation and findings.

Identification of Substances

As mentioned in the introductory statements, 3M was provided a lab analysis by BRFD performed by Florida-Spectrum Environmental Services, Inc. The lab report, cited in the IAFF advisory, identified the presence and amounts of certain substances. Although we do not dispute the validity of the report, the analysis protocols stated in the report require minimum amounts of material for testing to be conducted. In our own laboratory analysis, we were unable to collect or generate the amounts of substance required to perform testing in accordance with the cited Environmental Protection Agency (EPA) protocol. Despite deliberately inducing the operating conditions we now believe could generate substance inside the pressure

reducer, we only observed and collected a maximum of up to 1.3mg of substance from any individual reducer. The protocols cited in the report were:

- EPA 6010D/3050B. This protocol requires 200g (200,000 mg) of material.
- ASTM E3061-24 - Standard Test Method for Analysis of Aluminum and Aluminum Alloys by Inductively coupled Plasma Atomic Emission Spectrometry which requires 0.5g (500 mg) of material.

None of the unopened reducer samples we collected from member departments showed any amounts of substance more than what we were able to produce in our simulation testing. These low observed quantities of substance after up to 10 years of service lead us to conclude that the creation of greater amounts in any single reducer has never been observed and is unlikely to occur. We submitted questions to the laboratory that performed the analysis, through BRFD, on whether samples from multiple SCBA were combined to generate sufficient substance to meet the required test minimums, and the response we received from BRFD was that only a single sample was used.

We will therefore use the report cited as a guideline only. Some of the identified substances, such as silicon and aluminum, are present in the 3M reducer body and internal components. The toxicological review of these substances in the quantities observed is addressed in a later section.

Provenance of Substance and Actions

SCBA are not closed systems. They are used in dirty environments. As stated above, the aluminum and silicon made up the majority of the substances identified in the lab report. Aluminum and silicon are components used in the manufacture of our pressure reducer components and final assembly, and we can account for their presence. Many of the trace amounts of other substances can either be attributed to the aluminum alloys themselves or the possibility of a source on the fireground itself. Specific to provenance, our primary objectives were to:

- Identify why the silicon seats from the low cylinder transfer valves shown in the advisory images had de-bonded from the valve body.
- Confirm if and how the substance noted could have been generated within the pressure reducer body.
- Determine any required preventive actions.

Through our ongoing testing we have identified 2 potential sources of some of the identified substances:

1. Transfer valve seat debonding can be a source of the silicon substance within the reducer.
2. In simulated lifecycle testing, check valve oscillation was found to be a possible contributor to creation of the substance with metallic appearance reported to us.

    a. The lifecycle testing simulated usage in excess of normal SCBA life.

These findings have led us to investigate possible changes to materials to prevent occurrence over long SCBA lifecycles. A coating change for the check valve poppet is being finalized.

Migration of Substance and Potential Toxicological Impact on Users

Most importantly to this analysis, the samples of substance observed in field units and replicated in our lab settings were all observed to be captive within the pressure reducer of the SCBA. We were unable to find any cited test methods for measuring particle size and composition and whether it traveled through an air-supplied respirator of this type when present in the pressure reducer. We therefore created a test method to allow this to be analyzed.

Based on our testing, if particles of substance are observed in the reducer, they have been shown not to migrate to the interior of the nosecup. There was no evidence in any of the testing conducted that a SCBA user would be exposed to the substance while breathing air from the respirator.

Although the testing and observations noted above concluded that user exposure to any substance while wearing the respirator is unlikely, and no evidence has been observed or reported that this can occur, based on use of the analysis provided by BRFD and small quantities observed in the pressure reducers we can make the following observations.

The particles observed in the reducer are believed to stay captive within the body of the reducer and not to migrate any further along the inhalation path. Under anticipated conditions of use these particles are not available for inhalation exposure and thus do not present a health risk. Furthermore, even if the particles were able to migrate beyond the pressure reducer, given both the small amounts observed and the torturous pathway inside the SCBA, any potential exposure would be anticipated to be minimal. Based on our understanding of the identity of the particles, they would be expected to be poorly soluble and non-reactive.

Conclusion and Recommendations

Although we continue to study possible improvements to production fixtures and materials to minimize the possibility of this type of substance being observed in the pressure reducer of our 3M™ Scott™ Air-Pak™ X3 or X3 Pro SCBA models, we conclude that:

1. Although some of the reported substances may have originated from SCBA, particularly those SCBA in use for long periods of time, it is likely that some of the substances entered the SCBA from external sources.
2. There is no evidence that any substance travels into the respiratory area.
3. There is no evidence SCBA wearers can be exposed to the substance while breathing air from the SCBA.
4. Even if exposure were possible, toxicological impact of the substance in the quantities observed is negligible and not considered a risk to human health.
5. After use, or as instructed by the department's respiratory protection program, we encourage all users to follow our User Instructions as well as supplementary Cleaning Instructions for SCBA. Our service manuals, provided to authorized technicians provide instructions for cleaning of internal components if deemed required.
6. We will continue to work with regulatory agencies NIOSH / SEI to determine if any action is required beyond normal inspection of the SCBA on existing cycle and advise.
7. We have worked closely with IAFF leadership for assistance in ensuring messaging of these conclusions is relayed to their members to encourage continued safe use of SCBA.
8. We remain available to assist any member departments with questions or concerns. Any service-related queries or requests for supplementary inspections should be handled by authorized or in-house repair centers.

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