

Rebreather Accident Investigations

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Abstract

In 2006, representatives of rebreather manufacturers, training agencies, government agencies, rebreather users and Divers Alert Network (“DAN”) met to discuss objectives for rebreather fatality investigations. DAN had collected information on 80 recreational diving rebreather deaths from 1998 through 2006 and, although the annual number of rebreather fatalities appeared to have tripled since 1998, few conclusions could be drawn about what was causing these accidents because too little information was available from rebreather fatality investigations. Unfortunately, little has changed since 2006. The number of rebreather fatalities worldwide since 1998 is now approaching 200, and 12 to 15 new fatalities occur each year, but the diving community is no closer to determining the cause of these accidents because of inadequate medical, equipment and procedural investigations; little standardization in the way these investigations are conducted; and failure to include rebreather manufacturers in fatality investigations at the earliest possible opportunity. If government agencies and the diving community are truly interested in enhancing the safety of rebreather diving, there needs to be immediate improvement in cooperation between the various constituencies, as well as effective accident investigations, securing all available evidence and subsequently sharing of information to the maximum extent permitted by law.

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Introduction

According to published data, there were nearly 200 closed circuit rebreather fatalities worldwide from 1998 until 2010; currently, there are 12 to 15 new rebreather fatalities each year (Fock, 2014). “Rebreather fatalities” are classified as “a diver dies while wearing a rebreather,” a misleading characterization implying that equipment problems are the cause of many fatalities rather than, as it often appears, diver error or medical issues. In fact, although speculation abounds, little is actually known about the root causes of these accidents because investigations are haphazard and often performed improperly, and suspicion abounds between various stakeholders in the investigative process. This situation hampers efforts to increase rebreather diving safety by identifying the root causes of rebreather accidents and fatalities (Fock, 2014; Vann et al., 2007). Accurate and complete information is required to answer the question: “What is causing rebreather divers to die?” Cooperation between investigating authorities and rebreather manufacturers is essential if accident investigations are to improve. Evidence must be gathered, shared, and disseminated to the maximum extent permitted by law if there are to be improvements in training, equipment, and practice.

Why Should We Care About Accident Investigations?

The Problem

In 2006, representatives of rebreather manufacturers, training agencies, government agencies, rebreather users and the Divers Alert Network (“DAN”), met to discuss objectives for rebreather fatality investigations. DAN had collected information on 80 recreational diving deaths from 1998 through 2006 where the diver was wearing a rebreather, but conclusions concerning the causes of these deaths were limited because investigations had been inadequate (Vann et al., 2007). The meeting participants pledged cooperation with each other to improve the quantity and quality of collected information. Unfortunately, little has changed since 2006; rebreather fatalities continue to increase and cooperation between investigating authorities and rebreather manufacturers is inconsistent, at best.

The annual number of rebreather fatalities appears to have tripled since 1998, with the total number either at or exceeding 200 rebreather fatalities worldwide, and 12 to 15 new rebreather fatalities each year (Fock, 2014). The percentage of fatalities involving rebreathers among U.S. and Canadian residents increased from about 1 to 5% of the total number of diving fatalities captured from 1998 through 2004 (Vann et al., 2007).

Meanwhile, rebreather manufacturers have formed the Rebreather Education and Safety Association (“RESA”), an association designed to share information, improve training and manufacturing standards, and increase cooperation with investigators in the field. All of the major training agencies have joined RESA as supporting members, and significant efforts to improve training and safety are underway. Unfortunately, cooperation with investigative authorities remains elusive, even while critical information derived from rebreather accident investigations remains the key to identifying the most important points for action to avoid future injuries and fatalities.

Accident Investigations – The Three Track Process

Accident investigations follow three parallel tracks: (1) medical-legal autopsies of the deceased diver to look for medical issues causing or contributing to the person’s death; (2) determination of procedural issues causing or contributing to the person’s death, normally by conducting witness interviews and examining the deceased’s training and experience; and (3) investigation of equipment to look for problems or malfunctions causing or contributing to the person’s death. Unfortunately, current emergency response and accident investigation protocols for marine incidents are designed to handle the more common incidents occurring on the surface, such as boating accidents and swimmer drownings, and not the less common incident occurring under the surface, such as scuba diving accidents. This reality, when coupled with the fact that rebreather fatalities comprise just a small subset of overall scuba diving fatalities worldwide (Fock, 2014; Vann et al., 2007), means that current accident investigation protocols are woefully inadequate when it comes to uncovering facts that could lead to a substantial decrease in rebreather fatalities, and a lack of cooperation between investigators and stakeholders in the outcome of the investigation only exacerbates the resulting institutional ignorance.

The Typical Rebreather Fatality Investigation Today

A review of a typical rebreather fatality highlights the problem with the current state of accident investigations:

On any given weekend, particularly during the summer, a rebreather fatality is likely to happen somewhere in the world. The circumstances are often the same: a well-educated, successful male, aged 35 to 60, and highly experienced as a recreational and often technical scuba diver, dies while wearing a rebreather. The diver is often diving solo or with a buddy using open circuit scuba equipment, beyond normal recreational diving depths, on a wreck, reef or in a cave. Other divers who are present report that the deceased diver exhibited no signs of anxiety or lack of preparation before the dive; he seemed fine underwater; and they are shocked by the diver's death because he was highly experienced and meticulous about his preparing and maintaining his equipment. Typically, the deceased diver was found on the bottom, unconscious, with the mouthpiece out of his mouth, sometime after he failed to return to the surface. Alternatively, he died on the surface after making an unexpected and rapid ascent. Other divers on the scene and the vessel crew are usually unfamiliar with rebreathers; they do not know how to properly record or secure evidence, and they do not know how to interpret information on the rebreather's displays or from audible beeping or flashing lights.

The chances of determining what caused the diver's death worsen once the investigative process begins. First responders arriving at the scene, typically the U.S. Coast Guard or local ambulance and Emergency Medical Technicians, are there to provide medical assistance or retrieve the diver and take him to medical assistance – not to conduct fatality investigations. Consequently, first responders are normally unfamiliar with closed circuit rebreather diving equipment and, indeed, disinterested as their first priority is to render medical assistance or transport the diver to a hospital.

Investigative authorities subsequently arriving at the scene, typically police, sheriff or medical examiner investigators, are also unfamiliar with rebreathers (and possibly even scuba diving). Worse, many investigators do not know how to properly shut down the rebreather and secure evidence. Consequently, accident scene investigations are usually limited to taking cursory (and often conflicting and unhelpful) witness statements from people at the scene, gathering the victim's belongings and (rarely) taking photographs of the equipment. It is not unusual for people at the scene to interrogate the rebreather's electronic controllers and dive computer and inadvertently overwrite data and destroy evidence simply because they are being inquisitive and they do not understand how the equipment operates.

Next, the rebreather and other diving equipment are transported to an office and stored until they can be delivered to a local "expert" for an equipment examination. This entire process usually happens without the investigators contacting the rebreather manufacturer to ask for assistance or advice, or even to determine if there is anybody nearby who is qualified to perform a thorough and proper equipment examination. Instead, local investigators often avail themselves of the "I got a guy..." network, where the investigator asks around of people he knows until somebody he says "I got a guy who may know something about rebreathers and may be able to help you."

Thus, the equipment investigation track now heads down a path that may or may not involve someone who is knowledgeable about the equipment and can provide expert assistance to the overall fatality investigation. Sometimes, the investigator may seek the assistance or advice of the rebreather manufacturer, just as the manufacturer of an aircraft offers expert assistance to the National Transportation Safety Board (“NTSB”) during an air crash investigation. But, more often than not, the investigator fails to do so. Unfortunately, some investigative agencies are openly hostile to the idea of seeking or accepting expert advice or assistance from rebreather manufacturers, even when stop gap measures are employed to ensure neutrality and maintain proper investigative protocols. Consequently, the institutional ignorance becomes entrenched, even rising to the level of being willful.

Meanwhile, the local coroner or medical examiner conducts an autopsy of the diver’s body, often without following the proper forensic medical protocols (Caruso, 2010), such that evidence is not collected (or recognized) that might determine the trigger of the accident. Unless some obvious non-diving medical issue is recognized on autopsy, the cause of death is simply listed as “drowning.” Finally, when the rebreather manufacturer learns of the fatality, often within hours, and calls the investigating authority to offer assistance, the offer is met with suspicion and refusal or guarded skepticism and conditional acceptance.

This is the typical scenario in a rebreather fatality, at least in the United States and sets the stage for little good. Relevant information is not gathered, evidence is not preserved, questions are not answered, and safety is not improved. For lawyers specializing in prosecuting or defending rebreather lawsuits, this is wonderful as large legal fees are likely forthcoming. But for families of the deceased, currently active rebreather divers, rebreather manufacturers, training agencies, academics, first responders, government agencies, and anyone concerned with diving safety, the results are more than unsatisfactory.

Why should we care about accident investigations? Because the current state of affairs is untenable. Accidents are devastating for families as, more often than not, the victim is the primary breadwinner. Accidents are bad for business, and the consequences of poor investigation include increased litigation to the tune of millions of dollars, loss of cases and higher premiums, and less availability of accident insurance. Accidents are also bad for freedom. For example, the British government has financed the Royal Society for the Prevention of Accidents to consider what might be done to reduce the rising tide of rebreather accidents. Will this also apply to the U.S., European, New Zealand and Australian governments? In summary, if we do not know what the causes are, we cannot make rebreather diving safer. This uncertainty will lead to more accidents and fatalities. If there is to be any hope of determining the causes of rebreather accidents and making rebreather diving safer, all of the stakeholders in the investigative process must establish a surveillance system that improves data quality and completeness, as well as the dissemination of information gained from accident investigations to the diving community.

How to Conduct a Thorough and Useful Rebreather Fatality Investigation

Tips for First Responders

There is such a wide variety of rebreathers on the market, each with its own unique features (Fig. 1), that a single investigative protocol cannot apply to all models. A competent investigator needs to be familiar with the model in question or, at the very least, have expert assistance from the manufacturer or its representative so critical data can be retrieved and preserved and relevant procedural and/or mechanical issues can be identified at the outset of the investigation.



Figure 1: Some of the recreational rebreathers on the market today

If you are the first person on-scene, your primary responsibility is to obtain as many facts as possible. The following tips can be helpful to you, and the information obtained will certainly help the people that depend on you conducting an accurate investigation.

- Photograph everything, from all angles, many times.
- If possible, take video of the diver's equipment, the scene and rebreather. Even a simple cell phone video can yield important clues about what happened to the diver – clues that may not be readily apparent to the people on scene in the inevitable emotion that follows a fatality.
- Know what you are looking for and how to look for it.
- Pay particular attention to the displays on the rebreather's electronic controller(s) and the diver's dive computer. Photograph the images and information that appears on these displays.
- Make note of any visual clues or sounds emanating from the rebreather, and especially any visual or audible warnings.
- Make note of and photograph the serial numbers on the rebreather and its component parts.
- Make note of any parts that are missing or do not appear to be original.
- Know what you do not know, and do not be afraid to ask for help from somebody more knowledgeable than you.

- Equipment inspection protocols for many different models of rebreathers are posted on manufacturers’ websites and on the web site of the Rebreather Education and Safety Association. See <http://www.rebreather.org/links/>.
- Expert advice is always available either directly from the manufacturer or from their local product distributor or approved instructors. Do not be stubborn or afraid to accept assistance when it is offered, but make sure you are getting assistance from the proper parties.
- When writing a report, be honest about what you do not know and explain why.
- When you state an opinion, identify it as such and state the supporting facts.
- If facts are unexplained, state them and state why they are unexplained.
- Do not speculate.

Root Cause Analysis for Scuba Diving Fatalities

Scuba fatality investigations can be conducted using root cause analysis that classifies an incident into a series of four events (Fig. 2; Vann et al., 2007). The first event, the “trigger,” is the earliest identifiable root cause that transformed an unremarkable dive into an emergency. The second event, the “disabling agent” or “harmful action” is an effect of the trigger that leads to the third event, the “disabling injury.” The “disabling injury” either causes death itself or renders an incapacitated diver susceptible to drowning. The final event is the “cause of death” (“COD”) specified by the medical examiner, which might be the same as the disabling injury or drowning secondary to the disabling injury. It is not unusual for one or more of the four events to be unidentifiable.

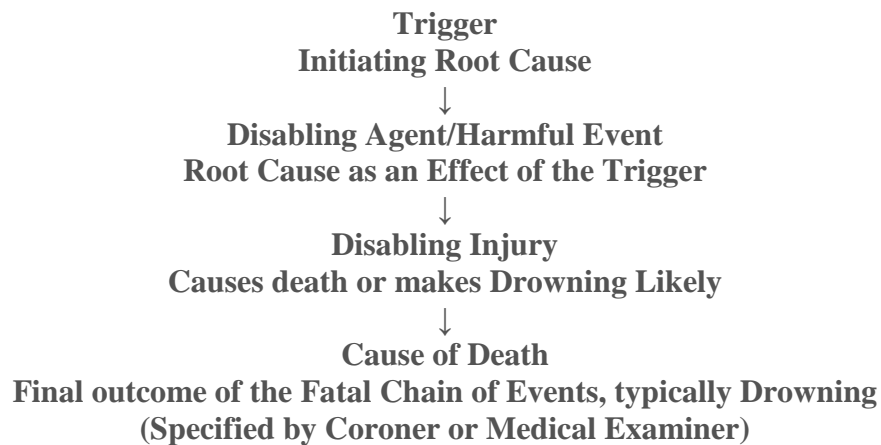


Figure 2: Root cause analysis of diving deaths.

Knowing the COD is interesting but ultimately not helpful in preventing further accidents. Fully 70% of all fatalities are classified as “drowning” as indicated in (Fig. 3; Denoble, et al., 2008). The important question is, “Why do divers drown?” To understand why divers have fatal and non-fatal accidents, investigations must focus on finding the triggers that cause accidents.

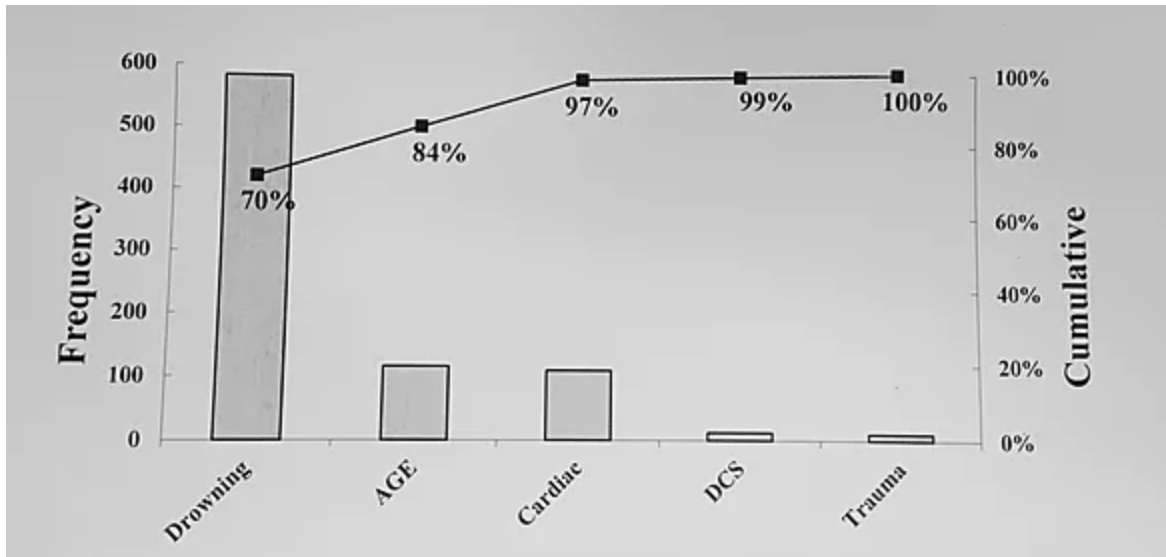


Figure 3: Causes of death in 814 of 947 open-circuit cases (Denoble, et al., 2008)

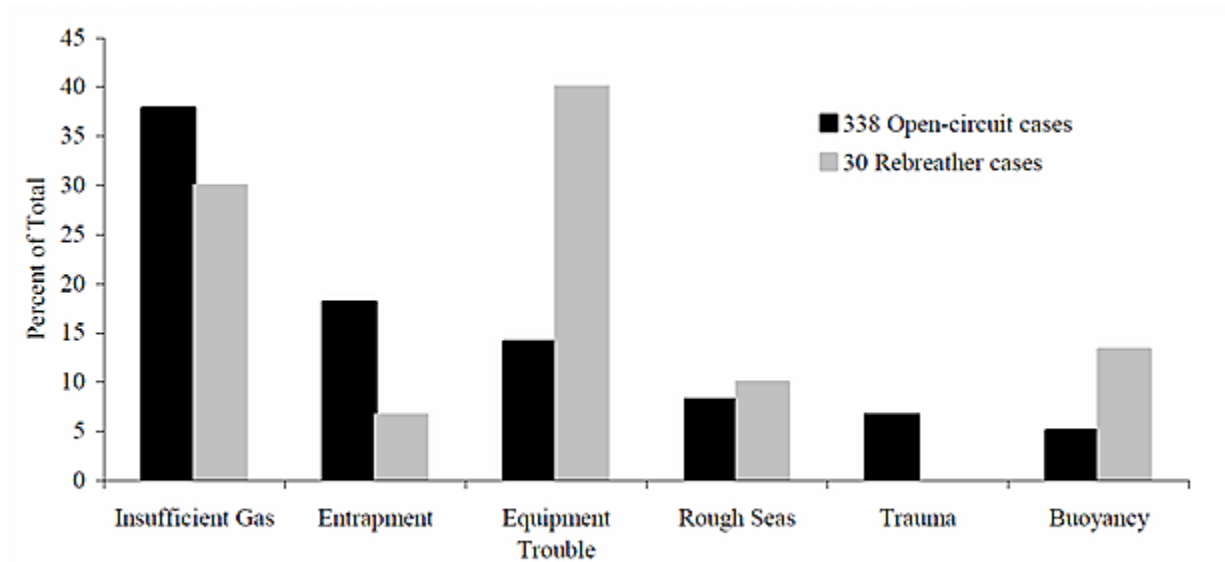


Figure 4: Triggers in open-circuit and rebreather diving fatalities.

Equipment trouble and buoyancy problems appeared more common for rebreathers than for open-circuit breathing apparatus. “Equipment trouble” included both procedural problems and equipment malfunctions that were relatively uncommon. Only three apparent equipment malfunctions were identified: a flooded display, an oxygen supply failure, and an unspecified malfunction at 330 fsw (100 msw) in a cave. There were 11 apparent procedural problems that reflected inappropriate preparation (including maintenance) or equipment operation by the diver: (a) oxygen valve not on; (b) two cases of electronics not on; (c) gases not checked and displays not on (d) oxygen sensor incorrectly installed; (e) oxygen valve partly blocked; (f) loose connections; (g) pre-dive malfunction of oxygen system in which the diver used an emergency semi-closed mode; (h) a gas leak in the breathing loop and bad oxygen sensor; (i) removed rebreather in wreck to bypass an obstruction; (j) a gas supply valve set to an external rather than internal source; and (k) mouthpiece valve sticking but dived anyhow. Buoyancy problems

occurred in seven cases. Four cases appeared rebreather-related involving mouthpiece removal after ascent with failure to close the mouthpiece followed by sinking due to negative buoyancy. Three cases were not rebreather-related and included: (a) tangled in lift bag, pulled to surface followed by fatal decompression sickness ("DCS"); (b) drysuit valve failure, blow-up with fatal AGE; and (c) corroded drysuit valve, blow-up from 300 fsw (91 msw), and fatal DCS.

There were a number of problems in the 2007 study related to investigation problems. Triggers were identified in only 30 of 80 rebreather fatalities, and this shortcoming has not changed at all since 2006. Only 3 of 30 triggers were apparent equipment malfunctions (a 1 in 10 ratio), 11 of 30 were apparent procedural problems reflecting inappropriate preparation (including maintenance) or incorrect equipment operation by the diver. The purpose of the 2007 study was to show that it is possible to identify the main factors associated with diving fatalities, but the authors admitted that their information was too incomplete for useful conclusions (Vann et al., 2007).

Cooperation is Essential for Effective Accident Investigations

One might rightly ask, what is wrong with the investigative authorities? One problem is that there are no centralized investigative authorities for diving; consequently, there is no consistency in investigations because there are no standard protocols covering all rebreathers and few resources for investigators to access. Moreover, and sadly, there is definite resistance to accepting help from the manufacturers when it is offered – particularly within the U.S. Navy and U.S. Coast Guard, whose stubborn resistance stands in stark contrast to the willingness of the NTSB and the U.S. Consumer Product Safety Commission ("CPSC") to cooperate with product manufacturers and engage them at the earliest opportunity. This institutional resistance to engaging with rebreather manufacturers helps nobody.

The success of a quantitative approach to solving the problem of rebreather fatalities relies on the collection of more complete information during the investigative process. This, in turn, requires cooperation of the entire rebreather community – divers, operators, training agencies, instructors and manufacturers – in addition to law enforcement agencies, government agencies and medical examiners. The rebreather community has begun the process of cooperation, with the formation of RESA in 2010, *see* <http://www.rebreather.org/history/>; the organization of Rebreather Forum 3.0 in 2012; more thorough and productive engagement between manufacturers and training agencies; and manufacturers' publication of unit-specific accident/incident investigation protocols online. *See* <http://www.rebreather.org/links/>, <http://www.apdiving.com/downloads/resa/>. DAN has been instrumental in pushing this effort forward.

Unfortunately, cooperation between investigating authorities and the rebreather community remains inconsistent, partly due to institutional ignorance which, given numerous efforts to cooperate with investigators that have been rebuffed, can only be characterized as willful. As the old saying goes, "If you are not part of the solution, you are part of the problem."

Equipment Inspections – Who Should Do Them and How?

Inconsistency in the way equipment investigations are conducted by various agencies is one factor that leads to ineffective accident investigations. However, this problem is easily remedied. Regardless of whom the inspector works for, the following questions must be answered before the inspection takes place:

- How is chain of custody of evidence maintained?
- Who is qualified to conduct the equipment inspection?
- What protocols are used to conduct an equipment inspection?
- Does the investigator know when to ask for help and who to ask for help?
- Will the manufacturer be involved?

The wrong way to conduct an equipment inspection is to use the “I got a guy...” network to find an “expert” to conduct an equipment inspection. Although investigators may be tempted to call on the local dive shop or rebreather instructor for assistance, this generally leads to unsatisfactory results because the local dive shop or instructor may not be familiar with proper equipment inspection protocols. A better practice is to consult with the rebreather manufacturer to determine if the manufacturer can assist with the equipment inspection by providing expert advice, or at least recommend a qualified local instructor or service technician that can conduct a thorough equipment examination without destroying evidence.

The manufacturer knows more about the functioning of the equipment and how to use it than anybody else and should be part of the investigation, at least in advisory capacity. Some investigative authorities are reluctant to involve the rebreather manufacturer in the official investigation due to an unfounded fear that the manufacturer will conceal or destroy evidence if an equipment malfunction is discovered. Indeed, this fear has been encouraged by plaintiffs’ attorneys hoping to represent accident victims’ families and certain “independent” rebreather experts who are actually connected to these attorneys. As stated earlier, only the lawyers benefit from the uncertainty created by a poorly conducted equipment inspection or fatality investigation. Meanwhile, victims’ families, divers, manufacturers and organizations dedicated to improving safety are left frustrated and out in the cold.

Moreover, few investigators realize that rebreather manufacturers are motivated to provide effective assistance to investigations because they have a legal obligation to do so. The U.S. Consumer Product Safety Act, 15 U.S.C. §§ 2051–2084, mandates that product manufacturers have a legal obligation to investigate and report a defect in their product that could create a substantial product hazard, or creates an unreasonable risk of serious injury or death, to the U.S. Consumer Product Safety Commission within 24 hours of receiving notice of an accident (*see* APPENDIX A). Rebreather manufacturers routinely conduct internal investigations of accidents involving their products to fulfill this legal obligation and as part of their product development and safety compliance programs for ISO 9001 and/or CE ratings. When a manufacturer offers to assist an investigator in a rebreather fatality investigation, it is not because they are trying to mislead the investigator. Manufacturers want to help investigators and investigators need the manufacturers’ help!

Finally, equipment inspections should not be conducted in secrecy. All of the stakeholders – including the divers’ families and manufacturers’ representatives -- must be involved. If not, investigators would be well-advised to videotape the inspection, and take numerous high quality photographs of absolutely everything, to ensure that the inspection is conducted properly and anything missed can be caught upon subsequent inspection. To conduct a proper equipment inspection, the process must be transparent to the maximum extent permitted by law.

Compiling and Disseminating the Final Report

Once all of the facts are compiled from the three areas of the investigations - medical, equipment and procedural – they must be presented in a final report. The report should state all facts and opinions leading to the conclusion as to the cause of death, with particular emphasis placed on identifying the trigger(s) of a particular accident. The final report should be disseminated using all available means. The diving community needs to promote a culture where incident reporting and the release of data are the norm, not the exception. Families should be encouraged to release data and autopsy reports to credible organizations (DAN, Rubicon Foundation, RESA, British Sub-Aqua Club and Diving Incident Monitoring Study). Coroners and medical examiners should be encouraged to submit anonymous case studies where privacy laws prohibit the release of personal information. Dive computer data, either alone or with the final report, should be provided to manufacturers and credible research organizations. For safety to improve, proper data needs to be collected during the investigative process and disseminated through reports to the people and organizations most qualified to make use of the data to promote safer rebreather designs, improved training and more thorough research.

One excellent example of the cooperative approach to diving fatality investigations is the San Diego Diver Death Review Committee (“SDDDRC”) (Sadler, 2013). The SDDDRC consists of personnel from the San Diego lifeguards, San Diego Police Department, San Diego County Medical Examiner’s Office, University of California San Diego Hyperbaric Medicine Center, Scripps Institute of Oceanography, San Diego State University Diving Safety, United States Coast Guard, and select members of the local scuba diving community. Per their mission statement, “the purpose of this committee is to review diving-associated deaths and (occasionally) serious injuries in San Diego County and provide related information to agencies and the public for purposes of prevention and education.” The committee has its own protocols for investigating deaths, spanning from a multi-agency dive team for scene investigation, equipment analysis at Scripps Institution of Oceanography, and autopsy by the medical examiner. A meeting of the committee is then called by the medical examiner once all of the information (including equipment analysis, toxicology reports, autopsy findings, etc.) is available. The case is discussed by all and the cause and manner of death is determined after input from the participants. The SDDDRC’s collaborative approach could serve as a model for rebreather fatality investigations.

Suggestions for Improvement

It is essential that more useful information is collected through more thorough data collection methods, and that this information is analyzed to determine the root cause of rebreather fatalities and near fatalities. Useful suggestions for improvement include:

- Stakeholders must increase cooperation with first responders and medical examiners to facilitate effective incident investigation, the collection and preservation of data, and accurate reporting.
- First responders and medical examiners must seek out and/or accept this cooperation when offered.
- Manufacturers involved in the investigative process.
- More protocols for effective accident investigations must be developed and distributed widely, with easy public access.
- Those involved in accidents and accident investigations must be educated about the need to collect facts and preserve evidence, including dive computer data and other relevant information, immediately upon the occurrence of an accident.
- Eliminate the “I got a guy...” network for finding “experts” to conduct rebreather accident investigations. Use only manufacturers’ representatives or factory-trained service technicians.
- Certifications should be offered for rebreather investigations.
- After collection, data must be disseminated to interested parties (DAN, researchers, equipment manufacturers, training agencies, families and the public) so problems can be identified and addressed more effectively.

The rebreather diving community and investigative authorities cannot wait several more years to begin this process. It has to start today!

References

Denoble PJ, et al. Common causes of open-circuit recreational diving fatalities. *Undersea Hyperbaric Med.*, 2008; 35(6):393-406.

Fock, A. Analysis of Recreational Closed-Circuit Rebreather Deaths 1998-2010. In: Vann RD, Denoble PJ, Pollock NW, eds. [Rebreather Forum 3 Proceedings](#). AAUS/DAN/PADI: Durham, NC; 2014; 324 pp.

Sadler, CA, et al. Dilemma of Natural Death While Scuba Diving. *Academic Forensic Pathology*, 2013; 3(2):202-212.

Vann RD, Pollock NW, Denoble PJ. Rebreather Fatality Investigation. In: Pollock NW, Godfrey JM, eds. *Diving for Science 2007*. Proceeding of the American Academy of Underwater Sciences 25th Symposium. Dauphin Island, AL: AAUS; 2007.

APPENDIX A

16 CFR § 1115.12 - Information which should be reported; evaluating substantial product hazard.

(a) General. Subject firms should not delay reporting in order to determine to a certainty the existence of a reportable noncompliance, defect or unreasonable risk. The obligation to report arises upon receipt of information from which one could reasonably conclude the existence of a reportable noncompliance, defect which could create a substantial product hazard, or

unreasonable risk of serious injury or death. Thus, an obligation to report may arise when a subject firm received the first information regarding a potential hazard, noncompliance or risk. . .

(c) Unreasonable risk of serious injury or death. A subject firm must report when it obtains information indicating that a consumer product which it has distributed in commerce creates an unreasonable risk of serious injury or death.

16 CFR § 1115.14 – Time computations.

(e) Time to report. Immediately, that is, within 24 hours, after a subject firm has obtained information which reasonably supports the conclusion that its consumer product fails to comply with an applicable consumer product safety rule or voluntary consumer product safety standard, contains a defect which could create a substantial risk of injury to the public, or creates an unreasonable risk of serious injury or death, the firm should report. . . . If a firm elects to conduct an investigation in order to evaluate the existence of reportable information, the 24-hour period begins when the firm has information which reasonably supports the conclusion that its consumer product fails to comply with an applicable consumer product safety rule or voluntary consumer product safety standard upon which the Commission has relied under section 9, contains a defect which could create a substantial product hazard, or creates an unreasonable risk of serious injury or death. Thus, a firm could report to the Commission before the conclusion of a reasonably expeditious investigation and evaluation if the reportable information becomes known during the course of the investigation. In lieu of the investigation, the firm may report the information immediately.