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Documents Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Dear Sir or Madam:

Allied Healthcare Products, Inc. would like to commend FDA for proposing to reclassify pressure regulators for use with medical oxygen from Class I to Class II and to establish a special control for oxygen pressure regulators as announced in the Federal Register/Vol. 68, No. 101/Tuesday, May 27, 2003. As this announcement states, this proposal has been made to address problems of fire and explosion associated with the use of oxygen pressure regulators. Allied agrees that reclassifying oxygen pressure regulators and instituting a special control is a good first step. However, as discussed below, to achieve the desired results, a special control must address the cause, not just the symptoms of the problems of fire and explosion associated with the use oxygen pressure regulators. Therefore, Allied is providing these comments to suggest parameters for a guidance that FDA will be preparing as part of this reclassification.

Regulators are not standalone equipment. They are used only as a component of a portable oxygen delivery system. The two other parts of the oxygen delivery system are the storage cylinder and the post valve that holds the oxygen in the cylinder until the regulator is attached. All three items (regulator, valve and cylinder) must be considered when addressing the safety and efficacy of portable oxygen delivery. The FDA is taking an approach that addresses only the regulator portion of the portable oxygen delivery system. While changing the classification of regulators from Class I to Class II and requiring those regulators to pass the PS-127 test is expected to improve the safety of regulators, this will *not* ensure safe portable oxygen delivery. To do so, additional requirements should be made part of the special controls.

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The reasons for this are twofold and will be discussed in greater detail below:

1. Passing the PS-127 test does not guarantee that the regulator will not "burn through" in the field.
2. Changing the classification of the regulators does not eliminate the root cause of fires; the special controls developed as part of the reclassification must also address these causes.

## PASSING PS-127 DOES NOT GUARANTEE THAT REGULATORS WILL NOT BURN

A test that is designed to confirm the fire tolerance of regulators should include a safety factor to expose those regulators to ignition-energy conditions that are at least as, and ideally more, severe than one might encounter in the field during actual conditions of use. However, this is not the case with the PS-127 test. Mr. Barry Newton, considered by many to be the foremost expert regarding fires in oxygen delivery systems, when describing the PS-127 test states, "The ignition energy of [the PS-127 test] probably deliver[s] ... 330, [or] 350 calories..."[1] Comparing the ignition energy (measured in calories) in the PS-127 test to the ignition energy in a standard post valve, Mr. Newton states that "...there's probably 550 calories in the Erie valve."[2] Thus, the PS-127 test exposes regulators to conditions 40% LESS severe than conditions that might occur in the field. This was done for a practical reason. Discussions with individuals close to the developers of the PS-127 test reveal that when tested under field conditions, few, if any, brass regulators were able to pass the test. This led the developers to reduce the severity of the test to a level that allowed some regulators to pass the test.

Because the PS-127 test exposes regulators to less severe conditions than are likely in the field, over the course of time fires are likely to occur — even in regulators that have passed the PS-127 test. To address properly the problems of fire and explosion associated with the use of oxygen pressure regulators, the FDA must address the root cause of the problem: the post valve.

## SPECIAL CONTROLS MUST ADDRESS ROOT CAUSES OF FIRES

According to Mr. Newton, the PS-127 test "was designed to be consistent with circumstances during and after ignition of the [post valve] seat."[3] In other words, the purpose of the test is to determine how regulators withstand fires that *start* in the post valve. This test *assumes* that post valve seats will not only fail, but will fail in a manner that causes the post valve materials to burn with sufficient intensity to ignite a regulator. The very existence of this test indicates that the root cause is upstream from the regulator. Instead of taking the *preventive action* of attacking problems of fire and explosions at the source, the focus has been on a *corrective action* of modifying regulators to withstand these post valve faults.

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[1] Barry Newton, BSME, PE sworn statement recorded in December 4, 2002 deposition, p. 117, lines 22 and following.
[2] Barry Newton, BSME, PE sworn statement recorded in December 4, 2002 deposition, p. 117, line 24.
[3] Barry Newton, BSME, PE sworn statement recorded in April 1, 2003 deposition, p. 213, line 4 and following.

The general approach for modifying regulators to minimize the effect of post valve failures is to make the regulators from brass. However, information in the field (See, *e.g.*, attached testimonial from the Chicago Fire Department) and MDR's filed with FDA demonstrate[4] that making regulators out of brass is not sufficient to preclude catastrophic injury and death.

**RECOMMENDATIONS**

There are two problems that post valve designs must overcome to minimize fires and explosions that ignite downstream regulators: 1) reduce the heat of compression and 2) prevent particulate matter from entering the gas stream. One approach to these problems is outlined in the white paper "The Solution to Safe Handling of Oxygen Systems" (see attached copy). In the white paper, you will find a description of a post valve design that first reduces to safe levels the heat of compression through the use of a pressure bleeding mechanism and secondly employs a straight forward filter to prevent particulate matter from entering the gas stream.

The underlying problem with regulator fires and explosions begins with the post valve. Therefore, the FDA, as part of the reclassification should not stop at changing regulators from Class I to Class II devices, but should ensure that special controls address the oxygen regulator and the post valve as parts of an oxygen delivery system to ensure the root causes of fires and explosions are addressed. We have provided in these comments one method of doing so.

Respectfully,

Eldon P. Rosentrater

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VP Administration/Corporate Planning

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[4] See MDR 182551, MDR 1526809 among others.