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November 25, 2003

RSPA-04-16866-1

HAZARDOUS MATERIALS
REGULATIONS
DOT/RS&M
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Mr. Del Billings
Director, Office of Exemptions
and Approvals (DHM-30)
Research and Special Programs
Administration
Department of Transportation
Washington, D.C. 20590-0001

Re: Application for New Exemption

Dear Mr. Billings:

On behalf of Stand-By Systems, Inc. ("Stand-By") of Dallas, Texas, and pursuant to the provisions of 49 CFR 107.105, this is to request an exemption from the provisions of the Hazardous Materials Regulations ("HMR", 49 CFR Parts 171-180). The requested exemption would authorize articles containing an oxidizer formulation used to produce medical (USP) oxygen for use by patients and other individuals for first aid in the event of cardiac emergencies to be described as "sodium chlorate" (UN 1495), Division 5.1, Packing Group II, and transported by motor vehicle, rail freight and cargo vessel under the regulations applicable to that description (including as "limited quantities" and ORM-D "Consumer Commodities"). The information below is submitted in accordance with § 107.105 of the HMR.

- Regulations From Which Relief Sought.** 49 CFR § 171.8 definition of "Oxygen generator (chemical)", and § 172.101 in that an article technically meeting that definition and containing a mixture of sodium chlorate and relatively small amounts of other oxidizing materials, would be allowed to be described as "Sodium chlorate" (UN 1495), Division 5.1, Packing Group II, and



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transported by motor vehicle, rail car and cargo vessel in accordance with the provisions applicable to that description (including as "limited quantities" and ORM-D "Consumer Commodities").

2. **Applicant.** HMT Associates, L.L.C., on behalf of Stand-By Systems, Inc., 9107 Devonshire, Dallas, Texas 75209 (contact: Mr. James R. Helbig, telephone: (972) 529-4343). Please address any questions concerning this application to the undersigned at the address and telephone number indicated in the letter head.

3. **Description of Proposal.** The applicant requests that an exemption be issued to permit the transport of an article containing sodium chlorate and relatively small amounts of other oxidizing materials to be described as "Sodium chlorate" (UN 1495), Division 5.1, Packing Group II, and transported by motor vehicle, rail car or vessel in accordance with the provisions applicable to that description (including as "limited quantities" and ORM-D "Consumer Commodities"). To provide for an equivalent level of safety in transport, the applicant proposes that the conditions and limitations outlined below be incorporated into the requested exemption.

Packaging Prescribed. It is proposed that the requested exemption prescribe use of the packaging meeting the following requirements:

- (1) Not more than 0.5 kg of authorized hazardous materials must be contained in a sealed, cylindrical, welded stainless steel container, with a nickel capsule "thimble assembly" imbedded in the top surface, and with the top of the unit containing this assembly further protected by a stainless steel seal fitted with a ring pull tab for removal of the seal;
- (2) Each such stainless steel container must be placed to fit snugly and securely within a form-fitting polystyrene packaging insert, with not less than 7/16 inch of polystyrene separating each article;
- (3) The polystyrene packaging insert must be placed to fit snugly and securely within a strong fiberboard outer packaging with not less than 7/16 inch of polystyrene separating any stainless steel article from any internal surface of the fiberboard outer packaging; and
- (4) Not more than 6 stainless steel articles may be contained in any package.

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Special Provisions. It is proposed that the following Special Provisions be incorporated into the requested exemption:

- 1) Each package would be required to be marked with the exemption number in accordance with § 172.301(c), and on two opposing sides with the words "NOT AUTHORIZED FOR TRANSPORTATION BY AIRCRAFT".
- 2) A person who is not a holder of the exemption who receives a package covered by the exemption would be permitted to reoffer it for transportation provided no modifications or changes are made to the package and it is reoffered for transportation in conformance with the exemption and the HMR.
- 3) A current copy of the exemption would be required to be maintained at each facility from which packages covered by the exemption are offered or reoffered for transportation.
4. **Hazardous Material to be Transported.** It is requested that the exemption permit authorized hazardous materials to be transported under the following description:

Hazardous materials description -- proper shipping name	Hazard Class/ Division	Identi- fication number	Packing Group
Sodium chlorate	5.1	UN 1495	II

The hazardous material contained within the article for which exemption is requested consists primarily of sodium chlorate, but also contains small amounts of other materials. In addition to the 390-gram solid (cast) body that is approximately 94.5 percent, by mass, sodium chlorate, a small, 28-gram activation cone is present which contains approximately 25 g of other Packing Group II oxidizers (e.g., sodium monoxide, sodium iodate) and approximately 3 g of certain perchlorates. Finally, the article contains a 28 g, thin layer of sodium peroxide that serves as a filtering medium for the oxygen produced. Thus, the hazardous material as a whole consists of not less than 85.5 percent, by mass, of sodium chlorate. Therefore, in terms of its intrinsic properties as an oxidizer, the formulation exhibits properties consistent with those of sodium chlorate, and it is requested

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herein that the exemption permit the article containing the formulation to be described and transported as "sodium chlorate" (UN 1495).

5. **Transport Modes.** Authorization is sought for transportation by motor vehicle, rail freight and cargo vessel. No modal-specific safety control measures are considered necessary.

6. **Duration of Exemption.** It is requested that this exemption be issued for a renewable, two year period.

7. **Justification for Exemption and Level of Safety.** For the reasons offered below, the applicant submits that the exemption requested herein is justified in that the provisions proposed above will achieve a level of safety in the transport of the hazardous material concerned that is equivalent to that afforded by the regulations from which exemption is sought.

Background information. To assist RSPA in the evaluation of this application for exemption, background information is provided below on the article to be transported under the requested exemption. Also provided is an explanation of the reasons for requesting the exemption and why it is considered to be in the public interest to grant the requested exemption. Finally, shipping and incident experience related to this application is provided.

Hazardous material and its use. The product for which exemption is requested is a two-part system that produces emergency USP medical oxygen, and which is named "LIFEDGE". The system consists of a thermos-sized dispensing unit with initiator mechanism, and a second, separately shipped chemical unit without initiator mechanism. The chemical unit - the article addressed by this exemption application - is a welded stainless-steel cylindrical article containing less than 0.5 kg (one pound) of dry oxidizer chemicals and a sealed nickel capsule (thimble assembly) embedded in its top surface containing 0.12 milliliter of a non-hazardous aqueous solution. Once a protective stainless-steel "pull top" seal is manually removed from the top of the article and the article is properly inserted into the dispenser unit, the dispenser's top may be opened and the actuator button inside may be manually depressed, causing a needle-like ram to penetrate two additional metal seals: first, the top of the chemical unit itself and second, the top of the embedded thimble assembly, contacting a plunger pin within the thimble assembly and causing it in turn to penetrate the bottom of the thimble assembly, thereby initiating the reaction which produces a

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nominal, non-dangerous amount of heat (180°C (356°F) maximum temperature as measured on the wall of the chemical unit) and USP oxygen at the rate of 6 liters/minute for 15 minutes.

Reasons for exemption. Because the article for which exemption is requested releases oxygen when activated by means of a chemical reaction, it meets the definition in § 171.8 of the HMR for an "oxygen generator (chemical)". However, for reasons that will be outlined in detail in this application, Stand-By believes that the risks posed in transportation by the article for which exemption is sought are not commensurate with those posed by the typical oxygen generator (for example, as used for emergency oxygen aboard aircraft) around which the current requirements of the HMR for the transport of oxygen generators have been developed. For example, apart from employing a substantially different technology, the article is not shipped with means of initiation attached, but nevertheless incorporates multiple positive features to prevent inadvertent or auto-actuation. Moreover, even after proper activation in the separately shipped dispenser unit, the temperatures achieved during operation are significantly lower (and, therefore, significantly less dangerous), during operation than are the temperatures experienced with the typical aircraft chemical oxygen generator.

Consequently, Stand-By submits that the requirements of the HMR governing the transport of standard chemical oxygen generators (such as are employed for passenger or crew emergency oxygen on aircraft) are unnecessarily burdensome for the article for which exemption is requested. These unnecessarily burdensome requirements render it impossible to transport the article in question under various regulatory exceptions in the HMR (e.g., "limited quantities" and "consumer commodities" exceptions) which would facilitate its transportation and make possible its wide distribution and use by medical professionals as well as the general public. For reasons that will be outlined below, this is not considered to be in the public interest. Accordingly, this application requests exemption from the requirement to transport this article under the provisions applicable to chemical oxygen generators, and to allow transport of the article in the manner that would be prescribed by the HMR for a steel inner packaging containing sodium chlorate - the principle hazardous materials component present in the formulation. In this regard, it is emphasized that exemption is requested only for transport by surface modes - no exemption authorizing transport by aircraft is requested herein.

Public interest considerations. The product addressed by this exemption application will provide an obvious, immediate and likely far-reaching benefit to the general public for medical

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emergencies once it becomes available. While this alone does not justify grant of the requested exemption, it nevertheless is a compelling reason to give expeditious consideration to this application.

In the year 2000 the annual cost for the treatment and rehabilitation of heart-attack and stroke was \$181.1 billion. Over 1.8 million people suffered from a heart attack or stroke, and 964,000 died. It is, and has always been^{1/} the number one cause of death in the United States. This cost associated with heart attack and strokes is more than the total costs of the next five causes of death combined. Despite this staggering economic impact, the rate of these traumatic events is decreasing even though the total number is increasing. It is still of small comfort that both the treatment and preventative regimens are conclusively making progress.

The first treatment-of-choice in each of these traumatic episodes is the administration of emergency oxygen. The deficiency of tissue oxygen causes brain damage to begin in about four minutes after a stroke, and causes heart muscle damage in eight minutes following a heart attack. These are permanent damages. Neither of these organs is regenerative. It is significant to note that among cardiovascular dysfunctional episodes, nearly 250,000 are classified as sudden-cardiac-arrest, for which no specific cause has yet to be identified. It is thought that a majority of these deaths were caused by ventricular fibrillation, although only 7% have been documented. About 80 percent of these happen at home and nearly 60 percent are witnessed.

It is at this point the enigmatic characteristic of the tragedy is profiled. Oxygen is universally applicable and profoundly integral to effective pre-hospital treatment. However, it has been classified as a drug, and therefore available only by prescription. That which is desperately needed has been regulated out of reach. However, the recent FDA approval for the LIFEDGE system for use as over-the-counter emergency oxygen makes available the most credible resource needed by the first-responders - those relatives, friends or bystanders - who are confronted with the traumatic episode and the opportunity to act on behalf of the stricken. The LIFEDGE System satisfies all of the fundamental traumatic episode response requirements: safety, effectiveness, simplicity, dependability, and economy. However, lacking wide-spread *availability* the full potential of this system in terms of preserving life and minimizing the long term effects of heart attack and stroke cannot be realized. It is for this reason that grant of the requested exemption, which would have the

^{1/} Except in 1918.

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effect of simplifying and facilitating the transportation and distribution of this product, is clearly in the public interest.

Prior shipping and incident experience. The LIFEDGE product has successfully undergone extensive independent physical and environmental testing and evaluation by the Food and Drug Administration (FDA) as the product successfully progressed through that agency's 510(K) submission process. This process subsequently led to the FDA granting Stand-By Systems permission to market the product over-the-counter (without a prescription) in 1994.

Perhaps more importantly, however, in relation to this request for exemption is the fact that an early version of the LIFEDGE product (functionally and operationally nearly identical to the current product) was produced for Stand-By Systems and approved by the Federal Aviation Administration (FAA) for use aboard commercial aircraft for crew and passenger distress in the early 1970s. This approval was granted only after extensive testing and evaluation under agency direction. Tens of thousands of units were manufactured, deployed and used. Of the units produced then (some of which were unused and remain intact and operational today some 30 years later), none has ever been actuated by any means other than via the dispenser actuator button described above, nor have any ever failed to operate properly when actuated.

Level of safety achieved. For the reasons offered below, the applicant believes that the requested exemption will afford the necessary level of safety in the transport of the hazardous materials concerned. Also provided below is information regarding the ways in which the article for which exemption is requested differs from the typical oxygen generator (such as is used for aircraft emergency oxygen) around which the existing HMR requirements were structured - particularly with regard to the risks posed in transport - and why, therefore, compliance with the stringent HMR requirements applicable to chemical oxygen generators is not considered necessary from the point of view of safety in transport.

Method of operation and heat produced. The standard chemical oxygen generator (such as is used for aircraft emergency oxygen) operates by combustion of iron filings in an oxygen-rich environment of sodium chlorate, the intense heat from which causes thermal decomposition of excess sodium chlorate in the presence of manganese dioxide and releases partially contaminated gaseous oxygen. The article for which exemption is requested, on the other hand, operates by a water-initiated exothermic catalytic reaction of sodium chlorate and a mixture of similar, proprietary

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oxidizer chemicals, producing USP pure, slightly moisturized gaseous oxygen and a relatively small amount of heat. Thus, the fundamental technology employed differs significantly from that employed in the standard chemical oxygen generator.

The typical chemical oxygen generator (such as is used for aircraft emergency oxygen) produces temperatures that reach 260°C (500°F) and higher - enough to cause ignition of common combustible materials as well as possible auto-actuation of similar devices in the same package. On the other hand, the article for which exemption is requested produces a maximum temperature of 180°C (356°F) as measured on the wall of the article - about the temperature of a 150-watt incandescent light bulb, and well below the carbonization/ignition temperatures of common combustible materials such as paper, wood, cloth and plastic.^{2/}

Risk of initiation in transport. Unlike the typical chemical oxygen generator (such as is used for aircraft emergency oxygen), the article for which exemption is requested is not transported with its normal means of initiation installed. Accordingly, inadvertent initiation in transport by the *normal* means by which the article is designed to be initiated is impossible. This being the case - and assuming it is demonstrated that unintentional initiation by means *other than* the normal means is virtually impossible - the hazard posed by the article in transport no different from the intrinsic oxidizer hazard posed by sodium chlorate in a metal inner packaging. It is for this reason that this application seeks authorization to transport the articles concerned in accordance with the provisions of the HMR applicable to that material (including as "limited quantities" and ORM-D "Consumer Commodities").

^{2/} The applicant also notes that this temperature is significantly below the 240°C (464°F) temperature above which a material in a solid phase is regulated in transportation by the HMR (see definition for "*Elevated temperature material*" in § 171.8 of the HMR). In the preamble to the Docket No. HM-189A notice of proposed rulemaking under which this definition was adopted (see *Federal Register* of September 21, 1989 [54 FR 38931], RSPA stated that the 464°F (240°C) temperature had been selected as the baseline for this definition because it "is slightly above the minimum ignition temperature for paper and many hydrocarbons." RSPA went on to state "[h]ot solid materials transported below 464°F (240°C) do not pose a threat of igniting combustible materials and pose a very limited thermal hazard..." (emphasis added). Consequently, the applicant submits that the significantly lower 356°F (180°C) temperature achieved at the surface of the article for which exemption is requested does not pose a thermal hazard in transportation and will not ignite common combustible materials (such as fiberboard).

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With regard to inadvertent initiation by other than the normal means of initiation, Stand-By has examined a number of possible scenarios and found that none are likely to result in an inadvertent initiation in transport. These are as follows:

- 1) Inadvertent depression of plunger to penetrate thimble assembly. The only free-moving mass within a Stand-By Systems LIFEDGE chemical unit conceivably capable of causing unit actuation is the plunger pin within the thimble assembly that penetrates the bottom of the assembly (in normal operation upon impact from the ram when the dispenser actuator button is depressed approximately 5/8 inch). Since the chemical unit will never be in the dispenser unit during transport, this plunger pin could only penetrate the solid nickel bottom of the assembly under its own impulse. The plunger pin has a weight of 0.00139 lb. Calculation of the impulse (change in momentum with respect to time) necessary to exert the necessary nominal point force of 3 lb. on the plunger pin to auto-actuate a chemical unit has been determined by analysis to be equivalent to that encountered as a result of a virtually instantaneous deceleration of the pin from a velocity of approximately 6900 ft/s (4700 mph). Such a rate of deceleration is not expected to be encountered in surface transportation, even under severe accident conditions.

- 2) Inadvertent release of aqueous solution from thimble assembly. The thimble assembly holding the aqueous initiation fluid is robustly constructed of the metal nickel that is inert both to the aqueous initiation fluid and the unit's contents, and is sealed through a welding process. Integrity of these thimble assemblies is verified by 100 percent X-ray inspection in the manufacturing process. Thus a corrosion-resistant sealed metal barrier would have to be compromised for the initiation fluid to activate the chemical unit. However, even if the 0.12 milliliter of initiation fluid were somehow to leak from the thimble assembly weld, which is at the top of the thimble assembly, it would have to traverse through approximately 0.5 in. of highly absorbent inert filter material as well as a filtering layer of sodium peroxide in order to reach the activation cone. Accordingly, the possibility of any fluid reaching the reactive chemicals below is nil. Thus, leakage of the aqueous solution past the thimble assembly's nickel wall through the filter materials into the unit's chemical contents, whether due to corrosion or faulty manufacturing, is simply not considered a plausible mode of actuation.

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With regard to thermal stability, the self-accelerating decomposition temperature of the hazardous material within the article is well above the 50°C (122°F) temperature criterion in § 173.21 of the HMR below which temperature control would be required in transport, and significantly above the 75°C (167°F) SADT temperature below which a material may be considered a candidate for classification as a Division 4.1 self-reactive substance.

In summary, based on these analyses, the applicant submits that inadvertent initiation under conditions normally incident to transport of the article for which exemption is requested by means *other than* the normal means is virtually impossible. Moreover, initiation in transport by the *normal* means is impossible since the chemical unit will not be transported installed in the dispensing unit - which contains the initiating mechanism.

Proposed packaging. The packaging proposed is designed to ensure maximum safety in the transport of the articles for which exemption is requested. The polystyrene packaging insert into which the articles would be placed is designed not only to secure and cushion the articles, but also to insulate the articles from external sources of heat, and from each other. When transported under the "limited quantities" provisions or as an OMR-D "consumer commodity", the outer packaging would be a non-UN standard "strong outer packaging", as permitted by the limited quantities exceptions applicable to the proper shipping name "sodium chlorate" (UN 1495).

Special provisions. Since the exemption requested would not allow transport by aircraft, it is proposed that each package be marked on two opposing sides with the words "NOT AUTHORIZED FOR TRANSPORTATION BY AIRCRAFT" as well as with the exemption number. This warning is intended to ensure that the package is not inadvertently loaded aboard an aircraft, in contravention to the terms of the requested exemption.

8. **Certification of Compliance With Security Requirements.** The certification of compliance with applicable security requirements required by § 107.105(c)(10) of the HMR is enclosed.

9. **Conclusion.** In conclusion, for the reasons outlined above the applicant submits that the conditions and limitations proposed in this application for exemption will achieve the necessary level of safety in transport of the hazardous materials concerned. Accordingly, the applicant respectfully requests that the exemption sought be issued at the earliest possible time.

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Please contact the undersigned directly if you have questions concerning this request, or if you require any additional information in order to process this application.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. A. Altemos', with a long horizontal flourish extending to the right.

E. A. Altemos

Enclosure

Certification of Compliance With Security Requirements

As required by § 107.105(c)(10), this is to certify that the applicant is in compliance with all Federal hazardous materials transportation training and security plan requirements as applicable to Stand-By Systems, Inc., on the date on which this application is filed.

Signed:

A handwritten signature in black ink, appearing to read "Kenneth J. Palmer", with a long, sweeping horizontal flourish extending to the right.

Kenneth J. Palmer
President, Stand-By Systems, Inc.