

LETTERS TO THE EDITOR

Dear Editor:

We read, with great interest, the President's message by James P. Dearing which appeared in Volume 14, Number 3, 1982. We strongly support one of the very important points that Mr. Dearing made: the need for AmSECT to cooperate with other voluntary agencies such as AAMI and ECRI in the development of product standards and the investigation and promulgation of information related to hazardous medical devices used in the practice of perfusion.

When our organization, ECRI, recently undertook an investigation of problems associated with blood filters, we were struck by the relatively insular attitude of a few perfusionists. (Fortunately, however, many AmSECT members responded to our requests for information and provided valuable information and perspectives. This included AmSECT board members, board representatives, committee chairpersons, and editorial staff.) We can understand why some perfusionists might not know of our existence, despite the fact that we are the largest bioengineering institute in North America or that we publish some 14 periodicals, ranging from monthly journals to weekly alerting systems related to defective products, or that our present medical device hazard reporting network was in operation years before the FDA established a Bureau of Medical Devices or its FDA-USP reporting system.

What baffled us, however, was the sometimes encountered attitude that because perfusionists and cardiovascular surgeons use blood filters, they are the only professionals able to appraise their safety and performance. Anything we might do was, by definition, invalid—even before the facts were known. Our full-time staff of 80 includes biomedical engineers, physicists, and physicians. We have investigated hundreds of hazardous medical devices and related accidents associated with injury or death, including detailed examinations of perfusion systems.

Our analytical capabilities are reinforced by our anti-conflict-of-interest guidelines. We accept no support from medical device manufacturers or

distributors, do no consulting work for them, nor do we permit our staff to own stock in such enterprises. Each employee's income tax reports are examined by our auditor each year. In short, we are not subject to commercial influences and our position in this regard has been universally recognized for over a decade.

ECRI analytical methods, survey and interview techniques, and institutional philosophy and policies can withstand any degree of scrutiny—far more than organizations which are supported directly or indirectly by commercial interests. AmSECT members need to understand that there are other competent groups with which they should cooperate in pursuit of the common goal of improved patient care.

AmSECT members are welcome to write to us for information or visit our laboratories.

Cordially yours,
Joel J. Nobel, M.D.
President
ECRI

Dear Editor:

In their discussion of "Toxicity and management of waste and anesthetic gases using the Sci-Med oxygenator," the authors (Springer, Murray, and Romo) raised valid concerns about the need for scavenging waste anesthetic gases. However, there are several significant misconceptions that should be brought to the attention of your readers.

First, the Occupational Safety and Health Administration (OSHA) has not established a federal standard limiting employee exposure to waste anesthetic gases in the workplace. Therefore, at the present time, there are no mandatory exposure limits with which anesthetizing locations must comply.

The National Institute for Occupational Safety and Health (NIOSH)* has developed the docu-

* NIOSH is a government research agency under DHHS, which should not be confused with OSHA, a regulatory agency under the Department of Labor.

ment Criteria for a Recommended Standard for Occupational Exposure to Waste Anesthetic Gases and Vapors,¹ in which NIOSH recommends ceiling exposure limits to anesthetic gases. The NIOSH *recommends* that exposure to nitrous oxide be controlled so that no worker is exposed to a time-weighted average (TWA) concentration greater than 25 ppm during the period of anesthetic gas administration. They further recommend that halogenated anesthetic agents be controlled so that exposure does not exceed 2 ppm (TWA) during the period of administration. The NIOSH-recommended exposure criteria are intended to apply to all locations where inhalation anesthetics are administered.

Current scientific evidence in epidemiological studies demonstrates that chronic exposure to anesthetic gases increases the risk of adverse effects on the health of exposed personnel.² Adverse effects indicated by these studies include an increase in spontaneous miscarriage, congenital abnormalities, liver disease, and other physiologic disorders.^{3,4} Human experiments have demonstrated impaired performance, cognition, and the loss of dexterity following exposure to nitrous oxide.⁵ Halogenated inhalation anesthetics, once considered to be nonreactive, now appear to be metabolized to some extent by the body.⁶

In addition, OSHA has not set guidelines for acceptable levels of anesthetic gases in the operating room or for the use of scavenging systems connected to a vacuum source which vents waste anesthetic gases to the atmosphere. There is, however, no doubt that in the absence of additional information, the NIOSH guidelines seem to be reasonable target limits to pursue. OSHA has not been able to legally enforce limits for anesthetic gases in the operating room. ECRI, the American Hospital Association, and other voluntary sector organizations have strongly protested OSHA's ability to enforce recommended limits they had not adopted as law. However, ECRI strongly believes that all corrective and preventive measures, consistent with patient safety, should be taken to keep exposure levels to a minimum. The authors correctly point out that the Joint

Commission on Accreditation for Hospitals (JCAH) recommends the use of scavenging systems in anesthetizing locations.

The method the authors described for scavenging waste anesthetic gases is typical of many "home-made" systems we review during our surveys of waste anesthetic gas exposure levels in hospitals. Data on how these systems should be operated are lacking. The system described by the author lacks adequate safety information to prevent excessive pressures (positive or negative) from being applied to the oxygenator, resulting in patient hazards.^{7,8,9} The surge volume provided by the coaxial Bain circuit is greater than that of the Y piece recommended by the manufacturer, but no data are given to show what is actually needed. It is easier to accidentally occlude a long scavenging tube by kinking or by compression by other equipment and, thus, it should be carefully attached to the oxygenator frame (not lying on the floor) in such a way as to prevent occlusion.

No data are given of characteristic outlet pressures of the oxygenator during normal and abnormal operations. These pressures are dependent on the gas flow rate being used through the oxygenator and the suction system. Suction gas flow must be greater than oxygenator gas flow for proper scavenging, but application of full line vacuum to the unit may result in excessive suction flow and excessive subambient pressure in the oxygenator.

We suggest that those wishing to properly scavenge oxygenators or other elements of the anesthesia system review the requirements of the recent American National Standard ANSI Z79.11 (1982) Anesthesia Gas Pollution Control (June 1981 draft).¹⁰

Sincerely,
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References

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