

## Joint Committee Issue Document

*NOTE: An issue document may be submitted at any time – it comprises two parts: the cover sheet (this page) and a description of the issue to be submitted to the Joint Committee (following page). A separate issue form is required for each issue submitted. Issue papers include proposals for modification of a standard, information reports and (of current research, etc.). An issue paper shall be categorized as being for ACTION or for INFORMATION. Submitters should limit the Issue Paper to 1 or 2 pages – attachments detailing full recommendations or background information may be attached with supplementary information. The Chairperson of the appropriate Joint Committee will respond within 30 days of receipt of the issue document advising what steps will be taken. Any issue document intended for discussion at a Joint Committee meeting must be received at least 21 days prior to the meeting to ensure inclusion in the agenda.*

Submit to:

NSF International  
Attn: Standards Department  
789 Dixboro Rd.  
Ann Arbor, Michigan 48105

Fax: 734-827-6831  
e-mail: [standards@nsf.org](mailto:standards@nsf.org)

Submitter's contact information:

Name: Carlton J. (Jeff) Kempter

Company: EPA, Office of Pesticide Programs, Antimicrobials Division

Mailing Address: EPA, OPP, AD (7510P), 1200 Pennsylvania Ave., NW  
City: Washington State: D.C. Zip Code: 20460

Telephone Number: 703-305-5448 E-mail: kempter.carlton@epa.gov

***I hereby grant NSF International the non-exclusive, royalty free rights, including non-exclusive, royalty free rights in copyright; in this item and I understand that I acquire no rights in any publication of NSF International in which this item in this or another similar or analogous form is used.***

Signature of Submitter \* Carlton J. (Jeff) Kempter Date: 6-25-09

*\*Type written name will suffice as signature*

**Please indicate if you wish the item to be considered as an action item or as an information item.**

Action: X

Information:

**NSF Standard(s) Impacted:**

■ NSF/ANSI Standard 49, Annex G, section G.7.3

**Issue Statement:**

*Provide a concise statement of the issue, which reference as appropriate any specific section(s) of the standard(s) that are related to the issue.*

The cited NSF-ANSI standard states that either paraformaldehyde or chlorine dioxide gas may be used to decontaminate Biological Safety Cabinets (BSC). However, this statement does not take into account that fumigation of BSCs with these chemicals is a pesticidal use (i.e., it kills microbiological organisms) and, therefore, these products are subject to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA). Further, neither of these pesticides is registered by EPA under FIFRA and, therefore, they may not be sold or distributed as fumigants or sterilants without first being registered under Section 3 of FIFRA or exempted under section 18 of FIFRA. Finally, the cited NSF-ANSI standard points out the need for product users to follow OSHA's regulations, but does not mention that FIFRA requires product users to follow all product label use directions and safety precautions.

**Background:**

*Provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc, and any other reason why the issue should be considered by the Committee.*

EPA is concerned that laboratory personnel may not be aware of basic FIFRA's requirements that apply to pesticide producers and themselves. By not mentioning FIFRA's requirements, the NSF-ANSI standard may give laboratory staff the misleading impression that paraformaldehyde and chlorine dioxide gas are legally available for use in fumigating BSCs, and that only the directions in the NSF-ANSI standard need to be followed. By not providing information about FIFRA's requirements, the NSF-ANSI standard could help perpetuate the illegal sale and distribution of unregistered pesticide products and could expose laboratory personnel to legal and personal risks for not following the pesticide label's directions and safety precautions. That is, laboratory staff could violate the label and/or expose themselves to hazards by following only the procedures in the NSF-ANSI standard and not following those specified on the label.

**Recommendation:**

*If action by the Joint Committee is being requested, clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of ~~strike-out~~ and additions by **highlighting**; e.g., reference of the issue to a Task Force for detailed consideration; etc. If recommended text changes are more than a half page, please attach a separate document.*

■ Revise paragraph G.7.3. as follows:

■ The procedures below describe how either depolymerized paraformaldehyde or chlorine dioxide gas may be used to decontaminate BSCs. Use of an alternative method such as vaporous hydrogen peroxide [VHP], however, requires that cycle parameters be developed and

validated for each model and size of BSC. Fumigants are regulated as antimicrobial pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and as such must be registered (under FIFRA Section 3) or exempted (under FIFRA Section 18) by EPA before they may be sold or distributed in the U.S. Currently, paraformaldehyde (from which formaldehyde gas is created) is not registered by EPA for this purpose. Only one product containing sodium chlorite (which generates chlorine dioxide) and one hydrogen peroxide product (from which HP vapor is generated) are registered for fumigation of BSCs. Any other unregistered products or unregistered uses of registered products must be exempted from FIFRA before they may be used for this purpose. Material compatibility in terms of degradation and absorption of an alternative decontaminant are critical for maintaining cabinet integrity and the time required for decontamination, respectively. Alternate methods are required in certain instances, e.g., slow disease viruses. The decontamination method should be determined by consultation between user and certification agency. When paraformaldehyde is used for gas decontamination, follow OSHA Regulations Code of Federal Regulations, Title 29, Formaldehyde-1910-1048, which address monitoring; posting of regulated areas, respirator selection, protection and fit testing; medical surveillance; hazard communication and training; and recordkeeping. When any registered pesticide is used, FIFRA requires that all label use directions and safety precautions must be followed; not following the label may constitute a violation of FIFRA. Automatic formaldehyde gas decontamination/neutralization may be used as a substitute to the formaldehyde procedure given below if the manufacturer's instructions have been followed. When using chlorine dioxide gas, similar precautions as used for formaldehyde should be followed. Similarly, automated chlorine dioxide gas systems are available which may be used if the manufacturer's instructions are followed.

Supplementary Materials (photographs, diagrams, reports, etc.):

*If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.*

N/A

Submitter: Carlton J. (Jeff) Kempter

Date: 6-25-09