

**ABSA**

American Biological Safety Association

1200 Allanson Road • Mundelein, IL 60060-3808 • 866-425-1385 • 847-949-1517
Fax: 847-566-4580 • E-mail: absa@absa.org • Web Site: www.absa.org**President**

Benjamin A. Fontes, MPH, CBSP
Yale University
Office of EH&S, 1st Floor
135 College Street
New Haven, CT 06510
203-737-5009
Fax: 203-785-7588
benjamin.fontes@yale.edu

President-Elect

Karen B. Byers, MS, RBP, CBSP
Dana-Farber Cancer Institute
44 Binney Street—LGM 23
Boston, MA 02115
617-632-3890
Fax: 617-632-1932
karen_byers@dfci.harvard.edu

Secretary

Paul J. Meechan, PhD, RBP, CBSP
Centers for Disease Control and Prevention
Office of Health and Safety
CLFT, Bldg. 20, Room 2211, MS F05
Atlanta, GA 30329-4018
404-639-3147
Fax: 404-639-0883
pmeechan@cdc.gov

Treasurer

Rosamond Rutledge-Burns, MS, CBSP
National Institute of Standards & Technology
100 Bureau Drive, MS 1730
Building 301, Room B116
Gaithersburg, MD 20899-1730
301-975-5819
Fax: 301-975-4895
rburns@nist.gov

Past-President

Robert P. Ellis, PhD, CBSP
Colorado State University
Environmental Health Services
Campus Mail Stop 6021
Fort Collins, CO 80523-6021
970-491-6729
Fax: 970-491-4804
robert.ellis@colostate.edu

Councilors

LouAnn Burnett, MS, CBSP (10)
Michelle McKinney, CBSP (12)
Barbara Fox Nellis, RBP, CBSP (11)
Richard Rebar, RBP, CBSP (12)

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Executive Director

Edward John Stygar, III, MBA, CAE
ed@absaoffice.org

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 750 MSC 7985
Bethesda, MD 20892-7985

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Ladies and Gentlemen,

The American Biological Safety Association (ABSA) is an international group of biological safety professionals and is known as one of the world's foremost resources on biological safety practices. ABSA has reviewed the redrafted proposed revisions to the "NIH Guidelines for Research with Recombinant DNA (NIH Guidelines)" which are part of the overall effort to consider work with synthetic DNA. These revisions were announced in the Federal Register on April 22, 2010,

We agree with the redrafted, proposed revisions to Section III-E-1 of the NIH Guidelines. We encourage the Office of Biotechnology Activities (OBA) to prepare and share a guidance document addressing how to apply this section to all known categories and risk groups of viral vectors, including adenovirus and adeno-associated viral vectors. The redrafted proposed revisions of this section only address lentivirus vectors and Risk Group (RG) 3 and RG 4 vectors. Additionally, the guidance document should include references or information on how to test the cell lines for helper functions, as well as examples and an explanation on how to use the vector sequence information to determine if the replication defective vector can be rescued via homologous recombination.

The availability of the suggested guidance document will provide additional information to biosafety officers and IBCs charged with reviewing a broad diversity of experiments, thus facilitating more consistent and complete reviews by those groups.

We appreciate this comment opportunity for these proposed revisions.

Sincerely,

Benjamin Fontes, MPH, CBSP
President
American Biological Safety Association